Hype Cycle for Life Science Manufacturing, Quality and Supply Chain, 2023

Published 27 July 2023 - ID G00788244 - 148 min read

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Initiatives: Healthcare and Life Science Digital Optimization and Modernization; Healthcare and Life Science Digital Transformation and Innovation

Life science manufacturers must continuously innovate and streamline processes to produce high-quality, regulated products. CIOs can use this Hype Cycle to identify opportunities and assess risks for technologies that optimize and facilitate manufacturing, quality and supply chain operations.

Analysis

What You Need to Know

Supply chains continue to be disrupted. As CIO, you need to work closely with quality, operations and supply chain leaders to sustain flexible production capabilities and build in extra resiliency. You must also make progress on digital manufacturing initiatives, such as “lights out” and “smart factory” while supporting IT modernization projects. This Hype Cycle highlights new and maturing technologies and innovations that will help you support these objectives.

CEOs will increase pressure on IT leaders and business professionals to reduce costs and build efficiencies at scale with technology-centric approaches in 2023 and beyond. You must do this under the significant regulatory compliance constraints associated with developing and selling products for which quality, safety and brand reputation are paramount. Our Hype Cycle highlights specific emerging technologies and innovations available to life science manufacturing organizations to build and deliver quality products and services. These include technologies for complex biologics manufacturing, predictive formulations and stability, smart factories, immersive experiences, and integrated quality and compliance.

The Hype Cycle

The contents of this Hype Cycle will help you as CIO better evaluate important technologies for manufacturing, quality, regulatory and supply chain capabilities for life science manufacturers (that is, pharmaceuticals, biotechnology and medical devices). Several innovations have accelerated, including immersive experiences in manufacturing operations, SaaS laboratory information management systems (LIMSs), Internet of Things (IoT)-enabled laboratories and digital twins.

This research is part of a family of four life-science-focused Hype Cycles. The others include Hype Cycle for Life Science Discovery Research, 2023, Hype Cycle for Life Science Clinical Development, 2023 and Hype Cycle for Life Science Commercial Operations, 2023. The combination helps you apply a comprehensive view on emerging technologies across the entire life science value chain.

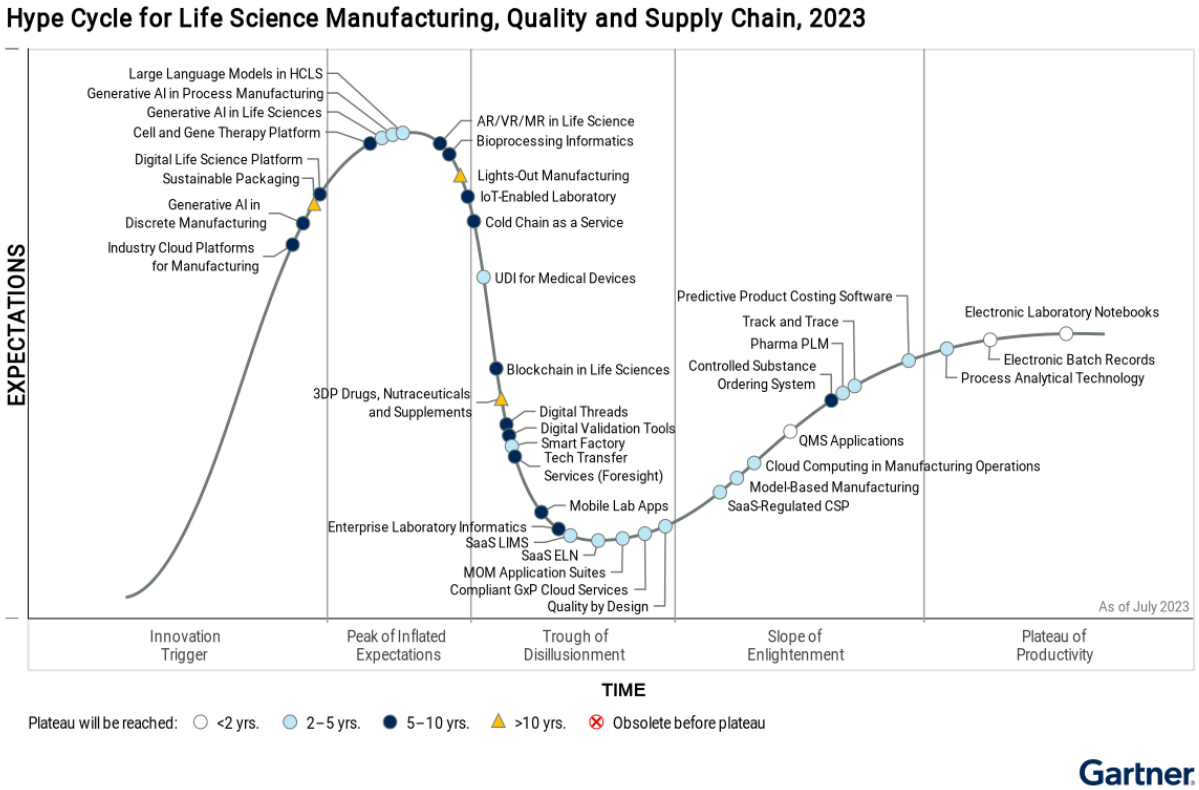
Several new profiles were added this year to better support business initiatives, including Sustainable Packaging, Large Language Models in HCLS, Generative AI in Discrete Manufacturing, Generative AI in Process Manufacturing, Cloud Computing in Manufacturing Operations, Digital Threads, Predictive Product Costing, Lights-Out Manufacturing, and QMS Applications.

The innovations we cover in this research span all phases of the Hype Cycle:

- The digital life science platform innovation is at the trigger phase and will take up to 10 years to mature.
- Recent innovations summiting the peak include end-to-end cell and gene therapy (CG&T) systems, augmented reality (AR)/virtual reality (VR) and bioprocessing informatics suites, and cold chain-as-a-service.
- Those at the peak will inevitably slide into the trough, before significant value will be realized. Examples include compliance services for cloud applications, intelligence mechanisms for operational data streams and equipment, and blockchain.
- Examples of technologies in the slope include serialization and cloud-based quality management system (QMS) suites, pharma product life cycle management (PLM), and track-and-trace solutions.
- Electronic batch records (EBR) and electronic laboratory notebooks (ELNs), fairly mature technologies, are situated on the plateau.

Use the information in this Hype Cycle to identify technologies that have the potential to deliver the value that your business colleagues demand. Evaluate and then mitigate the risks associated with those innovations based on their positions on the Hype Cycle curve.

Figure 1: Hype Cycle for Life Science Manufacturing, Quality and Supply Chain, 2023



Source: Gartner (July 2023)

The Priority Matrix

The Priority Matrix summarizes business impact versus maturity for the innovations, offering insight into which initiatives should be prioritized. Gartner judges the innovations closest to the upper-left corner of the matrix as having the highest priority to adopt, given they will soon be adopted by the mainstream. The timespan leading to mainstream adoption ranges widely. Gartner gauges time to technology adoption in four tranches — less than two years, two to five years, five to 10 years and more than 10 years.

Transformational opportunities that will have impact in the nearer term — within the next two to five years, include smart factory and digital twin technology. High-impact technologies that will reach mainstream in less than two years include predictive analytics and electronic batch records.

Table 1: Priority Matrix for Life Science Manufacturing, Quality and Supply Chain, 2023

(Enlarged table in Appendix)

Benefit	Years to Mainstream Adoption			
↓	Less Than 2 Years ↓	2 - 5 Years ↓	5 - 10 Years ↓	More Than 10 Years ↓
Transformational		Generative AI in Life Sciences Generative AI in Process Manufacturing Large Language Models in HCLS Smart Factory	Blockchain in Life Sciences Digital Life Science Platform Generative AI in Discrete Manufacturing Industry Cloud Platforms for Manufacturing	Lights-Out Manufacturing
High	Electronic Batch Records QMS Applications	Cloud Computing in Manufacturing Operations Model-Based Manufacturing MOM Application Suites Pharma PLM Predictive Product Costing Software Process Analytical Technology Quality by Design SaaS ELN SaaS-Regulated CSP Track and Trace UDI for Medical Devices	Cell and Gene Therapy Platform Cold Chain as a Service Digital Threads Digital Validation Tools Enterprise Laboratory Informatics IoT-Enabled Laboratory Tech Transfer Services (Foresight)	
Moderate	Electronic Laboratory Notebooks	Compliant GxP Cloud Services SaaS LIMS	AR/VR/MR in Life Science Bioprocessing Informatics Controlled Substance Ordering System Mobile Lab Apps	3DP Drugs, Nutraceuticals and Supplements
Low				Sustainable Packaging

Source: Gartner (July 2023)

Off the Hype Cycle

Predictive analytics in supply chain execution was removed. Those types of capabilities are now embedded in other supply chain execution applications, such as warehouse and transportation management solutions.

On the Rise

Industry Cloud Platforms for Manufacturing

Analysis By: Alexander Hoeppe, Marc Halpern

Benefit Rating: Transformational

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Industry cloud platforms (ICPs) address industry-relevant business outcomes by combining SaaS, PaaS and IaaS services into a whole product offering with composable capabilities. These typically include an industry data fabric, a library of packaged business capabilities, composition tools and other platform innovations. Manufacturers can use ICPs to build composable solutions and facilitate execution of supply chain processes within and beyond their organization's boundaries.

Why This Is Important

Cloud, software and service providers are launching ICPs by combining SaaS, PaaS and IaaS offerings with industry-specific functionality and composable capabilities to create compelling propositions for customers. Emerging manufacturing ICPs are using innovative approaches like composable packaged business capabilities (PBCs), digital marketplaces, data grids/DataOps and fusion teams to accommodate IT/OT to faster supply chain integration and platform adaptability due to transforming markets.

Business Impact

Broader cloud adoption within manufacturing will require more comprehensive solutions that follow defined manufacturing scenarios, process models and use cases, rather than technology-oriented solutions that enterprises have to largely configure and integrate themselves. Supply chain disruptions, more regulations, and the potential to servitize products to generate new revenue streams require an ecosystem-based approach based on a common platform to collaborate with suppliers and customers.

Drivers

- As the complexities of both business and technology continue to increase, enterprises are looking for more outcome-based engagements with solution providers. However, ICPs must also be flexible enough to be able to allow users to adapt to the changing boundary conditions.
- To be relevant and be able to resonate with enterprise audiences, such usage of ICPs outcomes must be business relevant, specific, measurable and tangible — a goal that is easier achieved when approached with a clear reference to manufacturing use cases.
- Currently, ICPs for manufacturing are largely being initiated and created by large technology providers, although we see some enterprises considering creating a dedicated ICP such as Catena-X as the basis for a more autonomous industry ecosystem.
- Manufacturing enterprises can gain business value from ICPs through the following: shared best practices; vertically specialized go-to-market (GTM) and implementation teams; compliance of the infrastructure platform with industry-specific regulations, such as General Data Protection Regulation (drafted and passed by the European Union), Center for Internet Security or National Institute of Standards and Technology; analytical capabilities to integrally mine the data from existing and new applications; industry-specific add-on functionality in front- and back-office enterprise applications; and fully vertical-specific solutions, such as digital twins for products, assets, processes, organizations and even supply chain, combined with collections of composable building blocks available in industry cloud marketplaces.
- Providers drive or engage in ecosystems to create comprehensive offerings that cater directly to the established needs of manufacturing enterprises by provision of a composable portfolio of packaged business capabilities. These business capabilities represent use cases like remote predictive maintenance of assets and tracking of products and supplies (location, environmental conditions, carbon footprint, etc.). Thus, ICP also facilitates scalability and tech transfer.

Obstacles

- ICPs for manufacturing are at risk of following the same path as community clouds, where providers added specific vertical functionality. And followed this, by breaking compatibility and upgradability with the parent cloud leaving enterprises on long-term unsupported or unsupportable versions of the cloud.

- ICPs can be overwhelming in terms of the breadth of functionality they cover. Therefore, customers and providers must be disciplined and not burn precious resources on fixing/replacing things that are not broken. Implementing an ICP must be approached as adding an exoskeleton by bringing new and improved capabilities rather than a vital organ transplant, and replacing or repairing functionality that was already present.
- Providers will create their own ICPs that will not adhere to the same standards, so they cannot coexist in one enterprise, resulting in diminished value.

User Recommendations

- Target ICPs to provide the backbone to complement the existing application portfolio by enabling new capabilities that add significant value as an exoskeleton, rather than as full-scale replacements.
- Examine the viability of vendors and their partners regarding technical integration, industry knowledge, and mature GTM strategies and implementation approaches following the best-of-breed principles with minimum risk of lock-in effects.
- Assess the industry-specific features promoted by various cloud providers for the manufacturing industry, and distinguish between real technology/functionality offerings and marketing messages.
- Formulate rules to deploy ICP capabilities as a productive platform for optimization and modernization by improving existing processes and actively recomposing them for more differentiating transformation and innovation initiatives.
- Create a governance and management plan that not only provides a composable management framework for individual cloud adoption in the short term, but also allows for a multicloud governance and management approach as industry clouds mature.

Sample Vendors

Amazon Web Services (AWS); Google; IBM; Infor, Microsoft; Oracle; Salesforce; SAP; Siemens Digital Industries Software; TraceLink

Gartner Recommended Reading

Quick Answer: What Makes Industry Cloud Platforms Different From Traditional Cloud Offerings?

Providers of Cloud Managed Services: Use Composable Industry Platforms to Productize Your Offerings

Changes and Emerging Needs Product Managers Must Address in the CIPS Market

Predicts 2023: The Continuous Rising Tide of Cloud Lifts All Boats

Leverage Gartner's Vertical Strategy Framework for Composable Industry Cloud Offerings

Generative AI in Discrete Manufacturing

Analysis By: Sudip Pattanayak, Marc Halpern

Benefit Rating: Transformational

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

Definition:

Generative AI technologies can generate new derived versions of content, strategies, designs and methods by learning from large repositories of original source content. Generative AI has profound business impacts, including on content discovery, creation, authenticity and regulations; automation of human work; and customer and employee experiences.

Why This Is Important

Generative AI will have a direct impact on the manufacturing subindustries such as automotive, aerospace, defense, medical, electronics and energy industries by augmenting core value through generating processes and associated data with AI models. In discrete manufacturing, significant investments are being made in advancing the use of AI as generative capabilities in product engineering, factory operations and aftermarket services to capitalize on the breakthrough of large language models (LLMs).

Business Impact

Generative AI in discrete manufacturing uses AI programs to create new or variations of original content such as product data, designs, images, video, audio, speech and text. When combined with LLMs, it results in improved product designs, supply chain and operational insights, intuitive training modules and better customer experiences by augmenting humanlike interactions with systems, applications and machines.

Drivers

- Business leaders seek to transform to smart manufacturing, providing a new ecosystem of open-source AI models and communities optimizing a variety of use cases. Examples are design optimization, factory and service frontline worker support, and augmentation of supply chain decision making.
- Generative AI can enhance employee and customer experience since it mimics humanlike natural language conversations and contextualizes large volumes of data compiled as language models. An example is interactions of factory workers using generative AI to interact with machines, which generates large data sets that need to be parsed and translated for consumption.
- Generative AI has tremendous potential in copilot support in engineering and smart operations, improving operational excellence and employee productivity. The capability of generative AI to alter and enhance existing content, creating new data elements and novel models of real-world objects, will advance augmented intelligence.
- New criteria-based solutions are being created to solve multiple problems in the real world, advancing the use of existing AI data models. A few examples are LLMs, pretrained transformer models that learn from large volumes of information from the web to create new artifacts and Language Model for Dialogue Applications (LaMDA), a pretrained transformer language model to generate high-quality natural language text to detect nuances in open-ended conversations. Such language models will blend in with the complexity of manufacturing industries, where tasks are still manually coordinated with human interactions.
- The use of OpenAI services will demand the manufacturing companies to set up co-innovation based working models with data and analytics (D&A) and AI vendors to scale use cases such as factory automation, problem reporting, visual quality inspection and predictive maintenance.

Obstacles

- Deepfake products can use generative AI for the material design that could create counterfeits that would pose threats to OEMs.
- Generative AI models that are pretrained and ready to use are becoming increasingly accessible, making the technology available to broad audiences. Along with broader accessibility comes risks, potentially exposing your organization to copyright and intellectual property exposure risks, including technology patents of new products.
- Data quality and reliability is a concern in manufacturing. Bad quality data and lack of evidence will impact the generative AI training data models.
- Manufacturing industries still use legacy systems in all facets of product development and factory operations. The use of generative AI with legacy tools can limit its effectiveness.
- Manufacturing processes and tasks are still human-driven in many value streams. Concerns of generative AI potentially replacing humans will limit the scale of adoption of generative AI across the value chains.
- Regulatory authorities responsible for manufacturing-specific compliance and IP protection might overregulate generative AI due to the lack of predictability of its impact on the industry and society.

User Recommendations

- Determine the business impact (benefits/risks) of generative AI in manufacturing subindustries to avoid legal complications due to misappropriated use.
- CIOs must work with internal and external stakeholders to evaluate generative AI use cases for business opportunities and threats and to assess the technical feasibility, organizational readiness and external factors for adoption or mitigation.
- AI leaders must choose vendors that provide tools for mitigating bias and that provide detailed model cards and transparency in training datasets and functionalities.
- AI and D&A leaders must ensure that good-quality data from the manufacturing value streams is used in your generative AI models to ensure traceability and evidence for validation.
- CXOs must consult with the right partners who can define and develop the use cases of generative AI.
- CIOs and manufacturing operations leaders must avoid overlooking the ethical considerations of the human element by educating the workforce on AI applications as cognitive assistants, not replacements, to humans.

Sample Vendors

Amazon Web Services (AWS); Autodesk; Beckhoff Automation; Dassault Systemes; IBM; Microsoft; NVIDIA; OpenAI; PTC; Siemens Digital Industries Software

Gartner Recommended Reading

Use Generative AI in Applied Innovation to Drive Business Value

Innovation Insight for Generative AI

Digital Life Science Platform

Analysis By: Michael Shanler

Benefit Rating: Transformational

Market Penetration: Less than 1% of target audience

Maturity: Emerging

Definition:

A digital life science platform (DLSP) is an architectural approach that enables companies to nimbly adapt their business and operating model, in response to external disruption and change in business strategy. The DLSP sources and integrates functionality from internal and ecosystem partners to create packaged business capabilities (PBCs). Nontechnical and IT staff can use PBCs to compose new experiences.

Why This Is Important

Life science (LS) organizations realize the limitations of monolithic ERP-centric or heavily customized or niche business application portfolios. The siloed nature of current architectures has stifled innovation and slowed digital transformation. Business users are exhausted by feeble attempts at interoperability by vendors, resulting in an excessive total cost of ownership (TCO) and fragmented user experiences.

Business Impact

The DLSP supports the following capabilities:

- Digital consumer and patient engagement for personalized experiences for drug regimens, device usage and therapies, using plug-and-play capabilities from external ecosystem players.
- Decentralized, digital clinical trials.
- Advanced health analytics, using tools that leverage data sources from R&D, precision medicine and real-world evidence.
- Digital laboratory research connected across multiple scientific and experimental disciplines, like chemistry and biology.

Drivers

- Business users want to transform the business. They want to enable a "composable" life science enterprise that leverages technologies to solve increasingly complex therapeutic issues. The composed experience will be realized through business-user-focused application experiences that are independent of the underlying set of commercial off-the-shelf (COTS) or legacy monolithic applications.
- Clients want a more effective means of bringing together different domains (e.g., clinical and AI subject matter experts [SMEs]) to provide a focus for democratized innovation among a range of stakeholders (see Fusion Teams: A Proven Model for Digital Delivery).
- The DLSP approaches are removing critical technological barriers to digital innovation and transformation (see Best Practices for Reimagining Your Life Science Company as a Digital Business Technology Platform).
- Organizations are starting to deliver business outcomes by delivering PBCs. These are application building blocks that have been purchased or developed internally or with third parties.
- Many clients and vendors are adopting a platform strategy as the primary vehicle for digital business transformation.
- As this is a relatively new concept, it is still in the Innovation Trigger phase of the Hype Cycle.

Obstacles

- This is an architectural approach that ultimately needs to be enabled by the end user. However, many end users want “holistic solutions” provided by vendors, which do not exist yet.
- Vendors often posture as having a platform. However, they think more in terms of software, and not architectural approaches, which creates confusion. End users, working with vendors, will need to provide a means of rapidly producing composable digital products and services from different sources (not just their marketplace or product offerings).
- DLSP requires vision and alignment with the business and IT, and may involve functional leads to help drive requirements. Since this is a big departure from application-centric thinking, we expect delays in design and essential partner selections.
- As the approach reaches peak hype, clients will inevitably be underwhelmed by either the vendor’s capabilities or their aspirations not meeting reality.

User Recommendations

- Align digital and IT strategy with existing business strategy through the power of people from business and IT backgrounds in the form of digital fusion teams (see IT-Business “Fusion” Teams and How They Can Deliver Innovation).
- Evaluate vendor solutions on their compatibility with the composable architecture that is emerging. Take appropriate actions on vendor and key technology sourcing across the current and future enterprise application portfolio (see Healthcare and Life Science Business Driver: Medical Technology Innovation).
- Drive technology and data architecture decisions, and organizational models that redefine the relationship between the business and IT. Plan to modernize legacy applications toward the PBC model.
- Verify the attributes of “composability” when assessing new vendor capabilities or solution offerings, and when renewing contracts with incumbent vendors. Explore strategic relations with hyperscale solution providers and channel partners.

Sample Vendors

Amazon; Google; IBM; Microsoft; Oracle, Salesforce; SAP; Veeva Systems

Gartner Recommended Reading

Innovation Insight for Digital Life Science Platforms

Democratizing Digital Delivery in Healthcare and Life Sciences

Healthcare and Life Science Business Driver: Strategic Technology Change

Quick Answer: What Should Life Science CIOs Know About Data Fabrics?

Quick Answer: What Are Packaged Business Capabilities in Healthcare and Life Sciences?

Sustainable Packaging

Analysis By: John Blake

Benefit Rating: Low

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Sustainable packaging is the development and use of packaging that results in improved utilization of materials, and decreases the negative impact of packaging on the environment. It can include recycling, recycled content, reuse, material substitution and reduction in the carbon footprint of packaging.

Why This Is Important

Sustainable packaging has become a core aspect of sustainability commitments as packaging and plastics have been deemed major contributors to pollution and greenhouse gas (GHG) emissions. Organizations need to address packaging to meet their environmental, social and governance (ESG) goals and the expectations of customers and consumers in order to protect their brand's reputation. In addition, the rapid advancement of global packaging legislation is heightening the urgency to adopt sustainable packaging practices.

Business Impact

Consumer and customer sentiment drove voluntary sustainable packaging goals, but now there is a rise in packaging legislation globally that will mandate changes in how packaging is designed and utilized. Sustainable packaging is complicated and can be costly to implement. It's estimated that many 2025 commitments will be missed, risking brand reputation. Significant levels of innovation and investments may be required to meet voluntary and mandated targets.

Drivers

- **Consumer/customer pressure:** There is an awareness of the harm that products and packaging have on the environment and this is driving purchase decisions. Brand reputation, waste and the contribution to Scope 3 emissions are being scrutinized.
- **Legislation:** 2022 marked not only the first of its kind — a Plastic Packaging Tax implemented in the U.K. — but it also marked California becoming the fourth state in the U.S. to pass Packaging Extended Producer Responsibility (EPR) legislation. Meanwhile, 2023 ushered in new packaging taxes in Spain and there are (at the time of publication) over 10 states in the U.S. with proposed packaging EPR legislation. These are just a few of the examples of global packaging legislation.
- **ESG strategy:** As the value of having a clear and actionable ESG strategy becomes clear, organizations are moving beyond focus on Scopes 1 and 2 emissions and are increasingly setting their attention to Scope 3, which includes packaging. Further, boards are increasingly stepping up their oversight of ESG, as they recognize its necessity for long-term resilience and the very visible nature of packaging and packaging waste.
- **The war on plastic:** As awareness of the impact of plastics and plastic packaging on the environment increases, organizations need to develop a position regarding its use. There is a desire to replace plastics, drive a circular economy through recycling, eliminate or minimize use of virgin or petroleum-based polymers and move from single use to reusable packaging.
- **Costs:** The overuse or misuse of packaging has cost implications as well as sustainability implications. Another cost risk is the growth in legislation. Organizations will be penalized for the quantity and types of packaging they produce. However, reducing or optimizing packaging through the lens of sustainability can also reduce packaging costs.

Obstacles

- **Complexity:** Visions of fully recyclable, reusable and plastic-free are harder to implement than anticipated, due to financial and technical feasibility (such as product protection, costs, recycling infrastructure and sourcing limitations).
- **Data maturity:** Packaging specification data practices are at a low maturity level. Common challenges include insufficient processes and systems of record, as well as accuracy/completeness of data. Software for packaging specification management is an emerging market.
- **Infrastructure:** Investments in recycling infrastructure and by packaging suppliers has not kept up with the promises or needs of brand owners.
- **Costs:** Material shortages, reusable packaging supply chain and manufacturing assets are driving cost pressures.
- **Collaboration:** Packaging's impact is cross-functional, requiring stakeholder support to navigate change management challenges.
- **Greenwashing:** Overpromising, under delivering or misleading consumers poses risks of legal or consumer backlash.

User Recommendations

- **Data:** Establish the baseline for any sustainable packaging strategy by capturing data on current packaging consumption.
- **Upstream innovation:** Optimize products and packaging through the lens of sustainability and consumer needs.
- **Feasibility:** Assess the business impact and feasibility of sustainable packaging by engaging cross-functional teams in the process of setting or resetting packaging goals. Key considerations include sourcing and quality of packaging, material and capital costs as well as operational changes.
- **Stakeholders:** Engage stakeholders to support necessary changes and investments. Sustainable packaging often involves development, financial commitments and change management to advance beyond pilots.
- **Investment:** Determine where investments are needed to support sustainable packaging by starting with specification data visibility. This will prove critical as legislation evolves. Map required investments in manufacturing assets, as well opportunities for strategic investments with packaging suppliers.

Gartner Recommended Reading

Quick Answer: How to Create a Sustainable Packaging Strategy

Quick Answer: How to Advance Sustainable Packaging Goals

Quick Answer: How to Comply With Sustainable Packaging Legislation

Market Guide for Packaging and Product Specification Management

At the Peak

Cell and Gene Therapy Platform

Analysis By: Reuben Harwood, Maria Nieradka, Michael Shanler

Benefit Rating: High

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

Cell and gene therapy (CGT) platforms are systems designed to help collect, analyze and prepare biological samples as therapies for patients. The American Society of Gene & Cell Therapy defines gene therapy as the use of genetic material to manipulate a patient's cells for the treatment of an inherited or acquired disease. Cell therapy is defined as the infusion or transplantation of whole cells into a patient for the treatment of an inherited or acquired disease.

Why This Is Important

Spurred on by the successful approval of new CGT products, life science companies are investing heavily in new platforms that support R&D. While research organizations have put experimental cellular therapies into practice for decades, solutions managing the end-to-end process did not exist until recently. Most CGT is supported using heavily customized supply chain and logistics software. A handful of vendors have developed configurable solutions that simplify the support and delivery of CGT.

Business Impact

Currently, most CGT operations are fairly manual and have complex and inefficient process steps that threaten the quality of delivery. Business teams are searching for marketed solutions that can meet timing, logistics and quality requirements. CGT solutions can automate many of these steps from a process and delivery perspective. They can also facilitate clinical trials and logistics and patient/subject/physician and manufacturer communications.

Drivers

- CGT is becoming a more centralized strategy at many pharmaceutical companies, augmenting traditional drug portfolios. Personalized medicines, individualized therapeutics and more targeted approaches to therapies are trends that are driving new business models and creating this market.
- There are currently 28 FDA-approved cell and gene therapies. The number of regulatory approvals is likely to rise significantly in the near future as more than 1,500 clinical trials for CGTs are currently registered in ClinicalTrials.gov. These cover a wide range of disease categories, such as oncology, rare diseases, regenerative medicine and others.
- The approval of the first CRISPR gene-editing therapy (from Vertex and CRISPR Therapeutics) may occur in 2023. If commercially successful, it will bring added momentum to the field of gene editing.
- The demand for CGT clinical trials has accelerated, making CGT platforms that match the therapy area essential to streamlining trials and getting commercial products to the market.
- The data associated with CGT increasingly has broader uses across the business throughout the product life cycle, from R&D and commercial areas to specialized manufacturing and supply chain operations. Those requirements are becoming more acute for organizations supporting a “personalized medicine” approach, where markets consist of individuals. Once patient, manufacturing, operations and clinical data policies are updated, CGT systems will be even more scalable for supporting different kinds of CGT research and medicine programs.

Obstacles

- High inflation has slowed the development of cell and gene therapies, with reduced investment in R&D and higher production and transport costs.
- Life science companies and other research institutes can expect adoption challenges due to the complex nature of these therapies. Solutions must support several different types of models: allogeneic (the donor is different than the recipient), autologous (the donor and patient are the same) and variations of stem cell and T-cell therapies.
- In each of these cases, clients have unique needs and wildly different interventions and touchpoints they must orchestrate among R&D staff, healthcare professionals, lab technicians and supply chain personnel. This will cause complexity in vendor selection and system design, delaying adoption.

- Given its early stage of adoption, we position this technology in the Innovation Trigger phase with plateau achieved in five to 10 years.

User Recommendations

- Ascertain from leadership (such as the chief science officer) if CGT platforms will be necessary to support your business strategy. Focus on the touchpoints between CGT and major systems, such as ERP, manufacturing execution systems, electronic batch records, quality management systems and patient and healthcare-facing systems.
- Evaluate whether the newly established vendors can provide the capabilities you need versus building a custom solution.
- Work closely with product leaders to understand the commercial challenges (such as high price per therapeutics), including payer contracts that may affect architecture- and CGT-related information communication.
- Ensure extensive process, clinical and IT system validation is performed by the software provider's organizations and that those vendors properly support CGT processes. Work with quality teams to verify that governance and policies are in place to maintain vigilant compliance and that patient privacy is protected.

Sample Vendors

Autolomous; Be The Match BioTherapies; CellPort Software; Cytiva; FarmaTrust; Hypertrust Patient Data Care; IDBS; L7 Informatics; Tenthpin; TrakCel

Gartner Recommended Reading

How Technology Can Support the Next Phase of Commercial-Scale Cell and Gene Therapies

Life Science CIO's Strategy for Delivering Cell and Gene Therapy Capabilities

Prioritize Patients in Supply Chain Design for Cell and Gene Therapies

Generative AI in Life Sciences

Analysis By: Michael Shanler

Benefit Rating: Transformational

Market Penetration: 1% to 5% of target audience

Maturity: Adolescent

Definition:

Generative AI can generate new derived versions of content, strategies, designs and methods by learning from large repositories of original source content. Generative AI has profound business impacts, including on content discovery, creation, authenticity and regulations, automation of human work, and customer and employee experiences. In the life science industry, generative AI can be applied for a wide range of scientific, medical and commercial purposes.

Why This Is Important

Generative AI exploration is accelerating, thanks to the popularity of Stability AI (Stable Diffusion), Midjourney, ChatGPT and other applications leveraging large language models (LLMs). Today, life science organizations are aggressively experimenting with generative AI to help tune AI for images, videos, audio, molecular- and engineering-based formats. Use cases include identifying new drug targets, improving clinical site selection, monitoring drug reactions and accelerating marketing content development.

Business Impact

Most technology products and services will incorporate some form of generative AI capabilities in the next 12 months, in turn, leading to their democratization. Generative AI will progress rapidly, especially in the area of scientific discovery and technology commercialization. The technology will have broad impacts for the entire organization, including education and training for appropriate use; updates to security and governance; and skills investments.

Drivers

- ChatGPT is a very hyped technology and the number of technology proofs of concept have escalated.
- Life science industry's interest in generative AI is rapidly growing. Engagements with analysts are significantly up to explore capabilities and vendors. Enterprises are examining generative AI as employee-facing tools for assembling information and creating reports that aggregate information from financial, HR, learning management and project management functions.
- In life science commercial operations, the technology is being explored for publication summarization in medical affairs as well as generating market performance insights for sales and marketing business users.
- Generative AI is already speeding up the drug discovery process. This includes creating research article drafts, aggregating research intelligence, identifying novel targets and predicting novel drug-like chemical structures, and generating validation reports,
- Generative pretrained transformer (GPT) enables non-native English speakers to be included in collaborations across the scientific community.
- Clinical and regulatory leaders are exploring the technology to improve site selection, develop enrollment, recruitment and retention reports, aggregate clinical intelligence findings, and create clinical summaries.
- Manufacturing, quality and supply chain staff are using the technology for creating SOPs for recipe and formulation, developing procedures for laboratory workflows, and assembling regulatory information.
- Generative AI will disrupt "low code" and "no code" software programming. Combined with development automation techniques, it can automate 30% to 40% of programmers' work. This is highly attractive across the life science value chain, especially with informatics and analytics applications teams due to prevalence of "high code" technology and heavily customized legacy systems.
- We are introducing this technology at the peak, and expect it to reach a plateau in two to five years.

Obstacles

- A wide range of new regulations on generative AI are emerging globally. For instance, in 2023, a call to pause giant AI experiments (Future of Life Institute) for six months was signed by many AI and technology dignitaries.
- The risk of generative AI creating incorrect scientific assumptions or recommendations that put patients at risk is causing pause at many organizations.
- Corporate policy on use of generative AI, especially those leveraging public models and applications, is driving “fit for purpose” rubrics while updating and educating staff on intellectual property, trust and privacy issues.
- The black-box nature and a lack of experience with a full AI life cycle for proprietary systems might preclude the use of generative AI for critical use cases where there are high barriers to explainability or validation.
- The validation requirements, such as GxP can challenge use of the tool in operations and decision making, as regulatory guidance on AI validation remains unclear.
- Some vendors will use generative AI terminology for trying to sell subpar “generative AI” solutions.

User Recommendations

- Accelerate clear and effective internal communications by ensuring business, clinical and technology leaders have a common set of definitions for key terms in generative AI and a foundational understanding of how LLMs, such as GPT, work.
- Establish a technology leader as the enterprise subject matter expert on generative AI technology by allocating time for this individual to digest industry updates as they unfold, create guidance and communications for leadership, and oversee experimentation and learning across the broader organization.
- Identify initial use cases where you can improve your solutions with generative AI by relying on purchased capabilities or partnering with specialists. Consult vendor roadmaps to avoid developing similar solutions in-house.
- Ensure your vendor partnerships are positioning their products and services to maximize the value and manage the risk by making generative AI a regular point of discussion.

Sample Vendors

Amazon; Atomwise; Google; Huma.AI; insitro; Microsoft; OpenAI; Schrödinger; Stability AI; Tencent

Gartner Recommended Reading

Innovation Insight for Generative AI

Emerging Tech Roundup: ChatGPT Hype Fuels Urgency for Advancing Conversational AI and Generative AI

Emerging Tech: Generative AI Needs Focus on Accuracy and Veracity to Ensure Widespread B2B Adoption

Glossary of Terms for Generative AI and Large Language Models

Generative AI in Process Manufacturing

Analysis By: Ellen Eichhorn, Sohard Aggarwal

Benefit Rating: Transformational

Market Penetration: 1% to 5% of target audience

Maturity: Adolescent

Definition:

Generative AI technologies can generate new derived versions of content, strategies, designs and methods by learning from large repositories of original source content. Generative AI has profound business impacts, including on content discovery, creation, authenticity and regulations; automation of human work; and customer and employee experiences. In process manufacturing, it generates insights for efficiency for factory floor, product formulation, consumer behavior and marketing effectiveness.

Why This Is Important

Generative AI (GenAI) will impact all processing manufacturing subindustries, including food and beverage, chemicals, forestry and agriculture. It can reduce time to market (through alternative product formulation, package design) and improve process efficiency and customer experience (better UI/UX, natural language based insights). However, regulation discussions are similar to the introduction of the internet — the appeal is tremendous, but so are the potential risks.

Business Impact

GenAI can:

- Transform smart manufacturing, providing a new ecosystem of open-source AI models and communities optimizing a variety of use cases. Examples are design optimization, factory and service frontline worker support, and augmentation of product formulation.
- Mimic natural language conversations and contextualizes large volumes of data from multiple sources. This can help to identify trends, patterns and sentiments and therefore accelerate product development which is a key priority in the process industry.

Drivers

- New foundation models and their new versions, sizes and capabilities are rapidly emerging, impacting language, images, molecular design and computer code generation. They can combine concepts, attributes and styles, create original images, videos and art from a text description, or translate audio to different voices and languages. This has the following impacts on creative work: Marketing — campaign design and content generation; Customer service — content creation and crafted responses in text, images, video and sound, improving customer experience via self-service; NLP — personalized copywriting; videoconferencing — noise cancellation and visual effects.
- Process manufacturers are looking at ways to improve efficiency and optimize cost. By using GenAI to combine different types of data (structured, semistructured and unstructured) from multiple sources (like IT, operational technologies and engineering technologies) they can: accelerate role-based and context-specific insights to predict failures, optimize processes and detect anomalies resulting in cost savings, higher asset utilization and decision intelligence; generate new ideas, design possibilities and product performance enhancements to meet evolving customer needs (for sustainable, innovative and personalized formulated products), shorten time to market and potentially increase revenue; apply natural language context to improve translation accuracy for work instructions, manuals and other training documents at a faster pace and free human capital for more productive work.
- In consumer goods, it generates consumer insights and advice. In e-commerce, it helps customers “try on” makeup and outfits. In manufacturing, GenAI helps create new materials targeting specific properties to optimize catalysts, agrochemicals, fragrances and flavors.
- GenAI can enable robots to deliver enhanced results from remote inspections of raw material silos and hazardous areas in the shop floor where human capital could be at risk.

Obstacles

- Applications in product design, shop floor, remote inspection etc., will require skills, long time frames and deep pockets, and may result in high costs.
- Low awareness and knowledge of GenAI-related legislative and regulatory changes from government/industry representatives can mean uninformed decisions.
- High-quality data is required for training domain/use case specific models. Data quality is already a huge concern and generative AI will only add to this complexity. It may adversely affect scalability.
- Synthetic data/output generated from generative AI tools may suffer from inaccuracies. Without proper validation and oversight use of such data/outputs may result in poor decisions or safety concerns, and may cause reputation damage.
- Concerns around ownership of GenAI-created information/product may result in loss of intellectual property, indemnity and liability when utilizing open-source software.

User Recommendations

- Establish a GenAI COE to start a clearinghouse for questions, policies and governance. Put the COE in charge of understanding the organization's intellectual property, liability and indemnity implications from use of GenAI.
- Collect information on domain-specific developments to identify high-value use cases by evaluating risks, opportunities, technical feasibility, internal readiness and external readiness.
- Embrace and democratize use of GenAI tools in different functions by creating an education program (for reskilling/upskilling), setting common definitions, governance on usage and encouraging discussion and questions.
- Improve your data quality. The quality of any algorithm is limited to the quality of data it receives. Identify critical data assets impacting prioritized use cases and focus on use of data governance and technology to improve their quality and maximize success probability.

Sample Vendors

Adobe; Amazon; Google; Hugging Face; Microsoft; OpenAI; Salesforce

Gartner Recommended Reading

Quick Answer: How Can Manufacturing CIOs Leverage ChatGPT Outside the Factory?

ChatGPT Research Highlights

Top Strategic Technology Trends in Consumer Goods Manufacturing for 2023

Large Language Models in HCLS

Analysis By: Jeff Cribbs, Sharon Hakkennes, Michael Shanler

Benefit Rating: Transformational

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

Large language models (LLMs) in healthcare and life sciences (HCLS) are a type of foundation model trained on large volumes of unlabeled textual data. Applications can use LLMs to accomplish a wide range of tasks such as content generation, content summarization, search, code generation, language translation and conversational chat for HCLS industry applications.

Why This Is Important

LLMs have demonstrated surprising and significant capabilities across industries and are likely to be a standard feature of both personal and enterprise technology experiences in just a few years. Within HCLS, LLMs' achievements in demonstrating medical knowledge, engaging patient questions with empathy and insight, and parsing complex administrative scenarios have been remarkable. HCLS technology leaders have been tasked with planning a strategic response.

Business Impact

LLMs will first impact areas where they can be deployed with simple design patterns and areas with higher tolerance for error and correction. Early pilot examples include autogeneration of clinical trial intelligence reports, natural language interaction with business intelligence, ambient digital scribes and scientific literature search. Long term, LLMs have the potential to disrupt many critical functions — from research agents and office visit discharge notes to interoperability protocols.

Drivers

- The general release, explosive adoption and media attention given to ChatGPT — just one of many applications leveraging LLMs — has captured enormous mind share of healthcare business, clinical, and technology leaders alike. This has drawn significant strategic planning attention in 2023, though the real investment result is still to be seen.
- A steady cadence of healthcare technology vendors are announcing integration with LLMs.
- Large technology companies are making enormous investments in developing new LLMs and applying them to new application areas, demonstrating and broadcasting their achievements in a race to achieve a strong position in the LLM space. For example, Microsoft Health Bot is being integrated with Azure OpenAI services.
- Medical and healthcare policy research will drive deeper understanding of the risks and virtues of LLMs in healthcare use cases. As this emerges, HCLS organizations will gain comfort in embarking on more ambitious use cases.
- A pressing need to reduce the contribution of healthcare technology to worker (especially clinician) burn-out will drive investment in use cases like digital scribing and patient message responses.
- A tightening fiscal environment combined with structural changes in patient populations drive the need for increased efficiency of the workforce. This will drive long-term use cases like chat-based self-triage and navigation, and automated back-office functions.
- Initiatives focused on improving data literacy, analytics self-service and data-driven decision making will drive interest and investment in chat-based interfaces with business intelligence and analytics platforms, whether those are deployed within functional applications (EHR, ERP, claims processing) or enterprise analytics.

Obstacles

- Software vendors and consultants often use the GPT, LLM and generative AI terms interchangeably. This creates confusion about what the technologies actually are, the relationships between them, and what is realistically achievable with investments.
- There is widespread misunderstanding of the technology. This results in unproductive strategic discussions and reflexive governance decisions to restrict or prohibit use of LLM tools.
- Truly transformative use cases will require higher degrees of proven accuracy and safety than the 80% to 90% general performance LLMs demonstrate today. This last decile of improvement often reveals complicated fringe scenarios and engineering challenges that take many years to resolve.
- LLM outputs are not currently explainable — at least, not in the sense we are accustomed to in healthcare when we validate rule-based software, clinical protocols or efficacy studies. LLM use case adoption will be constrained by the need for transparency about decision making.
- There is significant uncertainty about the future regulatory environment for LLMs. Issues include intellectual property in LLM training datasets, privacy and confidentiality of enterprise data, and legal liability for content generated by the LLM.

Analysts' Notes: It is difficult to position a technology moving as quickly as LLMs in an annual publication. We take enterprise deployments of LLMs (largely via cloud APIs) as our numerator to arrive at the low end of 1% to 5% of HCLS organizations. We place LLMs at the peak of hype and predict a year of vendor integration announcements, regulatory starts and stops, and reality checks for the near-term value of today's LLMs. Next year, we are likely to see new, specific use cases emerging across the HCLS Hype Cycles.

User Recommendations

- Accelerate clear and effective internal communications by ensuring business, clinical and technology leadership teams have a common set of definitions for key terms in generative AI and a foundational understanding of how LLMs work, along with their risks.
- Establish a technology leader as the enterprise subject matter expert on generative AI by allocating time for this individual to digest industry updates as they unfold, create guidance and communications for leadership and governing experimentation and learning across the organization.
- Engage your patient populations directly by convening sessions with patient advisory groups to understand current utilization of ChatGPT, ascertain perceptions of the technology, observe first usage where possible and trial messaging for safe patient usage.
- Ensure your vendor partnerships are positioning their products and services to maximize the value and manage the risk presented by LLMs by making generative AI a regular point of discussion.

Innovation in Practice:

- Three health systems (UC San Diego Health, UW Health in Madison, Wisconsin, and Stanford Health Care) are piloting the use of GPT-4 to autogenerate responses to patient messages in the EHR. These draft responses are reviewed and revised as necessary by the clinician prior to sending.

Sample Vendors

Facebook; Google; Microsoft; NVIDIA; OpenAI; Palantir

Gartner Recommended Reading

GPT-4 Impacts and Actions in Healthcare and Life Science

Board Briefing: Understanding ChatGPT, Other Large Language Models and Their Risks

Quick Answer: What Healthcare Provider CIOs Need to Know About LLM Applications Such as ChatGPT

AI Design Patterns for Large Language Models

AR/VR/MR in Life Science

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: 1% to 5% of target audience

Maturity: Adolescent

Definition:

Augmented reality (AR), virtual reality (VR) and mixed reality (MR) in life science are technologies that create immersive experiences for consumers, patients and employees. Within life science organizations, these applications span a range of business functions, including R&D, quality, manufacturing, therapy, field service and commercial.

Why This Is Important

AR/VR/MR technologies are rising in prominence as life science business users look to create more immersive experiences, improve collaboration and digitalize operations. These technologies allow for new ways to engage individuals, assets and information. Gartner expects increased applications and sophistication in a range of application areas that can help design and deliver better products, improve compliance in regulated processes, and assist with the creation of better user experiences.

Business Impact

AR/VR/MR will have the following business impacts:

- AR increases throughput, collaboration, quality, compliance and insights in the areas of labs, inventory, storeroom, diagnostics, and stockroom logistics and planning.
- VR is commonly used for molecular design, physician education, and manufacturing and facility design.
- While AR and VR are more mature technologies, MR is still evolving. It doesn't have as many clear business benefits beyond the current, more narrow applications — like logistics, robotic surgery, field service and sales enablement.

Drivers

- As health models evolve and new devices are coming online, organizations are funding more proof of concepts (POCs) for remote, digital and clinical experiences. This is driving adoption of AR, VR and MR.
- The popularity of immersive experiences as digital work tools has increased due to the effects of work-at-home policies. Most organizations have continued these staff engagement strategies now that digital workplace strategies have become the norm in many organizations.
- Consumer technologies have advanced to the point where AR and VR headsets are at manageable price points. Hardware usability and battery life are now amenable for mainstream consumption.
- New applications are being elevated and old ones are being reimagined. For example, apps for cancer lesions and skin health have existed on smartphones for over a decade for in-person doctor visits. Today, data collection — via in-person AR glasses capabilities — is being combined with remote cancer lesion detection using apps.
- VR gear has been adapted into molecular modeling simulation for R&D engineers and scientific groups.
- VR is in used for molecular modeling, optimizing facilities, physician training and patient education. It is also being used in clinical therapies, such as cognitive behavioral exposure therapy, PTSD, depression and dysmorphia, stroke, attention deficit, and autism spectrum disorders.
- MR is being piloted by numerous companies in medical devices (such as robotic surgical instruments), in sales enablement for socially distanced medical devices sales reps, and in field service engineering on analytical equipment. It is currently in limited use in plant operations and warehouses, where engineers make virtual changes to substrates (bodies, tissues, software and hardware), with automation updating the changes in reality.
- Based on this broad range of early implementations and excitement about the technology, we position this technology at the peak.

Obstacles

- Many life science teams are piloting the technology in vacuums, without a clear vision, resulting in failed attempts to move beyond POCs.
- Many vendors offer AR/VR/MR capabilities, but only a few can really support compliance and regulatory needs in the life science market.
- Most AR/VR/MR vendors don't have specific life science capabilities and need to be educated on electronic protected health information (ePHI), Health Insurance Portability and Accountability Act (HIPAA), good x practice (GxP) and validation activities. Life science firms can't quickly adopt the technology due to limited applications and form factors, along with few vendors that deeply understand the life science domain.
- Creating and maintaining regulatory-approved content, especially for VR use cases in promotional settings, is costly.
- Hardware design for wearable devices has improved, but they are still not easily applied into life science environments. For e.g., many AR/VR headset users report fatigue and some report nausea.
- We don't expect MR to show broad value until applications, hardware and informatics mature.

User Recommendations

- Evaluate with business peers the business justification for offering an AR/VR/MR capability either by building, buying or partnering.
- Review adjacent industry spaces to see where the innovations are delivering value. Specifically, life science clients have a lot to learn about how to pilot and scale AR/VR/MR from aerospace and defense, retail, and healthcare providers.
- Factor in extra staff resources and time in project plans to educate vendors on your specific compliance issues, like ePHI, HIPAA, GxP and life-science-specific validation. This is especially the case when dealing with "platform vendors" that do not have life science applications or consulting practices.

Sample Vendors

Apprentice; EON Reality; FundamentalVR; Goodly Innovations; Nanome; NNIT; PIXACORE; SightCall; Simplifier; SimuLyve International

Gartner Recommended Reading

Emerging Tech: Impact of Metaverse on Edge Devices and Infrastructure

Emerging Tech Impact Radar: Display Technologies

Quick Answer: What Are the 5 Essential Attributes of an Emerging Metaverse in Manufacturing?

Market Guide for Corporate Learning Technologies

Your Lab of the Future Strategy Must Enable Life Sciences Digitalization

Bioprocessing Informatics

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Bioprocessing informatics suites coordinate data and process sharing across experimental design, laboratory processes, recipes and formulations. They can plan, execute and analyze bioprocesses, and augment QA, regulatory and technology transfer activities. Using the outputs of research, they enable seamless downstream processing, including pilot production, scale-up and manufacturing of biologics.

Why This Is Important

Moving biologics out of research, and into development and manufacturing is a very complex process. It typically involves aggregating information from disparate laboratory, scientific, quality and production systems. Many organizations have attempted to simplify the process using expensive and complex customized or consultant-led solutions that span a patchwork of disparate systems and spreadsheets. Bioprocessing solution suites can simplify the process and IT approaches for this activity.

Business Impact

Bioprocessing informatics improves automation, methods, process development (qualification and validation), and compliance. It creates process intelligence using analytics across laboratory, scientific and formulation data, and reduces writing, calculation, procedure, and transcription errors in labs. It also predicts yields, purities and costs, by arranging and analyzing machine learning (ML)-enabled data, and improves visibility into product development, technical operations and quality issues.

Drivers

- Life science organizations continue to demand increased capabilities for biologics, R&D and manufacturing.
- Most Gartner clients with clinical portfolios are increasing their addressable markets via biologics — such as biosimilars, biologics, peptide-based drugs, modified ribonucleic acid (RNA) drugs, antibody drugs and other large molecule therapeutics.
- Today, over 44% of drug portfolios are biologic-based, representing a doubling over the last decade (see [downloads PDF] Pharma R&D Annual Review 2022, Pharma Intelligence).
- Clients report increased sophistication requirements, especially when dealing with numerous iterations of smaller batches of biologics.
- Biological medicines are widely considered one of the biggest cost drivers for rising drug prices. Many life science organizations want to get more biologics into portfolios and need systems and processes for getting these drugs through approval phases with more efficiency.
- Modified proteins, gene-edited products and biosimilars are also on the rise.
- Vendors are increasing the speed of acquisition within this space. For instance, Danaher acquired Cytiva (which has listed GoSilico as a product) and IDBS (which had acquired Skyland Analytic), over the past few years.
- Most clients report an increased frequency of technology transfers between labs, especially as labs and production facilities are being driven to become more automated and flexible.
- Many life science organizations are considering bioprocessing solutions in roadmap exercises and will make active investments in POCs over the next year.
- Automating and optimizing complex bioprocessing is still a rather difficult task, yet vendors posture as having full capabilities for integration, automation and insights. For these reasons, this is located at the peak.

Obstacles

- Many organizations have an existing laboratory information management system (LIMS), electronic laboratory notebook (ELN) and laboratory execution system (LES) solutions in place as “core” solutions used for laboratory support for biologics processing, complicating changeovers to new solutions.
- Bioprocessing requires stringent validation and compliance (such as GxP, IQ, OQ and PQ, and computer systems validation), leading to additional implementation costs when switching to new platforms.
- Many life science organizations have been persuaded by vendor promises that existing lab informatics platforms can perform in this new area. As a result, these legacy systems are heavily configured, creating even more IT complexity and technical debt, and making migration strategies to new technology platforms a complicated endeavor.
- The dominant method for developing bioprocesses is using spreadsheets, and many organizations are slow to adopt new methods and technologies.

User Recommendations

Evaluate where bioprocessing suites can add value to your organization. To do this, you must perform the following:

- Characterize the potential improvements in “turnaround time” for methods development for complex biologic processes. Examine the impacts on improvements of product release timelines or milestones with partners.
- Estimate the cost savings and reduction in staffing with a focus on integration, validation and overall life cycle.
- Determine the reliance your organization has on shadow IT to execute existing processes. Focus on the roles that are required to conquer the technical debt of old legacy systems and processes that are ingrained into the business.
- Evaluate how quickly you can change cell and expression systems, bioreactor formats and scale-ups. Outline for stakeholders how bioprocessing informatics solutions can improve agility with existing solution sets with analytics, process flow changes, new materials entry and formulation design.

Sample Vendors

Benchling; Bionet America; BioPharm Engineered Systems; Danaher (Cytiva, IDBS); Dassault Systèmes; Genedata; MilliporeSigma; Sartorius; Synthace; Thermo Fisher Scientific

Gartner Recommended Reading

Your Lab of the Future Strategy Must Enable Life Sciences Digitalization

Life Science CIO's Strategy for Delivering Cell and Gene Therapy Capabilities

How Technology Can Support the Next Phase of Commercial-Scale Cell and Gene Therapies

Healthcare and Life Science Business Driver: Medical Technology Innovation

Lights-Out Manufacturing

Analysis By: Simon Jacobson, Alexander Hoeppe

Benefit Rating: Transformational

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Lights-out manufacturing relates to factories characterized by digitized production processes that adapt with minimal to zero human intervention. It reflects the shift toward hyperautomation — the orchestrated use of multiple technologies, tools or platforms to automate processes and augment humans in factories. It also reflects the growth of autonomous things that can interact with and manipulate different factory environments with various levels of human guidance, autonomy and collaboration.

Why This Is Important

- Ambitions to operate autonomous supply chains supported by smart factories that are heavily automated that can adapt to changing internal and external conditions.
- Market uncertainties such as variable lead times and rising costs, and inconsistent labor inputs make automation an attractive option to maintain service levels or increase competitive stance.
- Ongoing developments in hyperautomation technologies such as robotics, AI/ML, AR/VR, and Internet of Things (IoT) expose the opportunity for factories to create new, virtual production processes and boost cost efficiency,and agility through reliable supply from factories.

Business Impact

The supply chain's demand for factories to flexibly adapt will only increase in the future. Lights-out production offers relief by combining process automation and augmentation to balance cost, compensate for labor gaps and deliver reliable supply.

Drivers

- Increasing localization and shortening of supply chains with different labor, demand and cost profiles reliably balance cost and service fuels interest in automation.
- Counteracting labor shortages by leveraging advances in AI, autonomous things (and other technologies supporting the hyperautomation trend) to remove physically demanding or mundane tasks, executing transactions and provide guidance at the point of decision — without compromise to speed, quality or cost.

Obstacles

- **Finding the starting point:** Different customer demands, labor inputs, utilities and other economic factors between high- and low-cost markets can make lights-out production an expensive ambition versus a cost-efficient reality.
- **Investment approval:** Accessing capital funds and securing funding to overcome expansive collective organizational debt for this expansive initiative might be impeded. Also integration costs of new and existing technologies with existing data, workflows, and decisions carry often under-budgeted-for hidden costs.
- **Complexity:** Decoupling processes and identifying where to augment existing processes with technology and where to apply a lights-out setup is not straightforward. Making trade-offs between agility and flexibility takes time.
- **Technology debt:** Reliance upon a single vendor or technology offers/as the complete solution is short sighted. Upgrades to existing IT and OT could be cost prohibitive.

User Recommendations

- Begin developing new skill sets now to train and maintain algorithms and process improvement.
- Budget extensively to modernize OT (programmable logic controllers, drives and other technologies that control a process) as well as legacy IT systems. Set aside extra funding for integration as its costs are always underestimated.
- Identify process standardization opportunities when differentiating human augmentation from automation. Use the degree of human interaction based on the task or activity as a guide.
- Prioritize cost, risk and technology maturity criteria when deciding what degree to invest in lights-out production by executing a rigorous assessment that examines the cost benefit of fully automating a process.
- Recognize that not all production activities will evolve in a common way and humans will always be needed. Manual processes — either human-driven, or those in isolated and legacy transactional systems — are a sufficient starting point.

Gartner Recommended Reading

Lights-Out Production Will Be a Reality by 2025

From Human Augmentation to Lights-Out Production: How Far to Go With Industrial Automation?

Hyper-Automation Is Changing Factory Workers' Jobs, and IT Will Help With the Transition

Video: DuPont's Journey to Lights-Out Manufacturing

Win More Business in Manufacturing With Composable Hyperautomation Capabilities

IoT-Enabled Laboratory

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Internet of Things (IoT)-enabled laboratories leverage sensors, beacons and systems, such as instruments, informatics systems and smart consumables, for communicating information between lab entities. By leveraging analytics across the portfolio of IoT-enabled capabilities and connecting previously disconnected data elements generated from the existing instrumentation, users can monitor performance and generate new insights. IoT enablement is foundational for the laboratory of the future (LoF).

Why This Is Important

Connecting laboratory entities helps in contextualized data exchanges and the enhanced evaluation of test results and analysis. IoT is no longer nascent in the lab space. While many organizations are still exploring how to connect entities such as lab equipment (e.g., pH meters and balances), laboratory informatics (e.g., ELN and LIMS), and smart consumables (e.g., buffers and reagents) with enterprise assets (e.g., RFID badges, ERP and environmental, health and safety [EH&S]), a small number of organizations have gone into full production.

Business Impact

IoT-enabled laboratories and connecting labs help CIOs and IT leaders enable:

- Smart lab and LoF strategies, driving autonomous processes based on algorithms and machine learning that leverage IoT data
- Organizations to converge their virtual and physical work and create digital twins for lab processes, improving innovation, efficiency, quality and compliance

Drivers

- Both PRISME and Pistoia Alliance included LoF as a topic at annual meetings over the last four years.
- Nascent strategies related to LoF, such as digital lab, laboratory 4.0 and Internet of Lab Things (IoLT), have taken root.
- Several instrument vendors are offering cloud-based IoT platforms. However, these are initially designed for remote field service and asset tracking and monitoring.
- A variety of vendors now enable data-lake-based instrument data management, which divorces lab connectivity components from traditional lab informatics packages such as electronic laboratory notebook (ELN) and laboratory information management system (LIMS) software.
- Given that most lab staff are now realizing the larger consulting service firms have limited knowledge of laboratory processes, the lab IT consultants aren't as familiar with IoT best practices, and the traditional laboratory informatics and automation software vendors have challenges with data management and regulatory compliance, we position this technology just past peak hype. It will quickly slide into the trough within the next two years.

Obstacles

- Life science institutions with laboratories already have high capital spending, hence incremental spending with clear ROI will be hard to justify. We expect smaller proofs of concept for IoT before typical users undertake any extensive approaches to modernize laboratory environments.
- IoT devices and platforms can be complex, and the setup and configuration process may require specialized knowledge and expertise. This can be a barrier for some organizations, particularly smaller ones that may not have dedicated IT resources.
- Incremental technology investments in tools and staff will be required in order to make sense of the data and leverage the analytics for insights.

User Recommendations

- Outline the business benefits your organization can achieve by "going digital" in its laboratories. Focus on how people, systems and things on equal footing will create new possibilities to improve quality, accelerate innovation and improve operational effectiveness.
- Identify opportunities for LoF efforts by focusing on where IoT analytics can lead to innovation, quality, operational efficiencies and improved safety/risk monitoring.
- Define "digital business moments" and model examples for laboratories that will have direct impacts on creating new value by identifying outcomes such as faster time to data lock, improvements in instrument operations and higher compliance.

Sample Vendors

Apprentice; Bosch Digital; Connected Labs; Elemental Machines; Labforward; Monnit; Scitara; Simplifier; TetraScience; WattIQ

Gartner Recommended Reading

Your Lab of the Future Strategy Must Enable Life Sciences Digitalization

Quick Answer: How Do You Know That You're Building a Truly Digital Life Science Lab of the Future?

7 Key Questions Life Science CIOs Should Ask When Selecting Laboratory Informatics Software

Market Trend: Moving From IoT Platforms to IoT-Enabled Applications

Emerging Technologies: AI-Enabled IoT

Sliding into the Trough

Cold Chain as a Service

Analysis By: Maria Nieradka

Benefit Rating: High

Market Penetration: More than 50% of target audience

Maturity: Adolescent

Definition:

Cold chain as a service is a rapidly evolving series of solutions, tools and services. They deliver applications and functionality for real-time visibility, tracking and condition-based monitoring specific to cold chain (temperature), using dedicated SaaS and hardware offerings for specialized IoT applications for multimodel, in-transit products and assets.

Why This Is Important

Maintaining full product integrity across critical supply chain phases, including sourcing, manufacturing, logistics and distribution, is growing in urgency and momentum, driven by environment-sensitive product lines. This is critical with high-profile vaccines and specialized medicines that require cold chain capability. Legacy temperature monitoring of a product in logistics is now being augmented to accommodate demands for real-time visibility, monitoring and security to mitigate risks.

Business Impact

New generations of medicines, vaccines and raw materials require real-time tracking, location and condition-based monitoring in logistics and transportation transactions. Cold-chain-as-a-service providers deliver portfolios of IoT software and hardware services, extending beyond traditional temperature tracking. It includes continuous monitoring of temperature, motion, security, humidity, tilt, shock and light depending on the profile, sensitivity and risk implications of the product itself.

Drivers

- As both large pharma and biotechnology companies deliver more sophisticated, tailored and precision-based medicines to patients, there are additional critical physical and digital risks that must be considered. For these products, supply chain leaders must now consider the environmental sensitivity of products as well as security implications at very high price points for certain categories of therapies (i.e., biologics and cell and gene therapy).

- Cold chain has been established across the pharmaceutical industry for many years, with solutions targeting the temperature profile maintenance through customized packaging and transportation mediums across specific logistics routes and product categories. New technologies are available that can radically optimize legacy cold chain approaches.

- New generations of solutions supporting cold chain as a service align specialized hardware modules and software applications directly to the changing nature of products and healthcare delivery. These solutions include expanded capabilities like specialized or packaged IoT tools and hardware including sensors, diagnostics, telematics, vision systems and specialist cameras, and real-time temperature monitoring and alerts. They also include GPS, and the location or position of product, order or asset, as well as shock, motion and tilt sensors, and idle time and critical deviations from established protocols or regulations. Other capabilities are tracking, mapping and reporting alert dashboards, interfaces and mobile applications, as well as specialized security applications for both physical asset and data security. Also included are a strong complement of service tools configured to roles and responsibilities, especially in visibility mapping for chains of custody, alerts and refresh relays on location, and status and condition in real time. Lastly, this could include embedded machine learning and analytics tools for continuous monitoring and capture of data, transactions and events.

Obstacles

- A major obstacle in value interpretation is around the language or terminology used to classify cold chain requirements. While traditional activities have exclusively focused on temperature reporting and continuity, service evolution and new generations of products will align to use cases that will need to deliver across a much broader range of conditions. These include real-time visibility and security monitoring tools, and applications and services.

- The diversity of extensive product portfolios, especially in midsize to large manufacturing organizations, may not align to border business objectives around enterprise integration opportunities to deliver cold chain as a service en masse through a standardized platform. The value of new generations of solutions is in their ability to be highly configurable and adaptable, often focused on dedicated tracking and monitoring at the physical product level in B2B or B2C transactions.

User Recommendations

- Identify service providers that offer configurable options around both hardware and software, either as dedicated hardware as an integral part of the success and value of the software and service fulfillment, or "bring your own device" agnostic connectivity.
- Prioritize vendors who have experience delivering to specific requirements impacting change and investments in the life sciences and biotechnology sectors, especially in areas such as regulatory, R&D, and clinical and patient engagement. This includes matching vendor capabilities with use cases as needed.
- Extend discovery beyond just using the keywords "cold chain." Assess a closely aligned group of vendors from across different market spaces such as real-time visibility, asset tracking, traceability and serialization that can offer services and applications aligned to use cases.

Sample Vendors

Arviem; Controlant; ParkourSC; Roambee; Sendum; Sensitech; SkyCell; Tive, Wiliot

Gartner Recommended Reading

Tracking and Monitoring Business Process Context: 'Magic Quadrant for Real-Time Transportation Visibility Platforms'

Power of the Profession Supply Chain Awards 2023: Global, Social and E2E Innovation Rise

UDI for Medical Devices

Analysis By: Salil Joshi

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Unique device identification (UDI) is an alphanumeric or numeric code (human- and machine-readable) assigned to a medical device to make tracking and identification as easy as possible across the supply chain. A UDI needs to be on the label of a device or, for reusable products, a direct marking on the device itself.

Why This Is Important

UDI solutions are required to align supporting formalized global UDI regulations, such as those from the U.S. Food and Drug Administration (FDA) and the increasingly influential EU Medical Device Regulation (of which UDI is a strategic component). UDI regulations adopt progressive risk-based approaches, targeted primarily at direct coding and marking techniques, as well as the management of unique identifier data elements to enhance safety, traceability and ongoing product vigilance.

Business Impact

UDI for medical devices impacts labeling, packaging changes and data submission requirements for manufacturers. It also affects scanning, data capture requirements and efficient recall management for healthcare providers. Solutions are anticipated to mature further to closely align to developing global UDI regulations, following requirements set out in U.S. and EU mandates. This year's positioning and progression to past the peak represent the potential for further regulatory mandates globally and refinement of solution evolutions to existing regulations.

Drivers

- The strategic importance of product life cycle management (PLM) for surveillance and tracking medical devices has also had an influence on requirements, emerging solutions and projected supply chain benefits. Early solutions supporting UDI have predominantly focused on the electronic process elements to fulfill U.S. legislation, such as management and submissions of multiple supply chain data elements and specific device attributes — for example, the U.S. Global Unique Device Identification Database (GUDID).
- Approximately four million medical device records have been added to the U.S. GUDID system by Class 1, 2, and 3 device manufacturers as of May 2023.
- The International Medical Device Regulators Forum (IMDRF) publishes harmonization standards to ensure uniqueness of a device wherever it is located or used anywhere in the world.
- As an indicator of further solution maturity, the FDA makes a special mention of the benefits of a UDI system for manufacturers, consumers and healthcare providers. Benefits include improved continuous and postmarketing surveillance, data integration to electronic health record (EHR) systems, reduction of medical errors via better data accessibility for supply chain stakeholders, and better control of medical device recalls.
- Other UDI benefits include harmonization of international and national governing networks of device registries, reducing counterfeiting activities, managing health reimbursement claims, and optimizing supply chain processes. Another UDI benefit is implementation of automatic identification and data capture (AIDC) options, such as RFID and data matrix bar codes. These also contribute to enhanced supply chain maturity through interoperability across supply chain stakeholders and electronic connectivity to patients.
- Healthcare providers in the U.S. have initiated pilot UDI projects focused on capturing UDI data at the point of care for implantable devices.
- A number of solution partners and specialist integrator companies have released regulatory-aligned products and services for this space.

Obstacles

- Previously anticipated regulations from other countries have yet to materialize formally, thus limiting the size and speed of maturity of the market space.
- Current IMDRF members are still expected to spur a wave of new regulatory requirements. For example, Australia, Brazil, Canada, China, Japan, Russia, Singapore and South Korea are aligned to these standards. Several other countries, such as India, Saudi Arabia and Taiwan, that are not currently members of IMDRF, have also introduced guidelines for UDI.

User Recommendations

- Establish continuous reviews to track global UDI requirements, and determine capabilities and solutions needed to support them.
- Initiate dialogue with solution providers to ensure their scalability and flexibility to meet existing and future updates to U.S. requirements, as well as diversification, as other countries' legislation comes into force.
- Deploy solutions that can deliver robust data mining, management and governance for reporting, submissions and supply chain integration purposes.

Sample Vendors

1WorldSync; Accenture (Inspirage); Freyr Solutions; InVita Healthcare Technologies; LexisNexis (Reed Tech Life Sciences); Peak Technologies; Rimsys; SteriTrack; Syndigo; USDM Life Sciences

Gartner Recommended Reading

Healthcare Provider Supply Chains Must Adopt UDI to Meet Regulatory Requirements

Blockchain in Life Sciences

Analysis By: Michael Shanler

Benefit Rating: Transformational

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Blockchain platforms provide the foundation to create and run blockchain solutions and decentralized networks. This includes support for distributed ledgers, decentralized consensus, tokenization and smart contracts. They enable the creation of blockchain solutions that provide immutability, transparency, decentralized contract execution, and tokenization of physical or digital assets. In life science (LS), blockchain can facilitate the secure exchange of health and LS manufacturer information.

Why This Is Important

Primary applications of blockchain technologies in the LS industry include anti-counterfeiting (serialization), genomic and/or clinical data sharing, revenue management and materials transfer. It is a popular strategy topic with Gartner clients, especially as blockchain-based topics run rampant in the mainstream media and organizations attempt to transform operations. Although blockchain is still hyped across many industries, the LS industry continues to be slower than others to develop use cases into production.

Business Impact

The impacts of blockchain in LS are:

- Blockchain and distributed-ledger concepts hold the promise of transforming LS industry operating models. Transformations are just beginning with projects such as PharmaLedger, Zuellig Pharma Holdings and MSD, and are largely unproven at scale.
- LS organizations want to reach new customers, extend relationships with supply chain partners, improve quality and create more complete links between events.
- Executives want to move the boundaries of traditional LS businesses including enabling direct-to-consumer models.

Drivers

- The number of active blockchain projects within the LS industry grew from 2020 to 2023. For example, Merck & Co. and Novartis are running very public supply-chain POCs. Gartner clients report a rise in blockchain to support platform-centric ecosystems including projects such as PharmaLedger. See Supply Chain Executive Report: Realizing the True Potential of Ecosystem Partnerships.
- Industry consortia have been active as well with 12 pharmaceutical companies joining PharmaLedger, an EU blockchain consortium.
- Some clients are exploring concepts where blockchain would streamline clinical trials and extended regulatory filings, exchange genomic information, manage intellectual property generation, handle payments to drug distributors, and conduct health record and exchange transactions.
- Blockchains are supporting technology architectures and digital interoperability for transitioning toward more tailored medicines, patient-centricity and virtuous cycles of data centered in and around cradle-to-grave product life cycle management.

Obstacles

- LS industry stakeholders are learning that blockchain-based models are difficult to scale due to disagreements on the degree of centralization and channels.
- Most industry professionals have still not settled on the right type of governance to drive the necessary innovation, collaboration and cultural shifts.
- Digital maturity, legacy infrastructure and siloed work practices could limit value realization for blockchain discovery or readiness to deploy.
- Today, there are few vendors, IT consultant firms and sponsor organizations that have a deep LScapability and that understand blockchain models and underlying technologies.
- There are only a few successes with scaling blockchain pilots for track and trace, verification services and wholesalers, much of which is driven by regulations such as the Drug Supply Chain Security Act (DSCSA) via stakeholder-led models.
- Blockchain was extremely hyped a few years ago, but many clients now realize the limitations and challenges. For this reason, this technology is positioned on the trough.

User Recommendations

- Assess the impact of change across the LS sector. The terminology surrounding blockchain is also in flux. This uncertainty masks the potential ability to meet business use cases.
- Identify how the term “blockchain” is being applied, both internally and by providers, to better understand the return on capital employed, especially compared to (or augmented with) existing, proven technologies.
- Proactively learn the differences between the four implementation options as part of your organization’s strategic planning efforts, especially as they relate to specific business use cases and operational risk assessments.
- Assign resources to track the evolution of blockchain across industries, such as consensus mechanism development, sidechains and distributed ledger.
- Develop knowledge around vendor solutions’ evolution, especially through formal stakeholder-led models addressing critical requirements, compliance mandates and the success of resulting proofs of concept (POCs).

Sample Vendors

Bloqcube; Chronicled; EncrypGen; EY; Genecoin; Nebula Genomics; Schrocken; ServBlock; Tech Mahindra; Wipro

Gartner Recommended Reading

Guidance for Blockchain Solution Adoption

Power of the Profession Supply Chain Awards 2023: Global, Social and E2E Innovation Rise

The Future of the Supply Chain for Life Sciences — 2023 Report

Supply Chain Executive Report: Fostering a Digital Supply Chain Ecosystem

Gartner’s Top Strategic Predictions for 2023 and Beyond — Seizing Uncertainty

3DP Drugs, Nutraceuticals and Supplements

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: Less than 1% of target audience

Maturity: Emerging

Definition:

3D printed (3DP) drugs, nutraceuticals and supplements are tablets and chewables that have been “printed” instead of made using traditional solid dose formulation and production methods. 3DP enables the individualization of drug concentrations and volumes by altering the surface characteristics and shapes. The technology enables the creation of individualized doses and specialty release characteristics, as well as the printing of multiple medications into a single form.

Why This Is Important

3DP drugs represent a change to the value chain and supply chain by designing personalized doses for individuals and/or specific formulations. While “drugs” have specific regulatory claims, this technology can also be applied to less-regulated (in regards to claims and clinical trials) nutraceuticals, supplements and vitamins segments.

Business Impact

3DP drugs represent opportunities for R&D to investigate improved safety and efficacy, as well as new indications:

- If 3DP drugs improve outcomes, then there could be broader impacts on drug pricing, rebates and approvals, which would also affect market penetration and market share.
- 3DP can be a useful approach for eliminating supply chain and inventory lags for low-volume tablet production and compounding product areas.

Drivers

- 3DP drugs are no longer science fiction — they are a reality. Aprecia Pharmaceuticals was the first company with a product on the market. They currently have partnerships with Prasco Laboratories (a generics company) and Syneos Health (a professional services, contract research organization) and have several other 3DP supplements in the pipeline.
- After FABRX released M3DIMAKER for 3DP personalized pharmaceuticals and demonstrated that 3DP could be used to create oral tailored-dose therapies in a hospital setting, other companies have expressed interest in similar developments and have been initiating proof of concepts (POCs).
- Multiple companies and institutions have been actively researching printed drugs and biologics, and working with regulators. Some life science organizations are asking about academic work, such as the University of Cambridge and the University of Copenhagen measuring the accuracy of printing active pharmaceutical ingredient (API) formulations. There is also the University College London School of Pharmacy's approach to a 3DP technique for "hot melt extrusion" to create unique pill shapes that will be more child-friendly using liquid-based tablets. Wake Forest University's approach is to use a computer algorithm to calculate dosages according to patients' biological and clinical parameters, instead of using predetermined dosages. Kyungpook National University is developing fused-deposition-modeling-built gastro-retentive floating tablets.

Obstacles

- Major pharmaceutical firms focusing on costs often see 3DP as a “niche” capability.
- So far, only one FDA-regulated medication — Aprecia’s ZipDose Technology for SPRITAM (levetiracetam) — is fully approved and on the market. In 2021, Triastek received two Food and Drug Administration (FDA) Investigational New Drug (IND) clearances for T19 and T20, 3D-printed drugs using melt extrusion deposition (MED), respectively to treat rheumatoid arthritis and cardiovascular and clotting disorder. As more 3DP drugs head toward regulatory submission and the pharmaceutical supply chain, we expect companies to experience some difficulty with internal quality and logistics processes, scaling and volume build.
- Because of the complexity of the POC process and limited partnering options, 3DP of drugs will take at least 10 years before becoming mainstream.
- Today, many Gartner clients are unsure about the future price points for 3DP drugs and FDA IND requirements. Clients have concerns about single-source contract manufacturing. For these reasons, this technology is in the trough.

User Recommendations

- Investigate 3DP drugs only if it aligns for therapeutic reasons (like controlled release of substance), or if it fits a supply chain focusing on individualized or personalized drug doses.
- Explore the possibilities for targeted dosing and personalized medicine. Formularies, supplement manufacturers and contract manufacturing organizations (CMOs) are also logical early adopters.
- Determine the sweet spot enabled by 3DP for your business — such as being used for developing on-demand products, and customized API doses with specific drug release and diffusion chemistries.
- Solicit stakeholder input as it relates to fitness for purpose, costs, supply chain, CMO requirements, logistics, skills, quality and complexity versus traditional tableting methods. Examine partnership opportunities while ensuring process alignment to future logistics, manufacturing and quality systems.

Sample Vendors

Additive Manufacturing Customized Machines (AMCM); Aprecia Pharmaceuticals; FABRX; Multiply Labs; REMEDY HEALTHCARE; Triastek

Gartner Recommended Reading

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

2023 Healthcare Provider Business Drivers of Technology Decisions

Healthcare and Life Science Business Driver: Strategic Technology Change

Digital Threads

Analysis By: Christian Hestermann, Marc Halpern, Rick Franzosa, Sudip Pattanayak

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

A digital thread is a framework of roles, processes and tools that enable the collection, organization and presentation of data for multiple factors that influence a product or process and their evolutions over their respective life cycles. The integration and organization of data and information enable multiple users to access, integrate, organize, trace and transform disparate technical and knowledge-based data from multiple operational and enterprise-level systems.

Why This Is Important

Digital thread is a fundamental concept of digital manufacturing. The digital thread supports digital twins by connecting multiple data and information sources across design, manufacturing, supply chain systems, processes, and other aspects of business with interdependencies and traceable history. It can connect the evolution of design requirements through production, delivery and service and then retirement or reuse to ensure a compliant and quality product is delivered to the customer.

Business Impact

Digital threads improve the efficiency and agility of decision making on cost, quality, traceability, sustainability and regulatory compliance of design, production, use and service of products. They provide insights on variations in cost and quality metrics impacted by changes to product designs and configurations. Their dynamic nature can streamline execution of standard work, improve suppliers' engagement, help organizations determine the most beneficial investments in the evolution of a product and its digital twin.

Drivers

- A broad vision of product life cycle management (PLM) encourages digital thread investments. Digital threads encompass a wide time horizon, and provide history and context specific to a product's or a process's life cycle.
- Technology advances and growing experience at governing data are enabling digital threads. Growing volumes of data come from a rising number of connected products supported by IoT platforms, edge devices and sensors. New technologies and tools (cloud services, industrial IoT platforms, and automated data synchronization and validation) can access, verify, validate and synchronize data — as well as offer analytics for simulation and pattern analysis. This is more than core manufacturing execution systems (MES), PLM and ERP systems can provide when used in isolation.
- Manufacturers across multiple industries understand digital threads' criticality to mitigate the complexities and risks associated with new configurations (and product-specific variants) or rising customer demand for smaller order quantities.
- Compliance with regulations, such as those of the U.S. Food and Drug Administration (FDA) and International Traffic in Arms Regulations (ITAR), will be more transparent and efficient.
- Mature management of bills of materials (BOMs) from engineering (eBOM) through manufacturing (mBOM) and service (sBOM) is a challenge, which digital threads can address.
- Cost optimization and time savings come from shortened decision cycles and improved agility on both global and local bases. Accelerating innovation and bringing products to market faster are also important values gained from digital threads.
- The growing demand for various environmental, social and governance (ESG) initiatives are well supported by digital threads.

Obstacles

- **Intellectual property protection concerns and cyber risks:** These can dissuade members of value chains from participating in digital thread initiatives.
- **Difficulty achieving consensus on architecture and scope:** Different roles in value chains have a stake in digital threads. Each of these roles has different priorities, different content needs and different ways of interacting with data. Satisfying each role causes delays, and increases scope, cost and the risk of failure when implementing digital threads.
- **Vendor lock-in:** Manufacturers that rely on a few vendors to deliver large "chunks" of digital threads will likely become increasingly dependent on that vendor, particularly as the content and workflows added to a digital thread increase over time.
- **Technology obsolescence:** Technology advances rapidly expand the possibilities of digital thread architectures. However, the risk of obsolescence derives from committing to digital thread technologies that become obsolete before the intended life span of the digital thread.

User Recommendations

Supply chain leaders and CIOs looking to invest in and manage the digital thread should:

- Focus on building the digital thread as a representation of a product and all the processes that evolve over the product's life cycles, instead of confining it to engineering and production.
- Use the digital thread as a tool for improving efficient decision making, cost, quality, traceability and regulatory compliance in product design, manufacturing and service.
- Adopt an industry data governance strategy for a digital thread by including members of the value network in planning for data oversight, data orchestration, data curation and data management.
- Overcome the absence of a complete data model by investing in standards to capture, connect and normalize data from different systems.
- Include open standards as much as possible in the digital thread roadmap.

Sample Vendors

Anark; Aras; Schneider Electric (AVEVA); Dassault Systèmes; Exentra; Hexagon; iBase-t; Microsoft; PTC; Siemens Digital Industries Software

Gartner Recommended Reading

Innovation Insight: Implement Digital Threads for Long-Term Flexible Access to Critical Data

Top BOM Practices for Building Digital Threads in Discrete Manufacturing Industries

How CIOs Can Use PLM to Optimize the Adoption and Value of a Digital Thread

Implementing the Technical Architecture for Master Data Management

Quick Answer: 4 Technical Prerequisites for Successful Digital Twins Implementation in Manufacturing

Digital Validation Tools

Analysis By: Jeff Smith, Michael Shanler

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Adolescent

Definition:

Digital validation tools deliver life sciences manufacturers tools, services, expertise and applications to assure that documents, software, operations infrastructure and processes remain optimized and comply with the requirements set out for specified purposes of their intended use. Tools and services may support specific regulations or requirements, such as the U.S. FDA's Title 21 Code of Federal Regulations (21 CFR) Part 11 and observed industry best practices (e.g., GxP, cGMP or GAMP).

Why This Is Important

Services and tools supporting GxP validation are on the rise. They enable global life science companies to ensure process methods, protocols, equipment and operations infrastructure and technologies continually comply with the requirements for their intended use. Gartner has observed renewed interest from manufacturers on how digital and virtual validation approaches will transform existing best practices as companies seek to transition to paperless and more automated operations in the cloud.

Business Impact

Validation is a globally adopted and expansive range of systematic principles to embed the delivery of continuous quality over the entire production process. This spans active pharmaceutical ingredients (APIs) through to finished goods manufacturing to postmanufacturing phases. Validation requirements can include an entire manufacturing site (or partner site), system audits or specific analytical methods, computer software and processing steps.

Drivers

- With more movement toward cloud and SaaS applications, validation tools and services are in higher demand. These help reinforce compliance across a very diverse set of process and workflow metrics, as well as robustly monitor on a frequent basis to check and ratify compliance and adherence.
- Key areas creating demand for these tools include: (a) wholesale adoption of equipment and software tools, such as laboratory information management systems; (b) cleaning and sterilization cycles pre- and postmanufacturing; (c) computer system validation, including paperless validation and automated testing for software and hardware; (d) vendor risk assessment and auditing; (e) process validation of packaging processes and equipment use; (f) mobile technology supporting manufacturing and logistics operations; (g) use of manufacturing systems for batch processing, such as manufacturing execution systems, serialization and quality management; (h) adoption of electronic and digital signatures for batch processing and release; (i) site validation for outsourcing partners, such as CMOs; (j) systems managing standard operating procedures and training materials for manufacturing associates; (k) regulatory validation and compliance.
- The increased adoption of cloud-based applications throughout the industry has enabled service providers to deliver enhanced ranges of digitized prevalidated documentation, templates and scripts.
- Use of broader service platforms that continually enable automated monitoring and continuous validation, without the need for resource-intensive customizations or retrospective upgrades.
- Compliant GxP cloud service variations include the hosting of validated applications, client infrastructure, the provisioning of managed compliance services and compliant cloud computing.
- The U.S. Food and Drug Administration's draft guidance of Computer Software Assurance is the latest in an industry push toward modernization of processes, this time focused on computer systems validation. This guidance provides clearer direction toward risk assessment of systems as part of a validation approach, further driving adoption of new technologies and methodologies.

Obstacles

- Increased product sophistication (such as a transition to biologics and personalized medicines) will require a more intensified and open approach to continuous monitoring and embedded levels of product excellence. Yet, companies remain overly reliant on legacy monitoring and 100% verification checks, slowing adoption of new continuous validation approaches.
- Historic validation processes have overrelied on paper-based systems of records (especially operating procedure, work instructions and process methods relating to manufacturing). Quality practices are highly ingrained and aligned to paper-based methodologies, with organizations slow to change.
- Despite regulators' new positioning on GxP Validation, deeply ingrained legacy approaches to validation slow adoption, with many companies slow to invest in an area where change may introduce additional risks to compliance. As a result, this technology is positioned in the trough.

User Recommendations

- Establish targeted teams assigned to specific validation assignments, ensuring a multidisciplinary level of representation from affected experts and stakeholders.
- Ensure services provider evaluation concentrates on supplementing internal resources around exceptions, critical path and process risk gaps.
- Assess vendors and integrators who can demonstrate expertise for delivering across life sciences phases of product development, processing and distribution.
- Determine solutions' readiness for robust "qualification" steps in areas including people, technology systems, physical machines and batch processing.
- Use providers that can offer a complement of services and tools for validation alongside cloud-based configurations for phased migration to standardized and digital validation scripts and templates.

Sample Vendors

IKCON PHARMA; Kneat; Onshore Technologies; OpenText; Performance Lab; SL Controls; Sware; Tricentis; ValGenesis

Gartner Recommended Reading

Life Science CIOs: Use Computer Software Assurance to Modernize Your GxP Validation Practice

Strategic Life Science Regulatory Information Management: From Fragmented to Holistic

Innovation Insight for Bias Detection/Mitigation, Explainable AI and Interpretable AI

Life Science CIOs, Accelerate Clinical Development With New Applications of Artificial Intelligence

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Smart Factory

Analysis By: Simon Jacobson, Alexander Hoeppe

Benefit Rating: Transformational

Market Penetration: 20% to 50% of target audience

Maturity: Adolescent

Definition:

Smart factory is a concept used to describe the application of different combinations of modern technologies with standard work to create a hyperflexible, self-adapting manufacturing capability.

Why This Is Important

Smart factories combine modern technologies and standard work to innovate how factories operate. Smart factories are an underlying capability of smart manufacturing and broader digital supply chain and Industrie 4.0 initiatives, providing an environment where frontline workers and technology interact in an open, connected and coordinated fashion.

Business Impact

Smart factory value creation and benefits happen across a wide spectrum, leveraging a vast array of technology combinations and use cases that will differ by industry, kind of supply chain supported and manufacturing style. The initial benefits are broadly rooted in improving site operations. Over time — as smart factories are synchronized with how the business works — improvements in flow, customer service, sustainability, agility and profitability are possible.

Drivers

- Industrie 4.0, smart manufacturing initiatives (including resiliency, automation and optimization), new value chain requirements and evolving operating model shifts are driving interest in smart factories.
- Competitive pressure is driving the innovation of production management by digitizing existing processes to improve data-driven decisions by workers.
- Improving operational resilience means sites can take on more orders, meet market changes faster, improve sustainability, or deliver newer and more complex products.
- Users are becoming dissatisfied with the value, scalability and cybersecurity risk inherent in legacy manufacturing technology (such as MES, ERP, OT).

Obstacles

- Outside-in designs for smart factories and the role they play in the network require aligning culture and individual job roles/responsibilities on a local basis.
- The majority of smart factory initiatives are upgrades of existing facilities. Complexity of integrating different modern technologies such as industrial Internet of Things (IIoT), AI or digital twins with existing information technology/operational technology (IT/OT) investments can be costly and time consuming.
- Belief that a single-vendor solution exists. Not one specific technology or vendor can deliver a smart factory.
- Funding models to overcome extensive backlogs of IT and operational technology (OT) upgrades, integration, and other technical debt are challenging to create.
- The emphasis of tactical wins at sites that are not synchronized with product supply strategy thereby create the risk of excess costs and constraints elsewhere in the business.
- The urgency of aligning and converging IT/OT and engineering technology (ET) is easily overlooked.
- There is a failure to acknowledge and adequately prepare for the cultural and change management impacts that come with process design or redesign, and new ways of working.

User Recommendations

- Avoid isolated technology projects by promoting the smart factory concept as part of an agile system designed to service demand. This keeps the focus on enabling profitable agility across the supply chain.
- Design for scalability by identifying capabilities first and applying a composable (i.e., modular) step-by-step approach. Then introduce standard use cases combining workflow, data processing, technology and user experience.
- Prioritize use cases based on site maturity and objectives.
- Utilize real-time factory data to improve decisions and mitigate risks in the supply chain.
- Include your workforce — people are your critical assets. Redefine learning and development (L&D) to give factory workers the digital dexterity to interact with new processes and technologies around them.

Gartner Recommended Reading

Innovation Insight for Smart Factory

Quick Answer: What Are the Differences Between Industrie 4.0, Smart Manufacturing and Smart Factory?

Video: DuPont's Journey to Lights-Out Manufacturing

Quick Answer: Differences Among Industrie 4.0, Smart Manufacturing and Smart Factory

Predicts 2023: The "Triple Squeeze" Will Require Manufacturing CIOs to Gain Visibility by 2026

Tech Transfer Services (Foresight)

Analysis By: Maria Nieradka

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Adolescent

Definition:

Tech transfer (sometimes called tech scale-up) services support life science companies in the delivery of controlled, documented and systematic approaches to the transfer of analytics and processing data, as well as product formulation knowledge. Services and tools support a risk-based and multidisciplined approach to seamless knowledge transfer of process and product knowledge between R&D, pilot scale-up and manufacturing or process transfer knowledge between manufacturing sites.

Why This Is Important

Tech transfer is a critical phase of product development and production realization life cycle. Historically, in many companies, it has been a customized, protracted and fragmented process impacting multiple stakeholders and touchpoints. Life science technical transfer is unique, requiring the very best practices and tools in project, risk and change management, alongside other key parameters including continuous quality monitoring and vigilance. This must be reflected in the range of services offered.

Business Impact

Tech transfer best practices and projects strongly reference the concept of “knowledge transfer” which, depending on the specific transfer, can have wide-ranging ramifications to business operations — especially in the accurate forecasting for product release and distribution. Knowledge transfer principles apply to processes, analytical testing and sampling methods, but also have significant impacts on people, equipment, intellectual property and life cycle planning.

Drivers

- Step-by-step mapping for procedures, quality gates, transfer schedules, responsible people for approvals, feedback loops and escalations criteria.
- Master formulations, data, specification planning and migration tools.
- Process equipment scale-up documentation for qualification, validation including deviations, and excursions mapping and resolution.
- Licensing activities, planning and incorporations into master planning with contract partners (for example, CMO and CDMO).
- Regulatory service and risk-based assessment tools for initial manufacturing authorization, ongoing compliance, required changes and submissions needed for new methods or protocols.
- Enterprisewide communications portals and digital applications for internal interoperability across R&D, regulatory teams, quality and manufacturing operations.
- Compatibility and feasibility studies, analytical and process testing documentation, assessment services and tools for alerts on variability, deviations or anomalies on phased scale-up pilots and testing.
- Parallel co-testing/development for process, production and analytics methods for outsourcing viability and planning.
- Validation and qualification for phased and scaled-up analytical, sampling and stability testing.
- Health and safety assessments — for example, site, process, people and scale-up activities.

Obstacles

- Tech transfer's unique nature and dynamic requirements make any level of standardization very difficult. Off-the-shelf or standardized templates of the platform are not likely to be common.
- R&D, regulatory, quality, analytical labs and manufacturing operations may often operate as separate business silos with dedicated tools and technology systems supporting functional centers of excellence.
- Inherent maturity and cultural gaps can create barriers for readiness to leverage technical transfer services, especially in areas concerning consensus-based decisions critical to successful outcomes.

User Recommendations

- Assess service providers that have a strong record in life science project and program management and that can demonstrate expertise for delivering across previous scale-up and transfer activities in all science phases of product development through to batch processing.
- Establish multidisciplinary collaboration immediately across all impact stakeholders. Identify executive sponsors with a strong industry presence who can demonstrate the ability to influence ongoing regulatory discussions and bring together key stakeholders during critical phases of the process phases or during key escalations.
- Leverage tools and services that are transitioning capabilities toward digital. Assess configurable tech transfer digital tools and accelerators for continuous learning, stakeholder onboarding, automation of tasks, communications data sharing and visibility.

Sample Vendors

Catalent; Lonza; Midas Pharma; Pharmaceutics International, Inc. (Pii); Piramal Pharma Solutions; Skyepharma; Thermo Fisher Scientific; UPM Pharmaceuticals

Mobile Lab Apps

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Mobile lab apps enable scientists and researchers to create and consume electronic laboratory data via mobile applications, and grant access via smartphones, tablets, and other connected devices. These purpose-built applications address laboratory science, process, experimentation, quality control and informatics.

Why This Is Important

Many laboratory automation, electronic lab notebook (ELN) and laboratory information management system (LIMS) providers support web enablement that allows user access to existing systems via mobile devices, such as smartphones and tablets. While true mobility has been hampered by ill-conceived layouts, devices that are incompatible with sterile or highly regulated environments, and difficult screen sizes, mobile-enabled lab apps represent a chance to improve user experience and productivity.

Business Impact

There are multiple opportunities for mobility to have an impact on lab and quality efficiencies, research innovations, and lab logistics. It can lead to strategic initiatives for improved operational efficiencies, quality and innovation. Mobility enables employees to have unfettered access to systems, which supports productivity. It also enables collaboration beyond the firewall, particularly when conveniently deployed onto personal devices.

Drivers

- Vendors have started to release a plethora of lab capabilities for smartphones and tablets, such as data review, instrument control, and operational analytics. More laboratory and scientific informatics providers have released specific cloud-native or progressive web apps with purpose-built mobile interfaces.
- The majority of enterprise informatics vendors offer some mobile applications. Many vendors are using HTML5 to facilitate adoption in the mobile laboratory space. Gartner expects this space to evolve quickly, as the remaining ELN and LIMS providers deploy solutions.
- The number of science-based apps that are relevant to the industrial laboratory has exploded. As these apps become more powerful and sophisticated, and have better integration with existing laboratory automation and informatics systems, the adoption rate will increase.

Obstacles

- Most companies are reviewing mobile security, as it relates to potentially patentable information and sensitive data being stored on personal mobile devices.
- Many clients report that these applications are often driven at the laboratory level with little oversight from corporate IT. This raises the potential for noncompliance and other challenges, due to a lack of IT involvement and limited processing power.
- While vendors are able to accommodate a variety of use cases, clients struggle to get value out of solutions, as remote access to equipment for simple functions often isn’t worth the investment in the application development.
- Many clients report that the interfaces being developed for lab equipment by lab-IT consultancies include too many features and functions, which makes the application difficult to use. There is a “sweet” spot for functionality that seems to be elusive by many teams.

User Recommendations

- Engage laboratory staff to build a comprehensive understanding of how both personal and company-issued mobile devices are used today in the laboratory, in the office, and beyond the firewall.
- Perform a preinstallation assessment with business teams to determine if mobile apps and software access via mobile devices for the laboratory are compatible with work processes, security, compliance, and culture.
- Work with business leaders to prioritize investments for mission-critical apps that have clear alignment toward innovation, collaboration, quality, compliance, effectiveness and traceability, as well as alignment with inventory visibility initiatives.
- Engage supplier R&D groups actively for their input into the next iteration of mobile apps. Many vendors actively seek customer participation to help guide the design of such systems and inform their app roadmap.

Sample Vendors

BioData (Labguru); BookitLab; Dassault Systèmes; LabArchives; LabCollector; METTLER TOLEDO; PerkinElmer; Sartorius; Tecan; Thermo Fisher Scientific

Gartner Recommended Reading

JavaScript: A Single Language for Web, Mobile and Microservices Apps

How to Effectively Test Mobile Apps

Key Considerations When Building Web, Native or Hybrid Mobile Apps

Decision Point for Choosing a Mobile App Architecture

Your Lab of the Future Strategy Must Enable Life Sciences Digitalization

Enterprise Laboratory Informatics

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Enterprise laboratory informatics (ELI) systems combine multiple laboratory informatics capabilities onto a single platform that an enterprise can extend across the product life cycle, from R&D through manufacturing. ELI systems enable informatics integration across functions spanning R&D, pilot scale-up, analytical, quality, scientific and engineering. The systems have robust capabilities to support sample- and process-centric activities, as well as sophisticated experiment-centric ones.

Why This Is Important

ELI supports a range of functions that extend beyond traditional electronic laboratory notebook (ELN) and laboratory information management system (LIMS) footprints, including inventory management, data management, billing, environmental monitoring, stability testing, process controls and analytics. ELI continues to accrue important benefits like a shared database (ELN + LIMS), shared audit trail, configuration tools, regulatory controls and commercial efficiencies, like simplified licensing, common support channels and shared upgrade costs.

Business Impact

Many manufacturers don't have the appetite to manage multiple laboratory informatics solutions and are moving toward broader platforms to reduce IT complexity. As the technology is refined, leaders should take opportunities to eliminate low-usage laboratory systems, especially if the high total cost of ownership (TCO) and poor vendor execution persist. Many IT, R&D and supply chain leaders want integration standards and common data models, which lead to improved quality, efficiency and innovation.

Drivers

- ELI systems enable informatics integration between R&D and the pilot manufacturing scale-up phase, as well as analytical, quality, scientific and engineering functions. Laboratory managers and informatics personnel see strong potential for ELI to reduce the innovation cycle times across product development phases that involve R&D, quality and manufacturing functions.
- Life sciences firms have increased their use of service-oriented architecture (SOA) and enterprise service bus technologies to integrate different types of platforms across the enterprise. This architectural approach is helpful where multiple solutions are necessary, and an SOA-based architecture optimizes processes through a service-based integration approach for a foundational enterprise-level system. ELI systems enable these approaches.
- ELI supports a broad range of functions that extend beyond traditional ELN and LIMS footprints, enabling other business processes in the R&D and quality/manufacturing functions, supporting digital lab of the future (LoF) strategies.
- Therefore, we advance ELI systems to the trough phase of the Hype Cycle and expect mainstream adoption in five to 10 years.

Obstacles

- Rearchitecting the enterprise to use a system like ELI is not an easy task. A few vendors have positioned their systems as capable of handling “end to end” processes in the value chain, but replacing or bridging adjacent informatics systems on one vendor’s platform is proving very complicated and the projects are slow-going.
- Developing the specifications to execute a change in approach, including migration costs, integration approaches and technology mapping is an intensive process. Only a handful of vendors and integrators truly understand global enterprise product development processes. It is rare to find a single vendor that has broad knowledge, as well as deep domain expertise in each phase and function.
- Since many organizations are struggling with aggressive ELI strategies for supporting end-to-end lab processes across phases, this technology is sliding into the trough but should accelerate through this phase over the next two years.

User Recommendations

- Evaluate the workflows and costs for the touchpoints among different functions (for example, R&D, quality and operations), as well as across phases (research, development and manufacturing), and determine the long-term labor and licensing investments required to manage multiple systems.
- Review the TCO, and evaluate the complexity and amount of effort it takes to keep multiple systems integrated. Use this as justification to invest in ELI initiatives.
- Reduce the footprint of legacy ELN and LIMS systems, if the situation presents itself. Consolidate them into one system that is more suitable for expansion across the enterprise and extend it to collaborators and supply chain partners.
- Investigate the underlying technology of the vendors. Many systems are built using aging programming languages such as Smalltalk and VB.NET, which may be too risky to support digital LoF strategies. Ensure vendor solution architecture is in alignment with these future-focused strategies.

Sample Vendors

AgiLab; Dassault Systèmes; L7 Informatics; LabVantage Solutions; LabWare; Sapio Sciences; Siemens Digital Industries Software; STARLIMS; Thermo Fisher Scientific

Gartner Recommended Reading

Your Lab of the Future Strategy Must Enable Life Sciences Digitalization

Quick Answer: How Do You Know That You’re Building a Truly Digital Life Science Lab of the Future?

7 Key Questions Life Science CIOs Should Ask When Selecting Laboratory Informatics Software

SaaS LIMS

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

A SaaS laboratory information management system (LIMS) is a vendor-managed laboratory informatics solution that focuses on sample- and process-centric laboratory testing — spanning results login to certificate of analysis issuance. Laboratory test data is used to support key processes, including R&D, clinical and production.

Why This Is Important

Many large life science organizations have become more comfortable with having their critical laboratory data in the cloud while smaller organizations are aggressively moving to SaaS models. Gartner expects the percentage of on-premises systems to continue to fall, especially as the functionality and configurability of SaaS-based solutions continue to improve.

Business Impact

Life science organizations are driving “cloud-first” IT strategies to better globalize lab capabilities. SaaS-based LIMSs significantly reduce upfront costs and fit with trends toward rationalizing legacy systems and reducing overall IT complexity, support and maintenance. Depending on the life cycle of existing applications, the ROI for hosted services is favorable, especially when legacy systems are at the end of life and implementation, and are in smaller or midsize organizations.

Drivers

- With organizations' intent on "going paperless," improving quality, creating knowledge platforms and driving collaboration, SaaS LIMSs will continue to see wider adoption and drive "digital lab of the future" strategies.
- Customers that have a legacy system, as well as smaller and midsize businesses and institutions, have a hunger for SaaS models as a means to lower costs and maintain a smaller IT profile.
- As-a-service options can ease the number of IT requirements for maintenance and validation and simplify the overall approach using internal resources to support lab capabilities.
- SaaS LIMS solutions can be easily scaled up or down depending on the needs of the laboratory. This flexibility is particularly beneficial for laboratories that experience fluctuating workloads or need to adapt quickly to changing market demands.
- IT groups are attracted to any means in reducing maintenance, patches and fixes that can be provided by vendors. Even though SaaS LIMS may still require some professional services for deployment, ongoing validation, upgrades, and connections are greatly simplified via the SaaS model.
- The technology is near the middle of the trough on the Hype Cycle with a plateau in two to five years.

Obstacles

- Larger organizations have been slow to adopt SaaS LIMSs due to system complexity and customizations for business processes.
- While most industries are subject to regulation, industries like food and beverage, materials and cosmetics do not require the same level of validation. Many lower-cost LIMS do not meet expectations for regulatory compliance in life science and represent a low end of the spectrum for lab testing methods and complexity. In life science, SaaS LIMS is easier to deploy in non-GLP research environments.
- While many vendors market cloud-hosted LIMS as SaaS LIMS, the lack of transparency in cloud architecture creates a confusing market landscape.
- Systems that have extreme quality and integration requirements are limiting the adoption of SaaS-based solutions.
- While cloud and SaaS are becoming more central to CIOs' strategies for lab processes, many organizations encounter difficulties satisfying Good X Practice (GxP) validation, intellectual property performance and risk-related requirements.

User Recommendations

- Pursue SaaS LIMS only if you have a strategy for cloud validation. GxP environments for labs, manufacturing, and clinical will require extra care, upfront discussions, revised quality policy, and planning to support risk-based validation, security, compliance and controls. These systems are not yet widely implementation-ready for manufacturing environments without a revised GxP validation process and support infrastructure.
- Explore SaaS-based LIMS opportunities if the application does not require customization, the instrument integration needs are light and the system does not need to support a complex environment (e.g., R&D).
- Investigate the degree of elasticity and multitenancy before investing. Solution vendors often use the terms "SaaS" and "cloud" interchangeably. This creates confusion within the marketplace, as most LIMS vendors sell single-tenant, managed hosted environments via partnerships — as opposed to multitenant, shared environments.

Sample Vendors

AgiLab; Autoscribe Informatics; CloudLIMS; Eusoft; LabVantage Solutions; LabWare; Sapio Sciences, STARLIMS; Thermo Fisher Scientific; Veeva Systems

Gartner Recommended Reading

7 Key Questions Life Science CIOs Should Ask When Selecting Laboratory Informatics Software

Your Lab of the Future Strategy Must Enable Life Sciences Digitalization

Quick Answer: How Do You Know That You're Building a Truly Digital Life Science Lab of the Future?

How to Establish Effective SaaS Governance

SaaS ELN

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

SaaS electronic laboratory notebooks (ELN) are cloud subscription-based laboratory informatics solutions. They are used by laboratory staff to securely collect intellectual property, store laboratory data, exchange findings and disseminate experimental data in the R&D process. They are also used as a collaborative platform for connecting with external scientific partners.

Why This Is Important

Many life science companies have been investing in more sophisticated, SaaS-based ELNs to support globalization and externalization strategies. These solutions replace on-premises and cloud-hosted versions and enable more collaborative approaches, thereby making data visible and available at a more optimized cost with simplified management. SaaS adoption will accelerate as leaders become more comfortable with storing intellectual property in SaaS solutions.

Business Impact

Adopting a SaaS-based ELN can reduce capital costs, increase the speed of deployment and reduce IT complexity, especially as it relates to management, revisions and upgrades. In many cases, using SaaS-based software ultimately reduces the validation challenges, system interfaces or APIs (if available from the vendor), and has positive impacts on IT staffing and operations.

Drivers

- Efforts to “digitalize” the research and laboratory processes are driving adoption of SaaS software for the laboratory.
- Many organizations are looking to reduce IT complexity and improve global standards for experimental data collection. SaaS-based ELNs are gaining popularity due to the ease of deployment and low startup costs when compared with on-premises or hosted ELNs. These solutions prove to be much more scalable for global organizations, as well.
- We expect SaaS adoption to increase more rapidly as ELN technologies improve and vendors begin to either acquire or build out solutions that are true SaaS as opposed to just managed/hosted in the cloud.
- Gartner estimates over 40% of ELNs are SaaS-based, which is following the general year-over-year adoption trends for SaaS software in scientific R&D environments.

Obstacles

- Many users are adjusting to SaaS models and are confronted with some restrictions — namely reduced capabilities due to the configuration-only approach supported by SaaS models.
- Many older generation ELNs were deployed on-premises and were heavily customized, making transitions out of those environments extremely difficult.
- The vast majority of ELNs in use in life science manufacturing still have not migrated to cloud due to good x practice (GxP) compliance and validation challenges. Vendors are struggling with support models for GxP.
- Although the platforms are evolving, many users are struggling with promised functionalities and inflated expectations set by vendors. For these reasons, we are accelerating this innovation profile toward the trough.

User Recommendations

- Evaluate your laboratory's needs, the depth of the vendor's domain expertise and your own internal capabilities in managing a SaaS-based ELN vendor.
- Ensure solution features are clearly aligned with business expectations to ensure successful adoption. Although many vendors claim to have the same features in cloud-based products as those that are deployed on-premises, there are often differences between the packages.
- Pursue cloud-based ELNs to facilitate scientific collaboration and reduce cost (particularly if you are a smaller company that does not have legacy systems or deep instrument integration requirements).
- Implement SaaS-based ELNs primarily for driving collaboration with external parties or to bridge scientific groups that operate in multiple facilities.
- Investigate security, maintenance costs and a software release schedule before committing to a solution.
- Outline the procedures for retrieving your data, and have a clear "exit strategy" when engaging a SaaS vendor.

Sample Vendors

Benchling; Bruker (Arxspan); Collaborative Drug Discovery; Danaher (IDBS); Dassault Systèmes; Dotmatics; Revvity (Perkin Elmer); Sapio Sciences; Scilligence; Thermo Fisher Scientific

Gartner Recommended Reading

Your Lab of the Future Strategy Must Enable Life Sciences Digitalization

Quick Answer: How Do You Know That You're Building a Truly Digital Life Science Lab of the Future?

7 Key Questions Life Science CIOs Should Ask When Selecting Laboratory Informatics Software

Market Guide for Laboratory Informatics

MOM Application Suites

Analysis By: Rick Franzosa, Christian Hestermann

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Manufacturing operations management (MOM) application suites extend manufacturing execution systems (MES) beyond production-execution management to include detailed production scheduling, production resource management (materials, assets and labor), process and product reliability (quality and compliance), and manufacturing data analytics.

Why This Is Important

The importance of MOM application suites is based on the need for extended application capabilities beyond traditional MES across manufacturing to provide more flexibility and agility at the plant level. The result of expanding these application suites is to help frontline workers make better decisions and respond in near real time to events on the plant floor without the need for communication with upstream systems (ERP/PLM/SCM).

Business Impact

The business impacts of MOM application suites are:

- They enable process optimization across different manufacturing disciplines. The trade-offs are required process changes and integration discipline between MOM suites and other enterprise applications.
- Process change will be high as MOM applications enable manufacturing operations process optimization and replace multiple disparate applications from different sources. This helps accelerate continuous improvement initiatives and digitization.

Drivers

- Users need capabilities beyond core MES to continuously improve upon efficiency, quality and cost. Seamless integration with capabilities such as material handling and warehouse management system (WMS), detailed plant-level scheduling, quality management and intraplant logistics are required to streamline plant processes.
- Increased focus on capabilities to support better manufacturing employee decision making and competency, fuel the need for better visibility of data from multiple manufacturing disciplines. This can be enhanced by MOM application suites that support a more diverse set of manufacturing functions.
- Manufacturers are looking for a common, scalable platform that can be deployed across multiple sites, enforcing standards and providing a unified view of production data.

Obstacles

- MOM application suites are positioned as functional applications, not enterprise applications, which creates an obstacle to enterprise and manufacturing network goals.
- They rarely have the same breadth of functionality as the built-for-purpose applications in production scheduling, resource management, quality or data analytics. Its value comes in providing an integrated, manufacturing plant-specific suite of tools.
- The preferred vendor approach is to build a MOM platform. This creates additional costs and challenges in integrating and rationalizing another platform into an enterprise.
- MOM implementations are more complex than MES, and are more likely to encounter cost overruns and are difficult to scale.
- Supply chain and manufacturing operations convergence are hampered by site- or plant-specific duplicative functions such as scheduling, inventory management and quality management.

User Recommendations

- Build out MOM functionality by examining the need in each solution area, and define where it makes sense to provide a capability (e.g., production scheduling, materials management and quality) as part of a MOM application suite, versus using a built-for-purpose enterprise-level application.
- Ensure implementation success by aligning the MOM application suites to your proven manufacturing operation processes and systems.
- Minimize MOM application suite integration challenges by teaming IT and end-user communities to define process and integration roadmaps that optimize end-user adoption and reduce integration complexity.

Sample Vendors

ABB; AVEVA; Critical Manufacturing; Dassault Systèmes; iBase-t; iTAC Software; Parsec Automation; Rockwell Automation; SAP; Siemens Digital Industries Software

Gartner Recommended Reading

Critical Capabilities for Manufacturing Execution Systems

Magic Quadrant for Manufacturing Execution Systems

Ignition Guide to Selecting a Manufacturing Operations Software Vendor

Innovation Insight for Smart Factory

Understand the Need for Supply Chain Execution and Manufacturing Operations Management Convergence

Compliant GxP Cloud Services

Analysis By: Michael Shanler, Jeff Smith

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Compliant GxP cloud services include compliant hosting, managed services and platform, application, and quality support, including services for validation. The associated infrastructure, platform or software as a service (SaaS) systems need to comply with the U.S. Food and Drug Administration's (FDA's) 21 Code of Federal Regulations (CFR) Part 11 and International Organization for Standardization (ISO) requirements for medical device quality management systems.

Why This Is Important

As life science organizations adopt a "cloud-first" strategy, they'll need help qualifying infrastructure and managing compliant cloud applications and platforms. Compliant GxP cloud services enable life science business areas like research, labs, clinical, manufacturing and supply chains to more easily leverage the benefits of the cloud for hosting a variety of applications and data. This is while relegating the work of maintaining a multiapplication environment in a validated state to a service provider.

Business Impact

The business impacts of compliant GxP cloud services are:

- The self-service nature empowers business teams to accelerate business operations as it improves scalability, adds more expansive data capabilities and is a less restrictive use of resources.
- Adopting GxP cloud services provides for more efficient use of IT resources and enables a governance-centric operational model.
- Compliant GxP cloud services provide flexibility and economies of scale, as well as access to on-demand expertise and resources to maintain these environments.

Drivers

- Life science organizations are continually focusing on reducing costs, resource use and complexity, increasing the need for GxP support on cloud platforms. Service providers bring their expertise and managed service capabilities to support cloud platforms for smaller biotechs that lack these capabilities and the range of related expertise.
- Life science organizations prefer to partner with companies that are transparent, open to audits, and committed to compliance and security. Compliant cloud services provide assurance of expertise from a specialized service provider managing compliant clouds for many clients.
- IT and validation teams are actively choosing partners with expertise in previous deployments (like managing Health Insurance Portability and Accountability Act [HIPAA] compliance or protected health information [PHI] data), or integration across the life science industry in heavily regulated environments.
- IT teams are looking to build credibility with internal stakeholders in support of cloud-first digital strategies and agile methodologies for development.
- As vendors evolve services to manage GxP cloud environments more effectively, IT teams increasingly see the advantage of leveraging market platforms, rather than maintaining these in-house, sourcing risk and cost of compliance externally.

Obstacles

- Adoption of cloud resources for batch-oriented, computing-intensive workloads may be temporarily hindered by industry-specific requirements, such as GxP compliance for pharmaceutical development.
- Life science organizations continue to deal with unrealistic expectations with changing cost models and overall complexity and cultural hurdles, given the highly regulated nature of the industry.
- Before cloud computing for general workloads can achieve mainstream adoption, GxP quality and security policies must be revised and embraced by organizations that have traditionally been resistant to change from on-premises approaches. As a result, we see this profile beginning to progress up the slope.

User Recommendations

- Factor in the total cost of ownership for a system delivered via GxP cloud services versus internal approaches. Take into consideration the fully loaded costs required for ongoing upgrades and maintenance.
- Research vendors that can expand with your needs, extending into different functional domains (like quality, clinical, regulatory and manufacturing).
- Favor service providers with add-on compliance services, dashboards, and other quality and compliance real-time reporting capabilities.

Sample Vendors

Ambit Software; Arbour Group; ByteGrid; ClearDATA; Epista Life Science; Iperion (GxP Cloud); MUSA; NNIT; Odyssey VC; Validated Cloud

Gartner Recommended Reading

Life Science CIOs: Use Computer Software Assurance to Modernize Your GxP Validation Practice

Quick Answer: Meet Healthcare and Life Science Buyers' Regulatory Compliance Needs

Survey Analysis: Industry Cloud Platforms — A Life Science Perspective

Healthcare and Life Science Business Driver: Strategic Technology Change

Quick Answer: 4 Factors for Build, Buy or Ally Decision Making in Life Science R&D

Quality by Design

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Quality by design (QbD) is a phased or systematic approach to product development and continuity of quality. It is managed through robust process protocols, combined with embedded centralized principles. These include systematic product and process excellence, mechanistic models, design of experiments (DOE), process analytical technology (PAT), along with science and quality risk management across the entire product life cycle, both phased or planned.

Why This Is Important

With significant industry shifts in product sophistication, QbD solutions are well-positioned to support proactive mapping of quality and regulatory issues across the entire product life cycle. QbD spans product development and production to include the configuration or integration of specific patient needs, based on robust science and quality requirements during the development of a product and its manufacturing process.

Business Impact

QbD is continuously evolving sets of recommended process techniques. It's an already well-established process concept with early origins in industries such as automotive. QbD capabilities and services targeting the live science sector appeal to both large and small startup manufacturing organizations. They also appeal to generics and virtual manufacturing life sciences companies with overarching objectives for ensuring consistent improvements for production of quality devices, diagnostics and drugs.

Drivers

- QbD principles and aligned technology and service solutions have seen a recent resurgence in interest in the life sciences industry, especially as part of the future vision for best practices for quality and risk set out by global authorities. Regulatory bodies, such as the FDA and EMA, periodically publish updates for production guidelines and for maintaining quality.
- Company supply chain networks are constantly being reconfigured around patient centricity and enhanced user experience, while proactively mitigating potential bottlenecks around optimization, compliance quality and validation. This drives new enhancements to internal QbD capabilities, which are an instrumental tool for helping companies adopt these guidelines and configure their supply chain networks for better quality products and outcomes.
- As quality-issue reporting continues to rise globally, QbD capabilities are in increased demand. As a result, companies will accelerate QbD capabilities for proactive mapping and coordination of robust and streamlined technology transfer protocols. This will ensure consistency in quality and manufacturing to equivalents in generic products or geographic site-processing transfer of original product.
- Life science organizations are continually performing risk assessments and DOEs on raw materials, ingredients, testing and analytical methods to prioritize process or knowledge gaps for further investigation. Additionally, final product continual vigilance, PAT assessments, continuous feedback loops for controls and measures over critical materials, and intermediate phases and control measures to meet the target product quality profile are included. Patient- and product-centric network redesign across process, transactional and operations phases of the products life cycle, including capacity utilization, yield optimization and resetting the bar for quality enhancements, are also included.

Obstacles

- Disconnected functional or data silos (particularly in regulatory, clinical and R&D) could impact the potential of QbD initiatives.
- Migration from paper-based systems of record requires validated process changes. Also, the complex integrations across layers of legacy and/or custom applications require careful documentation and revalidation efforts.
- Rigid processes involving quality systems, especially in manufacturing and packaging phases, are difficult to reengineer with validation and compliance.
- Culture changes, especially at large organizations, are difficult. Transitioning to new digital, collaborative and planning best practices for patient centricity and establishing product “center of excellence” hubs sounds nice, but is difficult to implement with existing engrained quality and design procedures.
- Solutions and methods for managing QbD are well-known within the industry, but QbD data isn’t integrated into product development in a holistic fashion. For these reasons, QbD is still in the trough.

User Recommendations

- Embed QbD as a tool for continuous quality imperatives from “cradle to grave.” This includes methods for capturing, sharing and communication of a wide range of criteria and parameters for safety, efficacy, sourcing, formulations, product stability, productivity and yield.
- Invest in solutions and services that are based on or enable you to use QbD principles across the life cycle of products. Create the capabilities to do this at individual SKU levels as well as at product family levels.
- Include data and analytics, smart factory or industrie 4.0 stakeholders when designing QbD approaches and implementing systems.
- Develop an enterprisewide communications plan to emphasize the value QbD brings to the organization to drive adoption.
- Ensure you have an organizational structure for execution through close collaboration with representatives from critical functions such as quality, IT, research, regulatory, manufacturing and distribution.

Sample Vendors

Agilent; Dassault Systèmes; GxpManager; MasterControl; QbDVision; Sartorius; Scilife; Skyepharma; S-Matrix; Valgenesis (4TE)

Gartner Recommended Reading

Your Lab of the Future Strategy Must Enable Life Sciences Digitalization

Market Guide for Quality Management System Software

Manufacturing Execution Systems' Critical Capabilities Comparison Tool

2023 CIO and Technology Executive Survey: A Process Manufacturing Perspective

Climbing the Slope

SaaS-Regulated CSP

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: More than 50% of target audience

Maturity: Early mainstream

Definition:

SaaS-regulated content services platforms (CSPs) are life-science-specific, cloud-based systems for managing documents and unstructured data in compliant, regulated environments. Previously known as electronic document management systems, CSPs support areas such as clinical, quality, pharmacovigilance, manufacturing, regulatory and marketing. Features include collaborative authoring, metadata management, search, regulatory tracking and publishing.

Why This Is Important

SaaS-regulated CSPs have been gaining traction among CIOs in the life science industry, largely due to their increased robustness, security and cost advantages over traditional on-premises systems. Although this transition has been uneven across various life science domains, SaaS-regulated CSPs are rapidly maturing and now offer some of the most mature cloud offerings.

Business Impact

Adopting SaaS-regulated CSPs can simplify deployments and reduce support resources, especially when content services platform as a service (CSPaaS) capabilities are used. Furthermore, SaaS-regulated CSPs enable and facilitate both global deployment and centralized control and governance, providing a cloud-native CSP, including built-in content workflow, automation, governance and content processing tools. This, in turn, provides more content flexibility and control to supported business areas.

Drivers

- At many larger companies, older systems are now at the end of their service lives and are unsustainable. As a result, there is new interest by life science companies in exploring simpler cloud-based solutions, rather than upgrading older on-premises IT systems with significant maintenance burdens.

- Life science companies are increasingly shifting from legacy CSPs to cloud-native CSPs, particularly in clinical development and regulatory, as well as quality areas. These are taking advantage of more powerful CSPaaS capabilities and robust global implementations supported by multitenant cloud deployments.
- Companies have started moving away from single-tenant-hosted cloud CSP due to more acceptance of multitenancy.
- The regulatory environment for life sciences is becoming increasingly complex, with multiple agencies and regulations governing different aspects of drug and device development and approval. SaaS-regulated CSP can help life science companies manage this complexity by providing a centralized platform for storing, managing, and sharing regulatory content.
- With continuous change in the regulatory environment, SaaS-regulated CSPs can be scaled up or down as needed, depending on the size and complexity of a life science organization's regulatory requirements. They can also be customized to meet the specific needs of different stakeholders, including regulatory agencies, internal teams and external partners.
- As many of the initial obstacles to acceptance of SaaS-regulated CSPs have evaporated and GxP validated cloud technology matures, this profile proceeds quickly past the trough and starts up the slope with two to five years' time to plateau.

Obstacles

- Some larger life science companies are challenged in adopting SaaS-based solutions in niche areas, due to overly complex processes that have resulted in legacy customizations on overengineered, monolithic systems.
- Many clients report the movement from on-premises CSP to cloud as challenging, especially when dynamic and historical data and documents are stored within the same system. Upgrading a CSP from a legacy system with lots of historical data to a new system often turns into two projects — a migration project and a software upgrade. In most cases, these are intensive projects with considerable professional services expenses.
- Many vendors use the terms "cloud" and "SaaS" interchangeably and are less clear about tenancy in the cloud. This adds confusion and slows adoption of more advanced CSP approaches.

User Recommendations

- "Think digital" and emphasize the need for search, analytics and dashboarding capabilities that will be more self-service-oriented. When going to a SaaS model, consider that adopting SaaS may also require different service and support models.
- Evaluate the differences between cloud-hosted and single-tenant versus multitenant SaaS architecture during vendor assessment. Be aware of vendors' hype and creative license around these terms, and ensure they support the correct type of cloud for business needs.
- Work with quality assurance and regulatory teams early in the process, to bring them along into cloud deployments from internally hosted architectures. Set expectations about SaaS license costs and ensure that cost projections reflect application growth under new licensing models.
- Review solutions that address all overlapping components of development — including clinical trials, quality and regulatory, and contract management — when considering pure CSP deployments.

Sample Vendors

Aurea; Box; DXC Technology; Egnyte; Generis Group; IQVIA; M-Files; OpenText; TransPerfect; Veeva Systems

Gartner Recommended Reading

Electronic Trial Master File Strategy Alignment

Market Guide for Life Science E-Clinical Platforms

Life Science Manufacturer CIO Top Actions for 2023

2023 CIO and Technology Executive Agenda: A Life Science Perspective

Market Guide for Content Services Platforms

Model-Based Manufacturing

Analysis By: Marc Halpern, Rick Franzosa

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Model-based manufacturing (MbM) refers to the use of digital models of factories, assets, resources and processes rather than document-based content and physical models to plan, validate and monitor the manufacturing of products.

Why This Is Important

MbM, moving up the slope, is core to digital manufacturing, MbM:

- Is key to digitalizing manufacturing businesses.
- Reduces manufacturing costs because factory layout, movement of materials, and factory operations are tested with computer models before committing to capital investments.
- Saves time and money by leveraging the manufacturing models to program, simulate and validate manufacturing processes.
- Is needed to create digital twins and digital threads of factories and operations.

Business Impact

MbM cuts iterations out of activities such as defining manufacturing facilities, processes and programming factory automation. Users identify bottlenecks and programming issues by simulating factory operations before commencing or changing/enhancing their factory operations. MbM saves substantial time and money in automation corrections and reduces scrap resulting from faulty manufacturing ramp-up. Some users reported 20% to 30% cost reductions during scale-up to production.

Drivers

- Manufacturing strategists believe that MbM saves considerable cost and time by reducing the number of iterations necessary to start manufacturing ramp-up.
- The technology enablers, such as Internet of Things, machine learning, modeling tools, simulation tools and remote access, continue to advance — building increased confidence in MbM.
- MbM has a very strong linkage to digital twins and digital threads, which are high in digitalization hype.

- MbM success stories are growing in number, with savings that are compelling enough to minimize initial cost concerns.

Obstacles

- MbM requires substantial planning and investment to build the technology platform. It involves the orchestration of engineering technology, information technology and operational technology.
- Interfaces must be built between ERP, MES/MoM, PLM, CAD and CAE. Interfaces are also needed for remodeling and simulation tools addressing factory layout, workcell layout, manufacturing operations, part and materials movements, machining operations and workflow.
- The cost and complexity of orchestrating these technologies can be an inhibitor.
- MbM requires training and experience to build skills and confidence. Engineering operations typically have deeply ingrained culture, practices and processes. Discomfort with making these changes can be an obstacle.
- The creation and validation of complex process simulation models requires skill sets that may not be readily available in manufacturing.

User Recommendations

- Plan for MbM by encouraging the creation of an integrated architecture for MbM and a roadmap to accomplish that architecture.
- Manage risk and complexity associated with MbM infrastructure by adopting model-based system engineering approaches to design and validate that the architecture brings together the ET, IT and OT elements.
- Continually nurture, maintain, improve and update MbM as manufacturing knowledge evolves.
- Set expectations properly by explaining to business stakeholders that MbM will require significant initial and ongoing configuration effort.
- Advise engineering and manufacturing leaders to adjust job training and performance metrics in ways that encourage MbM adoption, and cultivate collaboration with R&D and engineering to ensure that efforts are aligned.

Sample Vendors

AspenTech; AUCOTEC; Autodesk; AVEVA; Dassault Systèmes; iBase-t; PTC; Rockwell Automation; Siemens Digital Industries Software

Gartner Recommended Reading

Top Strategic Technology Trends in Asset-Intensive Manufacturing for 2023

Cloud Computing in Manufacturing Operations

Analysis By: Rick Franzosa

Benefit Rating: High

Market Penetration: More than 50% of target audience

Maturity: Early mainstream

Definition:

Cloud computing is a style of computing in which scalable and elastic IT-enabled capabilities that support manufacturing operations are delivered as a service using internet technologies.

Why This Is Important

Cloud's progress across manufacturing operations continues to expand, though it varies by industry and use case. While manufacturers are not abandoning on-premises models for mission-critical applications, we have seen further growth in hybrid cloud adoption, with on-premises components replacing full on-premises systems. Manufacturers are in modernization mode, and as a result, remote process/work and intelligent edge devices are reaching greater maturity in support of hybrid cloud deployments.

Business Impact

Impacts of cloud computing in manufacturing include:

- Enabling new styles for technology consumption and information access.
- Contributing toward a flexible and agile manufacturing network when leveraged properly.
- Helping an organization standardize and improve processes.

- Easing remote access to applications and supporting remote workers.
- Bringing cloud closer to the manufacturing process via edge capability.
- Over time, reducing on-premises IT total cost of ownership (TCO) for both hardware and personnel.

Drivers

- Provider offerings have evolved across all segments, spanning quality management, manufacturing execution systems (MES), production planning and varying degrees of analytics. New market entrants are taking a “cloud-first” approach, building their applications leveraging cloud infrastructure providers.
- General acceptance of cloud computing grows in all markets as pockets of concern over data security, latency and exchange (between on-premises and cloud) are diminishing.
- Cloud services combined with platform as a service (PaaS) provide cloud application infrastructure services for custom applications and solutions, where the cloud attributes of scale and internet availability encourage innovation and high performance in manufacturing operations applications.

Obstacles

- The issue of shifting funding models. Yearly capital expenditure (capex) planning and cloud do not go hand-in-hand; there is adjusting of operating expenditure (opex)/capex ratios needed.
- Some manufacturing environments require on-premises solutions, and cloud solutions with on-premises “failover” are uncommon.
- Initial cloud-native solutions lack content and maturity of readily available on-premises solutions.
- Buyers are apprehensive about control of cloud costs and vendor monetization of data.
- Cloud-native/cloud-friendly offerings in manufacturing do not reduce the need for complex integration.
- Manufacturers are now concentrating on the details (e.g., cybersecurity, vendor lock-in), and really determining what is mission-critical and what is not.

User Recommendations

- Identify use cases for cloud computing by focusing on broad applicability to enhance existing process capabilities and overcome IT skills deficiencies across multiple sites.
- Minimize disruption by performing hybrid deployments that leverage existing on-premises systems.
- Protect your organization by aggressively addressing and eliminating the challenges of cybersecurity in cloud and hybrid offerings.
- Avoid the mass customization of cloud-based applications to site-specific needs by focusing on shared functional requirements.
- Protect your investment by demanding transparency from vendors regarding their cloud offerings — especially on contract life cycle pricing, data ownership and long-term TCO, as well as service levels and security models.
- Establish a clear and realistic understanding of the expected benefits of a move to the cloud by understanding benefits and trade-offs.

Sample Vendors

Apprentice.io; AVEVA; GE Digital; iBASE-t; Oracle; Rockwell Automation; SAP; Siemens Digital Industries Software; Sight Machine; Tulip Interfaces

Gartner Recommended Reading

Cloud Computing in Manufacturing Is Foundational Today and the Requirement to Operate in the Future

Innovation Insight for Smart Factory

Transform How Smart Manufacturing Is Funded to Drive Adoption

QMS Applications

Analysis By: Sam New

Benefit Rating: High

Market Penetration: More than 50% of target audience

Maturity: Mature mainstream

Definition:

Quality management system (QMS) application software is the business information management system that manages quality processes across the organization. These processes may include, but are not limited to, customer requirements, quality documents and standard operating procedures (SOPs), ISO requirements, manufacturing capabilities, robust design, auditing procedures and protocols, nonconformance/risk management activities, testing criteria, and industry-specific regulations.

Why This Is Important

QMS applications provide workflows to manage cross-functional processes such as waste reduction, cost optimization, document management and training. They ensure compliance with policies and regulations, measure quality performance against KPIs, house quality documents, and promote process improvements. QMS applications are essential — companies pursuing enterprise quality management strategies increasingly upgrade, replace and consolidate outdated systems onto a single platform.

Business Impact

QMS applications reduce the risk that requirements impacting quality will be overlooked, reduce cost and time to enforce quality needs, and enable businesses to systematically review and improve quality metrics.

Drivers

- Key drivers for replacement and upgrade activity, coupled with the movement toward cloud-hosted solutions, include a desire to harmonize processes and data analysis across the organization that have traditionally been defined and enforced on a functional or localized basis.
- Software providers continue to morph their offerings away from siloed, one-off offerings and toward full-scale, configurable platforms with common process and data definitions, enabling clients to meet customer and regulatory requirements.
- The QMS market is active with new product launches, enhanced functionality and many vendors building new SaaS solutions that include enticing, business-facing features and low-code accelerators for quality processes.
- Many new low-code application platform (LCAP) QMS vendors are available, making use of broad workflow capabilities on these platforms to build out robust and secure QMS features. Availability of hyperautomation and AI capabilities on these platforms allow these new vendors to differentiate against legacy QMS providers.

Obstacles

- The lack of a disciplined approach to “enterprise” quality architecture that balances standard processes and regulatory requirements has delayed QMS adoption.
- Difficulties that are derived from integrating a new system into manufacturing, quality and supply chain architecture.
- Provider-centric challenges continue. These include an inability to offer pricing that matches cloud offerings in other software markets, and an absence of resources dedicated to ongoing technical and customer support.
- Providers have begun incorporating emerging technologies — including robotic process automation (RPA), machine learning (ML), Internet of Things (IoT) and artificial intelligence (AI) — into product roadmaps. Yet mainstream offerings and widespread user adoption remain limited.

User Recommendations

- Define QMS software requirements by assessing the current state of the quality organization, coupled with future business needs. These may include existing systems, industry standards, regulations, desired functionality, and licensing and hosting preferences.
- Assess potential providers' partners by examining relationships with deployment, system integration, hosting and adjacent software spaces.
- Ensure interoperability with existing and planned software solutions by partnering with IT. Consider compatibility and availability of APIs for ERP, product life cycle management (PLM) and manufacturing execution systems (MES), as well as laboratory information management system (LIMS) and learning management system (LMS) platforms.
- Evaluate the industry depth, geographic reach, proposed deployment and support plan, and product roadmap of providers and their partners by asking questions about each. Be cautious with regard to exciting but nascent product features that have not yet entered mainstream adoption.

Sample Vendors

ComplianceQuest; Hexagon (ETQ); Honeywell International (Sparta Systems); MasterControl; Oracle; Propel Software Solutions; SAP; Siemens Digital Industries Software; Veeva Systems

Gartner Recommended Reading

Market Guide for Quality Management System Software

Ensure Success in Quality Management System Software Selection

Tool: Quality Management System Software Vendor Evaluation Model

Controlled Substance Ordering System

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Controlled substance ordering system (CSOS) supports the Drug Enforcement Agency (DEA) of the U.S., EU drug precursor and similar global regulatory controls, which are designed to prevent diversion of legitimate controlled pharmaceutical drugs into illegal channels and to ensure a sufficient supply for legitimate medical uses. CSOSs enable digital signatures and secured electronic information to be transmitted and routed through public-key infrastructure (PKI) technology.

Why This Is Important

As life science organizations grow increasingly sophisticated with their chemical inventories, and are exposed to risks for misuse of chemical assets. Every year, more chemicals require security and monitoring measures. Unsecured chemicals can create safety incidents and endanger employees, or increase risks of theft. CSOS solutions help encourage good behaviors in securing dangerous chemical assets while improving the ability to meet compliance demanded by federal authorities.

Business Impact

Electronic interoperability across life science and healthcare stakeholders can enhance data governance and security protocols around controlled substances, thereby improving the visibility across the supply chain; facilitating quick audits; and reducing fraud, waste and abuse (FWA). Immediate benefits would be elimination of process waste that comes with the paper-based systems (like delays, errors and costs), enhanced B2B relationships, faster delivery times and improved customer validation.

Drivers

- Individual countries (e.g., the U.S., France, the U.K. and Canada) have increasingly strict policies on access to banned substances. This is driving CSOS adoption. Benefits include improved data quality, reinforced chains of custody, and more flexibility to adopt inventory optimization and reductions.
- Planned regulatory governance mandates for controlled substances reporting across other countries could potentially extend CSOS in the future.
- Digital-certificate-based programs are on the rise across all industry sectors. CSOS uses digital certificates transmitted via electronic files that use a digital signature to bind together a public key with an identity.
- Regulators and enforcement agencies are performing remote and virtual audits, asking vendors to provide the DEA-mandated single-sheet format for the U.S. Official Order Form for Schedule I and II Controlled Substances (DEA Form 222).
- Regulations allow electronic transmission of controlled substance orders for Schedule I and II substances with a supporting DEA 222 form following the electronic order. The final rule allows for electronic orders for Schedule I and II controlled substances using digital signatures. The DEA regularly reviews schedules based on globally reported incidents of controlled drugs. Valid digital signatures through encryption allow for secure electronic verification of controlled substances.
- Many environmental, health and safety (EH&S), and governance, risk and compliance (GRC) vendors are looking to holistic solutions. This is driving application development with a focus on the facilitation of DEA and PKI requirements.
- Life science organizations have improved their management of CSOS. For these reasons, CSOS is approaching mainstream adoption.

Obstacles

- Although U.S. compliance is critical, the broader benefit and potential for CSOS solution maturity is limited and subject to further updates to the mandates, with a broader adoption of similar processes required globally.
- Current CSOS addresses the specific needs of the country or regional mandates, such as the U.S. However, their overall ability to create broader opportunities for integration, governance and digitalization across high-risk product categories on a global scale requires extra consulting services.

User Recommendations

- Assess the cost of deployment versus immediate supply chain benefits (e.g., elimination of paper-based requirements), and ensure you understand the available solutions.
- Identify integration opportunities with existing IT infrastructure to support controlled substances or high-risk product categories with available solutions and services.
- Determine the applicability and scalability potential of extending CSOS solutions to all classes of controlled substances.
- Ensure regular review of schedules (including temporary schedules), regional/state legal requirements and plans for proposed deregulation (such as cannabis).
- Seek information on regulatory proposals, existing mandates for electronic registry and security for controlled substances across other regions, and their viability for integration to the emerging solutions marketplace.

Sample Vendors

Axway; Blue Link; CuraScript SD; Legisym; OpenText (Liaison Technologies); McKesson; Nexus Group (nCipher Security); Omnicell

Gartner Recommended Reading

Market Guide for Community Development, Regulation and Licensing Applications

Top Strategic Technology Trends in Asset-Intensive Manufacturing for 2023

Use the 5 Level Manufacturing Score Maturity Model to Support Strategic Planning

Pharma PLM

Analysis By: Michael Shanler, Michelle DeClue

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Pharmaceutical, biotech and vaccine product life cycle management (aka “Pharma PLM”) is the discipline of guiding products from an original concept through to retirement for life science organizations (LSOs). Pharma PLM emphasizes compliance with rigorous regulations and quality control requirements.

Why This Is Important

PLM tools are a way to evolve scientific products and move them into compliant manufacturing with enhanced capabilities for managing design, development, formulation and design transfer into production. Today, many LSOs use PLM in a very narrow fashion, as they are over-relying on heavily customized ERP environments that are not geared for handling life cycles, like dedicated PLM. Shifting capabilities to PLM represents an opportunity to standardize life cycle processes.

Business Impact

PLM has the following benefits in the pharmaceutical industry:

- Mitigates the risk of noncompliance and drives efficient workflows.
- Provides advanced governance for critical issues: compliance, quality, time to market and potential loss of exclusivity.
- Allows implementation of more digitalized processes, supporting quality by design (QbD), interoperability and digital data flows.
- Facilitates traceability of recipe and formulation-based components across product life cycles and supply chain processes leveraging product digital threads.

Drivers

- LSOs are among the most heavily regulated industries with the most significant long-term investments in their product pipelines, and they need better life cycle management approaches.
- LSOs are increasing digitalization efforts where life cycle data should be treated as an asset. This is opening the door for PLM solutions to be used to enhance capabilities that meet specific aspects of compliant quality and document controls.
- Interoperability requirements with Contract Manufacturing Organizations (CMO) and Contract Development and Manufacturing Organizations (CDMOs) are on the rise. Sponsors want the ability to share process design specifications using more standard approaches.
- LSOs need more capabilities for event-driven notification, coupled with batch reporting, so they can provide alerts to generate documents and reports to extend exclusivity rights. These universal capabilities should enable “cradle to grave” data in terms of business processes, governance and traceability.
- Several large LSOs have spent nearly a decade performing proofs of concept (POCs) and attempting to use PLM to improve R&D and portfolio efficiency. After many years of trials, the role of PLM has become more defined. Those large projects are finally moving into production.
- LSOs can use compliance tools within PLM, but the regulatory implications and development timelines are significantly greater in pharma than in food and beverage manufacturing.
- Over the past few years, PLM has moved beyond the scope of just formulations, packaging and labeling and is now being used to capture design inputs, batch records and design data. For this reason, pharma PLM is positioned as moving slowly on the slope.

Obstacles

- LSO R&D groups typically use science-, not engineering-centric systems. Pharma PLM has often been blocked out of portfolios at the expense of heavily customized ERP and scientific software. LSOs have an over-reliance on the automation of paper-based product design processes which prohibits the adoption of data-centric models supported by PLM especially when supporting CMO/CDMO relationships.
- Even though in other industries, product development management (PDM) systems have evolved into PLM-centric platforms that extend far beyond early R&D stages across the entire product life cycle, PDM and PLM methodologies are still generally misunderstood in LSOs. Thus, the adoption is still relatively slow compared to other process-based industries.
- PLM vendors often require education on LSOs issues, such as QbD, before they can deliver real value.
- Vendors often require education on what the LSOs' needs are, especially in the area of compliance and validation.

User Recommendations

Prioritize the following capabilities when selecting and implementing PLM:

- Quality assurance: Ensure data is supportive of compliance.
- Product history: Track product brief, specifications, and project milestones and reviews.
- Recipe and formulation: Map design specifications to outcomes.
- Regulatory submissions: Support data submissions for trials, manufacturing and launch.
- Clinical trials: Track product design, formulations and kit assemblies.
- Documentation: Generate template-driven documentation.
- Portfolio management: Use life cycle data and support costs and timelines.
- Bill of materials (BOM): Simulate and track virtual and actual BOMs.
- Artwork and labeling: Manage content blocks and traceability on label content.
- Track-and-trace: Set integration to track logistics, quality and performance.

- Intellectual property (IP) rights: Create granular access and documentation.
- Forecasting: Support sales and operations planning (S&OP) processes.
- Scenario modeling: Leverage formulation, launch and costing to optimize business plans.

Sample Vendors

Dassault Systèmes; Infor; Neo PLM; Oracle; Rockwell Automation (Kalypso); SAP; Siemens Digital Industries Software

Gartner Recommended Reading

Market Guide for Label and Artwork Management Software Applications

Market Guide for Packaging and Product Specification Management

Innovation Insight: Implement Digital Threads for Long-Term Flexible Access to Critical Data

PLM Vendors Must Update Their Roadmaps to Address Manufacturing Customers' Needs

Strengthen Supply Chain Planning's Role in PLM for Improved Cross-Functional Collaboration

Track and Trace

Analysis By: Salil Joshi

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Mature mainstream

Definition:

Track-and-trace and serialization solutions are comprehensive software, hardware and service solution stacks. They map closely to regulatory requirements for anti-counterfeiting and span finished-goods manufacturing through to healthcare fulfillment. Solutions focus on data configuration and capture, generation of serial numbers (bar codes), and enabling interoperable exchange of key datasets across networks of healthcare-value-chain stakeholders, governance bodies and regulatory agencies.

Why This Is Important

Anti-counterfeiting regulations for track and trace and serialization in life sciences continue to develop globally. For phased mandates in more established regulations, companies have already run pilots and small-scale implementations, or solutions are already in production. Solutions have evolved in areas such as serial number generation, data governance and data capture capabilities. Data is frequently integrated and communicated across enterprises, and with physical transaction capture via coding on labels or assets.

Business Impact

Compliance drives the need for track-and-trace and serialization solutions to work across multiple enterprises, and will require companies to revisit their end-to-end supply chain IT system architecture and interconnectivity across trading partners, healthcare networks, patients and consumers. Integration with manufacturing line systems, labeling and packaging systems, and enterprise resource planning systems should be included as part of track-and-trace initiative implementation.

Drivers

- Gartner expects clients will make continued investments in track-and-trace capabilities, since most midsize and large manufacturers have products moving across international borders, as well as priorities targeting compliance and last-mile fulfillment.
- More streamlined solutions for startup biotechs will also shape further solution development. Solidifying protocols and systems for track and trace and serialization will contribute to decreasing overall enterprise and business risks.
- Failure to act for compliance or counterfeiting incidences can result in detrimental brand performance.

- New thinking and approaches are additive to existing customer centricity focus. Change management for technical and regulatory serialization compliance across partners will become critical.
- Business leaders may need to scope serialization potential beyond compliance-based activity for continued business investment justification.
- Compliance-based mandates require redefining business processes and information flows inside the organization and with trading partners, healthcare providers and customers. Regulations, such as the Drug Supply Chain Security Act (DSCSA) in the U.S., require implementation of solutions to exchange transaction data with key attributes. These data attributes, which include product Global Trade Item Number (GTIN), expiration date, batch/lot number and serial number, are exchanged every time there is a change of ownership of products.
- The 2023 requirements for DSCSA compliance are focused on exchanging Transaction Information and Transaction Statement in a secure interoperable electronic manner at the unit level. Also, dispensers can only receive and dispense serialized products and should be able to verify product identifiers.
- Future value will be realized through increased operational and transactional efficiencies, as well as interoperable communication and analysis of existing and new types of data across stakeholders. Other opportunities in industry sectors, such as food and beverage and consumer products, could influence cadence.

Obstacles

- Many solutions are no longer life-science-specific or dedicated. The market is significantly fragmented as solution partners translate or expand their capabilities into other industry verticals and move away from the life science industry.
- Last-mile fulfillment, regulatory excellence, change management and integration are key elements of supporting services, which further complicate identifying the best-fit solution providers.
- It is anticipated that mature solutions targeting compliance mandates are only three to five years out, although further evolution cadence could be impacted by anticipated waves of regulations.
- Adoption of track-and-trace solutions by healthcare providers is still in early stages and will need to be monitored for optimizing the benefits of regulations. Key areas of focus will be 2023 requirements for dispensers that require dispensers to receive and dispense serialized products and verify product identifiers.

User Recommendations

- Assess the key differentiators and enablers of track-and-trace and serialization solutions at the enterprise level for global integration of common datasets, emerging standards and links to central repositories.
- Build a strategic plan for implementing a serialization program, including organization design and staffing, vendor selection for track-and-trace solution partners, implementation of pilots and eventual enterprise-level implementation.
- Implement data management solutions for governance, aggregation, randomization, data storage and encryption. Some of the focus areas related to data management include data configuration, security and capacity capabilities of the bar codes (such as 2D data matrix and RFID), and the value realization opportunities for that data.
- Implement operational-line-level solutions for material flow, automation, scanning, routing and data capture through vision systems. These solutions ensure that labeling requirements are met and are in compliance with the regulations.

Sample Vendors

Antares Vision Group; Navitas Life Sciences; Parabellum Investments (advanco); SAP; SEA Vision; SoftGroup; Supply Chain Wizard; TraceLink; TrackTraceRX; Vimachem

Gartner Recommended Reading

Vertical Industry Context: 'Magic Quadrant for Multienterprise Supply Chain Business Networks'

Predictive Product Costing Software

Analysis By: Marc Halpern

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Mature mainstream

Definition:

Predictive product costing software predicts, captures and manages product costs over product life cycles. Besides the enabling technology, this innovation includes the discipline, organizational factors and processes to continually improve product costing competency.

Why This Is Important

This innovation is in the mature mainstream, as the growing complexity of products and markets is compelling manufacturers to use software to manage product costs. It enables designers and engineers to more easily factor life cycle costs into their design decisions, reducing life cycle costs. For example, products in fast-moving consumer goods have short life cycles, and buyers are extremely price-sensitive; so small design changes can mean big cost savings.

Business Impact

Businesses can improve ROI with predictive product costing software, as:

- Predictions guide reductions in manufacturing, sourcing and warranty costs.
- Predicted costs guide negotiations with suppliers and outsourced manufacturing services.
- Analytics generated offer insights into how costs can be reduced with minimal impact on product performance throughout product life cycles.
- Costing provides insight into target pricing that will deliver profits.

Drivers

- As IT becomes increasingly important to business performance and business leaders involve CIOs more in business strategy, CIOs can add business value by enabling greater product cost savings without compromising product quality.
- Globally, manufacturing is becoming increasingly cost-competitive. Initiatives such as product cost management improve competitiveness.
- Digital methods of managing product costs align with digital business as a top initiative among manufacturers.
- Variation in cost of parts, raw materials and energy is encouraging more disciplined cost management practices supported by software.
- Increasing need for best sustainability practices has implications for product costs that must be managed.
- The enabling software applications have become increasingly mature due to enrichment with advanced analytics capabilities and deeper integration with core business applications such as product data management (PDM), manufacturing execution system (MES) and ERP, giving manufacturers more confidence to adopt them.

Obstacles

- Adopters need more reliable methods and data to predict the cost of materials, parts, services and processes to build greater confidence in product cost management.
- Product development teams must be more conscious of cost impacts when designing. Designing for function and reliability has traditionally been a higher priority. Cost as a priority must be elevated.
- In some manufacturing verticals, particularly durable goods industries, product costing professionals are not adequately connected to product development teams organizationally. This is challenging because cost estimators may not have the latest design changes that can impact costs.
- Poor data quality across different systems creating, sharing and updating product master data undermines confidence in cost management software.
- Product costing involves analysis of activities as well as material costs. This demands challenging integration of applications such as ERP, product life cycle management (PLM) and project management applications.

User Recommendations

- Find the best software fit for your company by investigating cost management software options. Consider the trade-offs of product cost management "add-ons" to ERP and PLM software and specialty software.
- Help the business build confidence in costing software by encouraging business units to calibrate the predictive cost models, leveraging historical data and generative artificial intelligence
- Contribute to the culture and practice of product cost management by working with business leaders to identify subject matter experts and creating a central group that provides ongoing oversight and governance of costing activities.
- Ensure product master data quality by creating common data models for product and product-related data, which need to be updated continuously during the course of regular master data governance processes.

Sample Vendors

3C Software; aPriori; Boothroyd Dewhurst; Cognition; FOG Software Group; Oracle; pVelocity; SAP; Saphirion; Siemens Digital Industries Software

Gartner Recommended Reading

Top BOM Practices for Building Digital Threads in Discrete Manufacturing Industries

Innovation Insight: Implement Digital Threads for Long-Term Flexible Access to Critical Data

Top Strategic Technology Trends in Manufacturing and Transportation for 2023

Top Strategic Technology Trends in Manufacturing and Transportation for 2023 — Presentation Materials

Entering the Plateau

Process Analytical Technology

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Mature mainstream

Definition:

Process analytical technologies (PATs) are technologies, systems and processes for continual analysis of raw materials in process, products and intermediate production materials during manufacturing. PAT enables in-process data to be used for assessing the quality and consistency of a batch during manufacturing, thereby significantly reducing the need for finished product testing and improving lead times.

Why This Is Important

Analytical capabilities through PAT can be executed through diverse techniques for measuring chemical, physical and microbiological properties, and for raw analysis of supply chain data in areas such as risk management. The U.S. Food and Drug Administration (FDA) outlines a PAT framework as a system for designing, analyzing and controlling manufacturing through timely measurements (i.e., during processing).

Business Impact

PAT is positioned to assist business objectives targeted toward digital robustness and resilience in critical product phases. Robust protocols delivered through PAT can be particularly valuable in process-critical or quality-intensive production workstreams. PAT is already proven in highly continuous manufacturing processes, such as oil refineries and petrochemicals, where quality problems need to be corrected before they contaminate large product volumes.

Drivers

- PAT has significantly appealed to all organizations seeking to eliminate error-prone manual activities, guesswork, and variability from complex and multistage production processes, which might allow nonconforming products to enter the supply chain.

- Life sciences companies can consider PAT in assisting them as their product portfolios transition toward biotechnology and biologics (large molecule) products. New generations of personalized and precision biologics products place increased demands on quality and technical requirements to deliver optimized workflows and process streams for highly intensive and intricate processing steps often from within a single compact manufacturing facility. This becomes significant when a single batch of product represents a multi-million-dollar revenue opportunity and when technology transfer for accelerated ramp up is needed.
- Output through multivariate analytics delivered from PAT capabilities will often map to process parameters that can be routinely monitored with lower-technology (univariate) probes, diagnostics or sensors. For example, formulations, materials, gas concentration, pH, and temperature can fundamentally have an impact on process purity and timing for production runs.
- The ability to reliably produce on demand offers massive reductions in product testing after production, scrap and discards, on-hold inventory, finished goods inventory, and lead times.
- Cadence for PAT technology adoption will depend on industry regulatory controls; legacy and planned IT infrastructure supporting manufacturing batch processing; technical and quality specifications; automation systems; and errors through continued monitoring and close-to-real-time process business intelligence.

Obstacles

- Most older pharma manufacturing and development processes were originally designed to operate without PAT, so adopting PAT requires introducing new real-time capabilities and vendors. The plateau represents solution maturity with its value proposition well-positioned for integration and deployments supporting a future shift to biologics and large molecule processing.
- As a part of a broader integrated manufacturing systems technology roadmap that accommodates emerging technologies, such as robotics, machine learning and 3D printing, these solutions will become prerequisites for a successful PAT architecture.
- In some instances, more established manufacturing support systems will need to be upgraded or replaced to be more accessible and/or participate in broader support of PAT.

User Recommendations

- Segment high-risk production streams and processes, or product parameters that cause serious quality issues, and look for ways to utilize PAT to reduce them.
- Scrutinize manufacturing systems architecture, and integration with R&D, quality and information, and product data management systems for information to be accessible as it is needed, to get a mature structure for data acquisition, integration and organization. Understand that a feedback loop from a single special sensor or an investment in a process historian will not deliver full value.
- Conduct a full evaluation of the potential and timing to deploy PAT. This will require a shift in organizational readiness as it will need to integrate across different scientific, operational and project management disciplines. This integration will cover the whole manufacturing process and closely integrated business operations, such as packaging and distribution.

Sample Vendors

AspenTech (Camo Analytics); Emerson; Eurotherm; IRIS; METTLER TOLEDO; Panacea Technologies; Sartorius; Siemens Digital Industries Software; synTQ; Thermo Fisher Scientific

Gartner Recommended Reading

Your Lab of the Future Strategy Must Enable Life Sciences Digitalization

The 3-Step Process of Contextualizing IoT and Manufacturing Data to Enable Smart Factories

Quick Answer: What Are the Differences Between Industrie 4.0, Smart Manufacturing and Smart Factory?

Electronic Batch Records

Analysis By: Michael Shanler, Rick Franzosa

Benefit Rating: High

Market Penetration: More than 50% of target audience

Maturity: Mature mainstream

Definition:

Electronic batch records (EBRs) are used for reporting the processes and procedures executed during product manufacturing. Tools supporting electronic batches are particularly relevant in process-intensive phases (formulated, recipe-based or continuous products) or large extended-volume production runs. Across life science companies, EBRs align with the U.S. Food and Drug Administration's (FDA's) 21 CFR Part 11 and EU Annex 11 requirements, allowing them to substitute for paper-based records.

Why This Is Important

EBRs are well-positioned to elevate the governance of critical manufacturing, technical and product datasets within established or planned manufacturing footprints. Through robust electronic protocols, workflows and data streams, EBRs can improve operational efficiency and decision making; help eliminate errors and unplanned manufacturing downtime; and enhance levels of interoperability across manufacturing, engineering, technology and quality stakeholders.

Business Impact

EBR solutions integrate across various systems, such as manufacturing execution systems (MES), laboratory information management systems, process control systems, quality management systems, and any solutions where data is reported, visualized or recorded during batch manufacturing. An EBR is the resultant output summary report that enables quality managers to approve releases based on electronic content alone.

Drivers

- Several providers, especially those newer to investing in EBRs, realize the need to build an architecture that also complements adjacent solutions, such as automation and quality systems. EBR evolution also aligns closely with emerging or innovative technologies supporting visibility, predictive analytics, collaboration and traceability.
- EBR, when synchronized with MES and automation activities is foundational to smart factory and industry 4.0 initiatives.
- EBRs provide a clear path to improving batch release times in regulated processes. They can significantly reduce the time spent cleaning data manually and approving product releases, decreasing the risk of an FDA warning or, even worse, a recall.
- EBRs deploy process engines to guide tasks and instructions for operations. Thus, they can be further leveraged for change management, integration and/or collaboration initiatives.
- EBR systems also act as data hubs for capturing and collating information about testing procedures, environmental monitoring, quality parameters, product life cycles and manufacturing automation data. Automated capture of this data reduces risks that can arise through manual input and processing errors in production areas that have traditionally relied on paper-based records and systems. Successful deployments will rely on robust data feeds of regulatory business intelligence.
- EBRs can promote expectations for process improvement, automation and reliability, as well as improved quality and data integrity release times.
- As clients began modernizing with automation nearly a decade ago, many MES vendors added EBR capabilities to reduce the amount of paper and to synchronize manufacturing and batch report generation. Thus, this technology is on the plateau.

Obstacles

- EBR solutions typically do not map specifically to compliance mandates, potentially limiting their impact for prioritization in less mature organizations.
- Careful planning around architecture is critical to EBR success, given the myriad systems that may be capturing and tracking identical or distinct datasets related to batch or lot processing.
- Workflows and tracking for key processing phases can be achieved only when a broad range of solutions and services integrate seamlessly and extend connectivity outside manufacturing footprints.
- An EBR's true potential will rely on its ability to cleanse and extract critical batch-related data from across the supply chain for responsive decision making.
- EBR benefits depend heavily on how the data required to drive them is captured and governed. The method of recording and communicating batch data varies based on the solution implemented and the products/markets in use. This variability directly impacts some EBRs' ability to adequately report on product manufacture controls.

User Recommendations

- Select one small-volume product, and review EBR requirements for each process stage from start to finish. Highlighting the time to value of these compact investments will help reinforce continued scale-up using EBRs.
- EBRs are mature and have proven value in the marketplace. Adopt a realistic mindset about the role of EBRs. Assess their integration and optimization attributes, but also account for their limitations, especially across specific batch- or quality-related mandates and legacy systems deployed to meet batch-related compliance objectives.
- Do not view EBR as a panacea for process issues. Rather, position it as a progressive hub that bridges operations, processes and technical support IT infrastructures.
- Review the integrated product supply architecture needed to sustain quality levels if you are looking to implement an effective EBR solution that drives a "right-first-time" approach for process excellence.

Sample Vendors

Apprentice; Dassault Systèmes; Emerson; Körber; L7 Informatics; MasterControl Solutions; POMS; Rockwell Automation; Siemens Digital Industries Software; Tulip

Gartner Recommended Reading

Magic Quadrant for Manufacturing Execution Systems

Market Guide for Quality Management System Software

Manufacturing Execution Systems' Critical Capabilities Comparison Tool

Life Science CIO's Strategy for Delivering Cell and Gene Therapy Capabilities

Electronic Laboratory Notebooks

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: More than 50% of target audience

Maturity: Mature mainstream

Definition:

Electronic laboratory notebooks (ELNs) are informatics solutions to help research and production analysts in R&D, manufacturing and quality organizations capture and manage scientific laboratory data. Additionally, ELNs are used to record potential intellectual property, perform calculations, port information from instruments to repositories, leverage operational technologies, initiate lab instrumentation instructions and execute processes within the laboratory.

Why This Is Important

With lab of the future initiatives and efforts to go paperless, ELN adoption continues to drive toward the mainstream with success stories for improving quality, creating knowledge platforms and driving collaboration. ELNs have moved from thick- and thin-client solution deployments toward web- and cloud-based solutions. This has made them integral to scientific processes and enables more streamlined scientific and experimental data capture approaches.

Business Impact

ELNs have a high impact on laboratory productivity in R&D and quality assurance (QA) and quality control (QC) groups and support innovation and automation strategies. They improve collaboration efforts between dispersed lab personnel and provide a system of record in lab test environments. ELNs enable replacing paper-bound notebooks and disparate electronic systems. Some ELNs can be augmented with scientific plug-ins, sophisticated workflow automation and instrument integration.

Drivers

- Business leaders demand capabilities from ELNs to increase productivity, improve quality and reduce the amount of paper used in laboratories. The technology is now widely available, and ELNs fit with modernization strategies for capturing, analyzing and reporting laboratory and scientific findings.
- Initially, ELNs were used as “electronic sticker books” to replace paper-bound laboratory notebooks. They now have technology embedded in the software that expands capabilities well beyond capturing electronic data for experiments and ideas, and are replacing paper-bound notebooks. In fact, ELNs have much deeper functionality spanning biology, chemistry and QA/QC.
- As scientific laboratories have become more virtualized and electronic, ELN providers have created application-specific templates, and solutions have been optimized for different disciplines, including materials, polymers, biology, chemistry, proteomics, genomics, bioanalytical contract services and QA/QC manufacturing.
- ELNs are being used as scientific knowledge management system portals and have been augmented with semantic search capabilities to leverage both internal and external data. Some laboratory information management system (LIMS) vendors are now offering ELNs as well.
- The new versions of ELNs enable organizations to increase productivity, improve quality and reduce the amount of paper used in laboratories. As organizations push to reduce transcription and writing errors, improve collaboration, and reduce the time it takes to recover necessary files during internal and external audits, ELNs will become a more standard tool and fully replace traditional paper notebooks.
- Due to all these drivers, we advanced ELN to the plateau on the Hype Cycle and expect mainstream adoption in two years.

Obstacles

- Many organizations support multiple ELN environments (such as biology, chemistry, QA/QC, formulation and analytical), with competing capabilities, which makes scaling those solutions difficult.
- The predominantly LIMS vendors have “bolt on” ELN capabilities, which have been marketed for extending into other non-LIMS groups, but most lack deep functionality.
- Clients report being overwhelmed and confused by the number of overlapping vendor messages. This hampers harmonization, rationalization and vendor selection processes.
- Most of the ELN companies are small, early stage businesses and lack the professional services required to sustain midsize and large organizations.
- Many legacy vendors have overengineered customized environments, which has damaged some of their credibility with clients.

User Recommendations

- Collaborate with decision makers who are familiar with laboratory processes when selecting a system. Different disciplines and research labs have divergent needs.
- Plan for the fact that an R&D-centric ELN will not function well in a quality/operations environment, and a quality management-oriented solution may not operate well in an R&D area.
- Evaluate ELNs with enhanced bioinformatics, analytical and reporting capabilities in organizations that conduct drug discovery or therapeutic research.
- Stay informed about future features that enhance collaboration by securely connecting scientists and analysts (such as tablet compatibility and handwriting recognition). Also, consider hybrid models that can be deployed as client/server and web-based models to support decentralized research activities.
- Assess laboratory execution system (LES)-centric ELNs for use in good x practice (GxP) environments or environments that have stringent quality, regulatory and compliance requirements.

Sample Vendors

Agilent Technologies; Benchling; BioData; Dassault Systèmes; Dotmatics; IDBS; LabVantage Solutions; Revvity; Sapio Sciences; Thermo Fisher Scientific

Gartner Recommended Reading

Your Lab of the Future Strategy Must Enable Life Sciences Digitalization

Quick Answer: How Do You Know That You're Building a Truly Digital Life Science Lab of the Future?

7 Key Questions Life Science CIOs Should Ask When Selecting Laboratory Informatics Software

Market Guide for Laboratory Informatics

Appendixes

See the previous Hype Cycle: Hype Cycle for Life Science Manufacturing, Quality and Supply Chain, 2022

Hype Cycle Phases, Benefit Ratings and Maturity Levels

Table 2: Hype Cycle Phases

(Enlarged table in Appendix)

Phase	Definition
Innovation Trigger	A breakthrough, public demonstration, product launch or other event generates significant media and industry interest.
Peak of Inflated Expectations	During this phase of overenthusiasm and unrealistic projections, a flurry of well-publicized activity by technology leaders results in some successes, but more failures, as the innovation is pushed to its limits. The only enterprises making money are conference organizers and content publishers.
Trough of Disillusionment	Because the innovation does not live up to its overinflated expectations, it rapidly becomes unfashionable. Media interest wanes, except for a few cautionary tales.
Slope of Enlightenment	Focused experimentation and solid hard work by an increasingly diverse range of organizations lead to a true understanding of the innovation's applicability, risks and benefits. Commercial off-the-shelf methodologies and tools ease the development process.
Plateau of Productivity	The real-world benefits of the innovation are demonstrated and accepted. Tools and methodologies are increasingly stable as they enter their second and third generations. Growing numbers of organizations feel comfortable with the reduced level of risk; the rapid growth phase of adoption begins. Approximately 20% of the technology's target audience has adopted or is adopting the technology as it enters this phase.
Years to Mainstream Adoption	The time required for the innovation to reach the Plateau of Productivity.

Source: Gartner (July 2023)

Table 3: Benefit Ratings

Benefit Rating ↓	*Definition* ↓
Transformational	Enables new ways of doing business across industries that will result in major shifts in industry dynamics
High	Enables new ways of performing horizontal or vertical processes that will result in significantly increased revenue or cost savings for an enterprise
Moderate	Provides incremental improvements to established processes that will result in increased revenue or cost savings for an enterprise
Low	Slightly improves processes (for example, improved user experience) that will be difficult to translate into increased revenue or cost savings

Source: Gartner (July 2023)

Table 4: Maturity Levels

(Enlarged table in Appendix)

Maturity Levels	Status	Products/Vendors
Embryonic	In labs	None
Emerging	Commercialization by vendors Pilots and deployments by industry leaders	First generation High price Much customization
Adolescent	Maturing technology capabilities and process understanding Uptake beyond early adopters	Second generation Less customization
Early mainstream	Proven technology Vendors, technology and adoption rapidly evolving	Third generation More out-of-box methodologies
Mature mainstream	Robust technology Not much evolution in vendors or technology	Several dominant vendors
Legacy	Not appropriate for new developments Cost of migration constrains replacement	Maintenance revenue focus
Obsolete	Rarely used	Used/resale market only

Source: Gartner (July 2023)

Document Revision History

Hype Cycle for Life Science Manufacturing, Quality and Supply Chain, 2022 - 26 July 2022

Hype Cycle for Life Science Manufacturing, Quality and Supply Chain, 2021 - 20 July 2021

Hype Cycle for Life Science Manufacturing, Quality and Supply Chain, 2020 - 12 August 2020

Recommended by the Authors

Some documents may not be available as part of your current Gartner subscription.

Understanding Gartner's Hype Cycles

Tool: Create Your Own Hype Cycle With Gartner's Hype Cycle Builder

2023 Life Science Business Drivers of Technology Decisions

Life Science Manufacturer CIO Top Actions for 2023

The Future of the Supply Chain for Life Sciences — 2023 Report

Table 1: Priority Matrix for Life Science Manufacturing, Quality and Supply Chain, 2023

Benefit	*Years to Mainstream Adoption*			
↓	*Less Than 2 Years* ↓	*2 - 5 Years* ↓	*5 - 10 Years* ↓	*More Than 10 Years* ↓
Transformational		Generative AI in Life Sciences Generative AI in Process Manufacturing Large Language Models in HCLS Smart Factory	Blockchain in Life Sciences Digital Life Science Platform Generative AI in Discrete Manufacturing Industry Cloud Platforms for Manufacturing	Lights-Out Manufacturing
High	Electronic Batch Records QMS Applications	Cloud Computing in Manufacturing Operations Model-Based Manufacturing MOM Application Suites Pharma PLM Predictive Product Costing Software Process Analytical Technology Quality by Design SaaS ELN SaaS-Regulated CSP Track and Trace UDI for Medical Devices	Cell and Gene Therapy Platform Cold Chain as a Service Digital Threads Digital Validation Tools Enterprise Laboratory Informatics IoT-Enabled Laboratory Tech Transfer Services (Foresight)	

Benefit	*Years to Mainstream Adoption*			
↓	***Less Than 2 Years*** ↓	***2 - 5 Years*** ↓	***5 - 10 Years*** ↓	***More Than 10 Years*** ↓
Moderate	Electronic Laboratory Notebooks	Compliant GxP Cloud Services SaaS LIMS	AR/VR/MR in Life Science Bioprocessing Informatics Controlled Substance Ordering System Mobile Lab Apps	3DP Drugs, Nutraceuticals and Supplements
Low				Sustainable Packaging

Source: Gartner (July 2023)

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