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

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Initiatives: Healthcare and Life Science Digital Transformation and Innovation; Manufacturing Operations

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

Analysis

What You Need to Know

CIOs, IT leaders and business professionals in life science manufacturers (pharmaceutical, biotechnology, medical device, consumer health companies) are continuously looking to reduce costs and build efficiencies at scale. They do this under the significant regulatory compliance constraints associated with developing and selling products for which quality, safety and brand reputation are paramount. This Hype Cycle highlights specific emerging technologies and innovations available to LS 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.

What CIOs learned from COVID-19’s disruption of global pharmaceutical manufacturing operations is that they must work closer still with quality, operations and supply chain leaders to sustain production and build in extra resiliency. At the same time, CIOs must make progress on their digital manufacturing initiatives or myriad IT modernization projects in progress. This Hype Cycle supports both of these objectives.

The Hype Cycle

The contents of this Hype Cycle will help CIOs better evaluate and plan for important technologies for manufacturing, quality, regulatory and supply chain requirements. Going into 2021, we added several innovations to provide a more complete picture that is specific to life science quality, manufacturing and supply chain functions. These include bioprocessing informatics, validation services, tech transfer services, digital twin, generative design, cold chain as a service and IoT platforms.

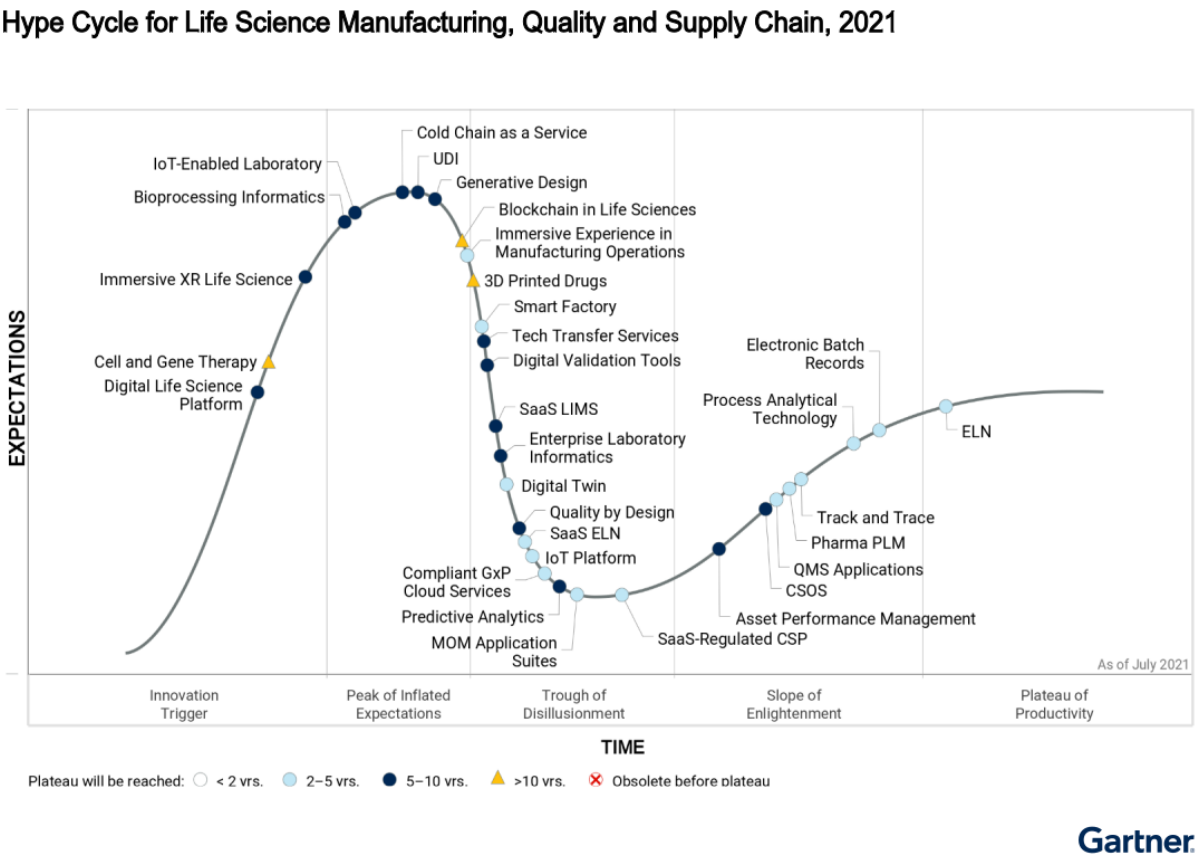
This Hype Cycle is part of a family of three life-science-focused Hype Cycles. The two others focus on: (1) R&D (Hype Cycle for Life Science Research and Development, 2021); and (2) commercial sales and marketing operations (Hype Cycle for Life Science Commercial Operations, 2021). The combination of the three help CIOs apply a comprehensive view on emerging technologies across the entire life science value chain.

The innovations we cover in this research span all phases of the Hype Cycle (see Understanding Gartner's Hype Cycles).

- The technologies in the Innovation Trigger phase, although exciting, are still developing and will take more time to mature. These include end-to-end cell and gene therapy (CG&T) systems, and augmented reality (AR)/virtual reality (VR) on drug manufacturing production lines.
- Those at the Peak of Inflated Expectations will inevitably slide into the Trough of Disillusionment, where many clients may start to second-guess their investments, before significant value will be realized. Examples include compliance services for cloud applications and intelligence mechanisms for operational data streams and equipment.
- Technologies in the Slope of Enlightenment are mature enough for CIOs to more easily move them into production as they are primed to experience wider-scale adoption by life science organizations in the Plateau of Productivity. Examples of technologies in this phase include serialization and cloud-based quality management system (QMS) suites.

Use the information in this Hype Cycle to identify technologies that have the potential to deliver the value 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, 2021



Source: Gartner (July 2021)

Downloadable graphic: Hype Cycle for Life Science Manufacturing, Quality and Supply Chain, 2021

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.

We include several examples of technology transformation opportunities — most of which will reach mainstream in five to 10 years. IoT-enabled labs represent an opportunity to transform lab activities and drive capabilities for operations, digital twins and evolved science. Blockchain is also transformational and has already disrupted the financial and retail industries. However, it is evolving slower in the life science industry. This means that the vendor ecosystem and business models are not quite ready for widespread adoption, with most blockchain projects still in proof of concept (POC) and mainstream adoption at least 10 years away.

Table 1: Priority Matrix for Life Science Manufacturing, Quality and Supply Chain, 2021

(Enlarged table in Appendix)

Benefit ↓	Years to Mainstream Adoption: Less Than 2 Years ↓	2 - 5 Years ↓	5 - 10 Years ↓	More Than 10 Years ↓
Transformational		Digital Twin Smart Factory	Cold Chain as a Service Digital Life Science Platform Generative Design Immersive XR Life Science	Blockchain in Life Sciences Cell and Gene Therapy
High		Electronic Batch Records ELN Immersive Experience in Manufacturing Operations IoT Platform MOM Application Suites Pharma PLM Process Analytical Technology QMS Applications SaaS ELN SaaS-Regulated CSP Track and Trace	Asset Performance Management Digital Validation Tools Enterprise Laboratory Informatics IoT-Enabled Laboratory Predictive Analytics Quality by Design Tech Transfer Services UDI	
Moderate		Compliant GxP Cloud Services	Bioprocessing Informatics CSOS SaaS LIMS	3D Printed Drugs
Low				

Source: Gartner (July 2021)

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

Digital Life Science Platform

Analysis By: Michael Shanler

Benefit Rating: Transformational

Market Penetration: Less than 1% of target audience

Maturity: Embryonic

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 and heavily customized or niche business applications portfolios. The siloed nature of current architectures (as seen in research informatics packages, clinical development tools, sales CRMs and manufacturing suites) has stifled innovation and slowed digital transformation. Customers are exhausted by feeble attempts at interoperability by vendors resulting in a bloated total cost of ownership (TCO).

Business Impact

- 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 leveraging data sources from R&D, precision medicine, and real world evidence
- Digital laboratory research
- Digital prescriber engagement for personalized communications and information sharing

Drivers

- Clients want to enable a composable life science enterprise (or perhaps a “digital therapeutech”) that is realized through business-user focused application experiences that are independent of the underlying set of COTS or legacy monolithic applications.
- Clients want a more effective means of bringing together different domains (e.g., clinical and AI SMEs) to provide a focus for democratized innovation among a range of stakeholders (see Fusion Teams: Cross-Functional Collaboration for the Digital Era).
- 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 packaged business capabilities (PBCs). PBCs are application building blocks that have been purchased or developed internally or with third parties.
- Many clients and vendors are including platform strategies as the main vehicle for ushering in a new era for digital business, where individualized experiences that mash up both application data, as well as analytics, created by underlying PBCs and supported via broader data fabrics, are underpinning this IT transformation.

Obstacles

- Leading vendors in this space will be those that can provide a means of rapidly producing composable digital products and services from different sources (not just their own marketplace or product offerings).
- Clients are already reporting being overwhelmed by vendor messaging regarding platforms. This is creating some paralysis for decision making.
- DLSP requires vision and alignment with both 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 on design and key partner selections.
- We expect this innovation profile to reach the Peak of Inflated Expectations in three years as new visionary platform entrants and large sponsors force incumbent vendors to open up their architectures. As this happens, clients will inevitably be let down by either the vendor capabilities or their own 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 Fusion Teams: Cross-Functional Collaboration for the Digital Era).
- Take appropriate actions on vendor and key technology sourcing across the current and future enterprise application portfolio (see A CIO's Hype Cycle Reference Guide for the Healthcare and Life Science Industries).
- 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.
- Use the attribute of "composability" as a high priority in making and renewing vendor relationships.
- Explore strategic relations with hyperscale solution providers and channel partners.

Sample Vendors

Amazon; Google; IBM; Microsoft; Salesforce; SAP

Gartner Recommended Reading

Tool: Life Science CIO's Executive Presentation for Building the Composable "Digital Therapeutech"

Predicts 2020: Life Science CIOs Must Digitalize for Business Growth

Best Practices for Reimagining Your Life Science Company as a Digital Business Technology Platform

Life Science CIOs Need to Improve Their Organization's Digital Partnerability

Future of Applications: Delivering the Composable Enterprise

Cell and Gene Therapy

Analysis By: Andrew Stevens, Jeff Smith

Benefit Rating: Transformational

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

Cell and gene therapy (CGT) platforms are systems (and services) designed to help collect, analyze, prepare and transport 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 the infusion or transplantation of whole cells into a patient for the treatment of a disease.

Why This Is Important

The concept of "vein-to-vein" is increasingly being referenced when describing emerging CGT solutions. CGT personifies the concept of personalized medicines given that the time from sourcing to healthcare fulfillment is just one of the several critical factors impacting sourced material and finished products including stability, real-time visibility, security and temperature sensitivity.

Business Impact

CGT products start with initial "apheresis," (blood extracted from a specific patient) for processing and transportation to formulation sites which directly incorporate acquired source materials for making the personalized therapies. Solution evolution is anticipated to further progress as CGTs become a stronger component of life sciences and healthcare product portfolios.

Drivers

- Early solutions are fragmented, mapped to different phases or criteria of the product's development and fulfillment life cycle. New platforms and services that help map synchronize data and streamline operations across full vein-to-vein product life cycles are expected to further evolve especially across partnered models or through industry stakeholder models.
- The first gene therapy was tested by the National Institutes of Health (NIH) in 1990, and research organizations were experimenting on and putting cellular therapies into practice for decades. However, dedicated software for managing the components of end-to-end processes did not exist until recently.
- In many companies, CGT requirements are supported using custom-made or proprietary supply chain and logistics software. It wasn't until the last 10 years that new entrants started to support the growing market of CGT trials and commercial operations with a CGT platform such as TrakCel and Vineti. Further vendors have developed capabilities, especially focusing on the stringent supply chain and service elements.
- As demand for CGT clinical trials accelerates, a CGT platform that matches the therapy area and is scalable will be essential to streamline trials and get commercial products to the market.
- The data and new supply chain business models associated with CGT have broad potential across the business throughout the product life cycle such as R&D, commercial as well as specialized manufacturing, supply chain operations and retained logistics partners. The requirements become the most acute for organizations supporting a "personalized medicine" approach, where markets consist of individuals. This requires organizations to assess solution maturity in line with remodeling across supply chains built around the patient. Once patient, manufacturing, operations and clinical data policies are updated, supporting different CGT programs will be more scalable.

Obstacles

- There is complexity in accommodating very specific needs and requirements for key participants in newly developed end-to-end (vein-to-vein) supply chain business models. With frequent interventions and touchpoints, emerging CGT solutions must appeal to a wide range of stakeholders including principal orchestration among R&D staff, healthcare professionals, lab technicians, supply chain professionals as well as appointed logistics and transportation partners.
- While only a handful of CGTs are available as therapies, manufacturers will see both significant opportunities and challenges as it becomes more differentiated and essential across life science (LS) portfolios including: (1) allogeneic (the donor is different than the recipient); (2) autologous (the donor and patients are the same); and (3) variations of stem cell and T-cell therapies.
- CGT's new patient-centric models will need to empower change management around digital maturity and elimination of functional/data silos.

User Recommendations

- Form a cross-functional working group to identify major process parameters, criteria and full chains of custody needed starting with the patient. Invite senior members from the office of the CIO, supply chain and logistics and quality in adopting a no-limits approach of developing new fulfillment models from scratch to meet demands presented through CGT.
- Identify if CGT platforms will deliver against major touchpoints and integration to major systems, such as ERP, manufacturing execution, transportation management, laboratory analysis, quality management, and patient- and healthcare-facing systems.
- Shortlist retained and new technology service integrators invested in life sciences expertise as well as portfolios of technology solutions. These can facilitate opportunities for future partnering to deliver against requirements anticipated for new vein-to-vein supply chains, e.g., condition-based monitoring, location tracking, security and real-time visibility.

Sample Vendors

Autolomous; Be The Match BioTherapies; Cytiva; FarmaTrust; L7 Informatics; Ori Biotech; Synthace; TrakCel; World Courier; Vineti

Gartner Recommended Reading

Product Leaders: Understand Healthcare CIO Business Drivers for 2021

Industry Insights: Healthcare Providers Should Embrace Medical Technology Innovation

Industry Insights: Healthcare Providers Must Modernize to Transform

Critical Capabilities for Manufacturing Execution Systems

Immersive XR Life Science

Analysis By: Andrew Stevens

Benefit Rating: Transformational

Market Penetration: 20% to 50% of target audience

Maturity: Emerging

Definition:

Augmented reality, virtual reality and mixed reality in life sciences apply technologies to create a digital and virtual immersive environment whose use cases span the entire healthcare value chain, including R&D, quality, manufacturing, therapeutic and commercial. AR, VR and MR, collectively referred to as extended reality (XR) technologies, are used by LS firm employees and healthcare provision in areas including cancer detection, immersive training, and remote diagnostics and triage.

Why This Is Important

The extended life sciences and healthcare value chain is highly complex, regulated and interconnected across multiple phases of discovery, manufacturing and extending to the provision of healthcare. The critical safety, efficacy and technical attributes associated with new precision and personalized medicines lend themselves well to assessing new generations of immersive experiences that can enhance quality, safety, continuous improvement, yield, optimization, change management and rapid diagnosis.

Business Impact

Immersive experiences use applications supporting physical devices, integrated software and specialized user interfaces. Empowered by new generations of AI and IoT tools, 5G data services, and edge computing, new immersive user applications in life sciences will use a range of head-mounted displays (HMDs), interactive virtual assistants, wearables, smartglasses, object recognition tools and graphic processing, and apps to map to specific use-case objectives across the healthcare value chain.

Drivers

- AR, VR and MR today have selective impacts on LS business. Clients have shared metrics for throughput, collaboration, quality, compliance and insights in the areas of labs (such as LoTF), molecular design and service inventory logistics. Immersive experience technologies present new interaction models through the product life cycle not only with humans, but with other core processes, machines and applications, such as manufacturing execution systems (MESs), quality management systems (QMSs) and warehouse management systems (WMSs).

- New interaction models could augment human capabilities across standard paper-based or manually intensive processes and work practices to enhance continuous improvement and robustness in areas such as quality, safety and yield in manufacturing. Early examples of immersive applications in life sciences and across healthcare value chain include MR pilots in medical devices (such as robotic surgical instruments) for field service engineering on analytical equipment, augmented operating instructions in manufacturing, and wearables trials in aseptic manufacturing environments for operator safety enhancements. They also include VR for molecular modeling, physician training and patient education, as well as clinical therapies, such as cognitive behavioral exposure therapy, PTSD, depression and dysmorphia, stroke, and attention deficit disorders. Additional examples include VR headsets and remotely controlled haptic gloves for ultrasound scanning and diagnosis with 5G-enabled ambulances, remote onboarding and interactive simulation training for R&D tools and systems, and AR iPhone-based skin cancer lesion detection companion app. It has also been integrated into a lab informatics environment for laboratory execution systems.

Obstacles

- Regulatory impacts on new generations of AR, VR and MR tools and services, especially those in healthcare fulfillment, diagnosis and patient monitoring, and transitions from 2D to 3D simulation.
- Inertia due to legacy challenges and barriers that still impact many life sciences companies, such as functional silos, regulatory and especially digital maturity.
- Early use cases adoption will be optimized through co-development with secure and robust levels of data and communications services provided through Wi-Fi and generations of enterprise data services .Functionality enhancing 5G, data speed and latency (among others enablers) will play an influential role in trials and pilots transitioning to scalable and actual deployments.
- Change management certification, maintenance and regular training for new updates and configurations of AR, VR and MR solutions and physical hardware.
- Security implications for remote, virtualized operations, and privacy and integrity of shared and communicated data.

User Recommendations

- Group the technologies typically used in concert with or complementary to immersive experiences, such as AR, VR and MR, to create an immersive experience often in combination with other technologies such as modeling, digital twin and IoT.
- Evaluate increasing expectations for UX approaches and experiences to effectively aggregate XR for staff members, patients and physicians. The aggregate AR, VR and MR, applied together to create an immersive experience, is positioned as climbing the hype curve near the Peak of Inflated Expectations.
- Identify technology solutions likely to evolve through dedicated or partnered solutions to operate successfully in the life science domain and healthcare value chain. Design for accommodations to legacy barriers and changes that impact the patient experience.

Sample Vendors

AccuVein; Apprentice; ARdVRk; EON Reality; Fundamental VR; Goodly Innovation; Nanome; Sightcall; Varjo

At the Peak

Bioprocessing Informatics

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

Bioprocessing informatics suites coordinate data and process sharing across experimental design, laboratory processes, recipe 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 and 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

- Improves automation, methods and process development (qualification and validation) and improves compliance.
- Creates process intelligence using analytics across laboratory, scientific and formulation data.
- Reduces writing-, calculation-, procedure-, and transcription-errors in labs.
- Predicts yields, purities and costs, by arranging and analyzing ML-enabled data.
- Improves visibility into production development, technical operations and quality issues.

Drivers

- Life sciences 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 RNA drugs, antibody drugs, and other large molecule therapeutics. Today, nearly 40% of drug portfolios are biologic-based, representing a doubling over the last decade.
- 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. According to a recent IQVIA Institute study, biologics drugs represent 2% of all U.S. prescriptions, yet they account for 37% of net drug spending. 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 on the rise as well.
- Most clients report increased frequency of technology transfers between labs, especially as labs and production facilities are being driven to become more automated and flexible.
- Many life sciences organizations are considering bioprocessing solutions in roadmap exercises and will make active investments in POCs over the next year. With the growing attention and excitement, we position this technology in the Peak of Inflated Expectations section of the hype curve. It will reach peak hype in the next 12 months and will reach mainstream adoption in the next 5-10 years.

Obstacles

- Many organizations have existing entrenched LIMS, ELN, and 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/PQ, IT validations), leading to additional implementation costs when switching to new platforms.

- Many clients 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 by focusing on these areas:

- Characterize the "turnaround time" for methods development for complex biologic processes. Examine impacts on product release timelines or milestones with partners.
- Estimate the IT costs, staffing costs with a focus on integration, validation, and overall life cycle.
- Determine the engagement requirements with "shadow IT" and focus on which roles are required to conquer the technical debt of old legacy systems and processes that are ingrained into the business.
- Impacts to agility with existing solutions sets with analytics, process flow changes, new materials entry and formulation design.

Sample Vendors

Benchling; Bionet; Bioprocess Engineering Services (BPES); BSSN Software; IDBS; Genedata; GoSilico; Riffyn; Sartorius; Synthace

Gartner Recommended Reading

Healthcare and Life Science Business Driver: Medical Technology Innovation

IoT-Enabled Laboratory

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

Internet of Things (IoT)-enabled laboratories leverage sensors, beacons and systems for communicating information between lab entities such as instruments, informatics systems and smart consumables. 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 (LotF).

Why This Is Important

IoT is nascent in the lab space but is delivering initial value in the consumer and industrial world. Organizations are exploring how to connect entities such as lab equipment (e.g., pH meters and balances), laboratory informatics (e.g., electronic laboratory notebook [ELN] and laboratory information management system [LIMS]), and smart consumables (e.g., buffers and reagents) with enterprise assets (e.g., RFID badges, ERP and environmental, health and safety [EH&S]).

Business Impact

IoT-enabled laboratories and connecting labs help IT leaders:

- Enable “smart lab” and LotF strategies and drive autonomous processes based on algorithms and machine learning that leverage IoT data.
- Enable 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 LotF as a topic at annual meetings over the last four years.
- Nascent strategies related to LotF, such as “Digital Lab,” “Laboratorie 4.0” and “Internet of Lab Things-Io(L)T” will take root through 2021.
- The impacts of COVID-19 on the ability of laboratory personnel to access laboratory operational data will accelerate this technology.
- 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 the nascent nature of IoT in the lab space, we position this technology as approaching the Peak of Inflated Expectations.

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 “big bang” approaches to modernize laboratory environments.
- 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 LoTF 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.IO; Connected Labs; Elemental Machines; Labforward; SAP; Scitara, Simplifier; TetraScience; WattIQ

Gartner Recommended Reading

Market Guide for Laboratory Informatics

Life Science CIOs’ Plans for the Lab of the Future Must Enable Digital Business

Envision the IoT-Enabled R&D Digital Laboratory of the Future

Chart a New Course With Io(L)T-Enabled Life Science Laboratory Business Moments

Cold Chain as a Service

Analysis By: Andrew Stevens

Benefit Rating: Transformational

Market Penetration: More than 50% of target audience

Maturity: Emerging

Definition:

Cold chain 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 in-transit products and assets.

Why This Is Important

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 service providers deliver portfolios of IoT software and hardware services, extending beyond traditional temperature tracking. It includes continuous temperature monitoring, motion, security, humidity, tilt, shock and light depending on the profile, sensitivity and risk implications of the product itself.

Business Impact

Maintaining full product integrity across critical phases of the supply chain, including sourcing, processing, logistics and distribution is growing in urgency and momentum, driven by the prevalence of environment-sensitive product lines. This is critical with high-profile vaccines supporting the COVID-19 pandemic. Legacy temperature monitoring of a product in logistics (cold chain) is now being augmented to accommodate increased demands for real-time visibility, monitoring and security.

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 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, including:

- Specialized or packaged IoT tools and hardware including sensors, diagnostics, telematics, vision systems and specialist cameras.
- Real-time temperature monitoring and alerts.
- GPS, location or position of product/order, asset.
- Shock, motion and tilt sensors.
- Idle time and critical deviations from established protocols or regulations.
- Tracking, mapping and reporting alert dashboards, interfaces and mobile applications.
- Specialized security applications for both physical asset and data security.
- 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, status and condition in real time.
- 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. Value of new generations of solutions are in their ability to be highly configurable and adaptable, often focused at dedicated tracking and monitoring at the physical product level in B2B or B2C transactions.

User Recommendations

- Identify services 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.
- 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; Cloudleaf; Controlant; Modum; Roambee; Sendum; Sensitech; SkyCell; Tive

Gartner Recommended Reading

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

Hype Cycle for Supply Chain Execution Technologies, 2020

How to Assess the Benefits and Return on Investment of a Real-Time Transportation Visibility Platform

UDI

Analysis By: Andrew Stevens

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

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 the U.S.'s Federal Drug Administration (FDA) and the increasingly influential EU MDR regulations (for 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

Solutions are anticipated to mature further to closely align to further developing global UDI regulations observing core requirements set out in U.S. and EU mandates. This year's positioning and progression to post peak 5% is representative of potential for further regulatory mandates anticipated globally that will build from several years of momentum and solutions evolutions refined 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).
- 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, which includes improved continuous and post marketing surveillance, data integration to electronic health records (EHRs), reduction of medical errors via better data accessibility for supply chain stakeholders, reduction of, and better control of, medical device recalls. Also included are harmonization of international and national governing networks of device registries, reducing counterfeiting and diversion activities, managing health reimbursement claims and financial tracking, and optimizing supply chain processes and system integration and expansion through the flexibility of automatic identification and data capture (AIDC) options, such as RFID, data matrix bar codes and quick response (QR) codes. This also contributes to enhanced supply chain maturity through interoperability across supply chain stakeholders and electronic connectivity to patients.

Obstacles

- Previously anticipated regulations from other countries have yet to materialize formally thus limiting the size and speed of maturity of the marketspace.
- Current International Medical Device Regulators Forum (IMDRF) members are still expected to spur a wave of new regulatory requirements; e.g., South Korea, Russia,and Brazil are aligned to these standards.
- A small number of vendors and specialist integrator firms have released regulatory aligned products and services for this space.

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

Coridian Technologies; Freyr; Inspirage; Rimsys; Sparta Systems; SteriTrack

Generative Design

Analysis By: Marc Halpern

Benefit Rating: Transformational

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

Generative design is an automated process that systematically evolves a design, using algorithms that learn from prior designs. The approach continually improves its ability to create designs, based on an objective and conditions that the design must meet.

Why This Is Important

Generative design has great potential to automate non-value-added design activities. Despite the hype surrounding it, it is understood and adopted by a small minority of its potential market. Potential generative design users are attracted by the concept that generative design can be multidisciplinary. Its criteria can include aesthetics, cost, sustainability, function, reliability, manufacturability and serviceability. As such, software continuously improves.

Business Impact

- Generative design accelerates design activities by eliminating manual design iterations.
- By automating some design, organizations can discover alternative designs, and generate new design knowledge, giving companies more time to focus on innovative design.
- Generative design makes the use of 3D printing more viable for industrial parts, because generative design can produce designs that are expensive to manufacture by conventional means but relatively inexpensive to produce using 3D printing.

Drivers

- As experienced designers and engineers retire, their knowledge leaves with them. Manufacturers seek ways to either recreate or retain knowledge. While generative design cannot fully recreate the cultivated knowledge acquired over decades of experience, it can partially offload design burden from remaining and new employees.
- It provides manufacturers with greater ability to manage the periodic changes in demand for design and engineering skills. Designers and engineers leave with the knowledge they gained when laid off during low-demand periods. Manufacturers struggle with sufficient design capacity during high-demand periods. Generative design offsets the business risks caused by fluctuations in demand and available design and engineering talent.
- The hype surrounding artificial intelligence (AI) encourages the exploration and adoption of generative design, which is AI applied to design activities.
- Generative design technologies continue to gain capability, as technologists continue to advance the maturity of generative design, making it increasingly attractive to adopt.

Obstacles

- Users face the risk that parts that are generatively designed in isolation deliver poor performance when included in assembled products. The need to further validate the parts may raise doubts about the efficacy of this technology.
- Potential users often confuse simulation and optimization techniques with generative design. Generative design uses simulation and optimization techniques but adds machine learning, which enables the designs to continually improve in systematic and automated ways.
- Like many AI applications, generative design algorithms require “training” to reliably automate certain categories of design. Users must build confidence as to when they can adopt generative design and when they should be cautious because the design requirements are outside the scope of what a particular generative design algorithm can reliably perform.
- Veteran designers and engineers may be resistant to adopting this technology, because they view it as unreliable or a job threat.

User Recommendations

CIOs should:

- Set expectations for generative design value by working with design and engineering leaders to assess and determine how generative design performs and its limitations before adopting and implementing.
- Increase the likelihood of generative design success by suggesting a knowledgeable resource be assigned to input design goals and constraints into the software. This requires skills in describing requirements in a syntax and semantics that the generative design engine can digest.
- Provide training in generative design processes for designers and engineers.
- Acquire extensive compute power for generative design algorithms to work. Assess the extensive compute capabilities of the cloud.
- Explore the use of generative design with 3D printing.

Sample Vendors

Augmenta; Autodesk; Dassault Systèmes; ELISE; ESTECO; nTopology; PTC; Siemens

Gartner Recommended Reading

The Manufacturing CIO's Role in Adopting and Scaling 3D Printing

Blockchain in Life Sciences

Analysis By: Andrew Stevens, Michael Shanler

Benefit Rating: Transformational

Market Penetration: 1% to 5% of target audience

Maturity: Adolescent

Definition:

A blockchain is an expanding list of cryptographically signed, irrevocable transactional records shared by participants in a network. Each record contains a time stamp and reference links to previous transactions. A blockchain is one architectural design of the broader concept of distributed ledgers. Blockchain in life sciences is contextualized for the biotechnology, pharmaceutical and medical device sectors for use cases where value exchange transactions are sequentially grouped into blocks.

Why This Is Important

Primary applications of blockchain technologies in the life science industry include anticounterfeiting (serialization), genomic and/or clinical data sharing, and materials transfer. It is a popular strategy topic with Gartner clients.

While blockchain is still hyped across many industries, the life science industry continues to be slower than others to develop use cases into production.

Business Impact

- Blockchain and distributed-ledger concepts hold the promise of transforming life science industry operating models; however, these transformations are still widely unproven at scale.
- Blockchain will enable efficiencies for reaching new customers, extending relationships with supply chain partners, better quality and more complete links between events, and it should expand the boundaries of traditional life science businesses.

Drivers

- Across 2020, there were a growing number of active blockchain projects within the life science industry.
- 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, among others.
- Blockchains could have the potential to support 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

- Life science industry stakeholders are learning that blockchain-based models are difficult to scale.
- Most industry professionals have still not settled on the right type of governance to drive innovation, collaboration and the cultural shifts needed.
- 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 life science capability, and 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.

User Recommendations

- Assess the impact of change across the life sciences 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 understand 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

Blockpharma; Bloqcube; Chronicled; EncrypGen; EY; Genecoin; Nebula Genomics; Tech Mahindra; Wipro

Gartner Recommended Reading

Four Compelling Blockchain Initiative Types for Healthcare and Life Science

Predicts 2020: Life Science CIOs Must Digitalize for Business Growth

Immersive Experience in Manufacturing Operations

Analysis By: Simon Jacobson, Marc Halpern

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

There are three kinds of immersive experiences — augmented reality (AR), virtual reality (VR) and mixed reality (MR). Immersive experience enables the perception of being physically present in a nonphysical world or enriching people's presence in the physical world with content from the virtual world.

Why This Is Important

Immersive experiences transform how workers perceive, interact and control the physical and digital worlds. These new experiences:

- Enable factories to sustain resource efficiency and reliable supply amid concerns of global labor availability.
- Enhance judgments about actual or planned items in the physical world, based on the visualization of 3D models and related information.
- Accelerate problem solving and broadening continuous improvement dialogue through virtual or remote access.

Business Impact

Immersive experiences are a low-risk way to connect the virtual and physical worlds and amplify human capabilities by impacting:

- Efficiency as simulations and remote work (equipment acceptance, supplier audits) eliminate time and cost without consequence to performance.
- The nature of work by redefining jobs and roles as certain tasks shift off-site.
- Knowledge management across value chains as collaboration levels increase.

Drivers

- Exposure to the risks of available labor and depleting knowledge in manufacturing over the past 18 months — manufacturers have shifted investments to improve the employee experience, in turn accelerating what was already a strong interest in immersive experiences.
- Cost and time savings — as well as efficiencies — from remote collaboration to fill specialist skills gaps (maintenance), audit suppliers or commission new equipment in the absence of on-site availability.
- Ambition to standardize how certain methods and procedures are executed.
- Ability to onboard new or contingent employees and new partners faster through digital overlays with content (work instructions to 3D models) and guided procedures to create experiential learning and training simulations at the point of need.
- Low benefits ceiling — Error proofing, resource efficiency (primarily labor) and shortened training cycles are easily measurable minimal viable outcomes.
- Ability to capture, retain and reuse manufacturing knowledge within immersive experience technology.

Obstacles

- Manufacturing workforces lack the digital dexterity and struggle to adapt to new experiences.
- AR/MR and VR are separate technologies that will all drive future immersive experiences. Today, they do this separately through purpose-built solutions.
- The supplier ecosystem must expand beyond narrow use cases and limited breadth and quality of content.
- The time and resources to create, test and deploy immersive experiences pose scalability challenges. These are factors of the 3D environment that surround a user for VR and the range of workflows and real-time information in the form of text, graphics, video and other virtual enhancements integrated with real-world objects for AR/MR.

- Anticipating differences in expectations and human-machine interactions and accounting for those differences when setting up immersive experiences make it challenging to define the scope of implementation.

User Recommendations

- Focus on the immediate need with AR/MR. Remote knowledge and connecting workers will help create communities of knowledge that are needed to keep operations running. Evaluate VR for higher consequence situations.
- Devise a strategy for how immersive experiences will integrate with core processes and incumbent applications. This will help identify feedback loops between operator interactions and these applications.
- Investigate the human-machine interface (HMI) for the proposed environment to evaluate response times, the quality of the displays, and the intuitiveness and ergonomics of interacting with the content.
- Don't confine the development of use cases to internal operations. Examine how partner use cases, especially for maintenance and quality, can be leveraged. Partners may be developing their own business models for equipment and product as a service, which can supplement your existing resources.

Sample Vendors

Apprentice; Augmentir; iQ3Connect; Microsoft; PTC; ScopeAR; TeamViewer; Voovio

Gartner Recommended Reading

Supply Chain Brief: Successful Return-to-Work Strategies for Factories

The 2020 Top Strategic Technology Trends for Manufacturing Operations

Top 10 Strategic Technology Trends for 2020: Multiexperience

2021 Top Trends in Manufacturing Industries

The 2021 Supply Chain Technology Themes

3D Design and Device Convenience Hinder AR and VR Adoption

Sliding into the Trough

3D Printed Drugs

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: Less than 1% of target audience

Maturity: Emerging

Definition:

3D printed (3DP) drugs are pharmaceuticals 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 shape upstream and in line with the manufacturing process. The technology enables the creation of individualized doses and specialty release characteristics, as well as printing 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 was the first company with a product on the market. They currently have partnerships with Prasco (a generics company) and Syneos Health (a professional services, contract research organization), and have several other 3DP supplements in the pipeline.
- In 2020, FabRx released M3DIMAKER for 3DP personalized pharmaceuticals after demonstrating that 3DP could be used to create oral tailored-dose therapies in a hospital setting.
- 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 gastroretentive floating tablets.

Obstacles

- While this technology has been covered quite a bit within the life science industry and some mainstream sources, so far, only one medication — Aprecia's ZipDose Technology for Spritam (levetiracetam) — is approved and on the market.
- As more 3DP drugs head toward the pharmaceutical supply chain, we expect companies to experience some difficulty with internal quality and logistics processes, scaling and volume builds.
- Because of the complexity of the 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. Having only one vendor in the mix with a regulated claim on the product in a commercialized process creates concern about becoming reliant on a single source or contract manufacturer. For these reasons, Gartner places this technology in 2021 at the entry to the Trough of Disillusionment.

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 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, customized API doses with specific drug release and diffusion chemistries.
- Solicit stakeholder input as it relates to fitness for purpose, costs, supply chain and 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

Aprecia; FabRx; Multiply Labs

Gartner Recommended Reading

Predicts 2019: 3D Printing Accelerates, While 4D Printing Is Getting Started

Innovate Faster With Digital Twins and 3D Printing

Healthcare and Life Science Business Driver: Medical Technology Innovation

Smart Factory

Analysis By: Simon Jacobson

Benefit Rating: Transformational

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

The smart factory is a concept used to describe the combination of existing and modern technologies with standard work to create a hyperflexible, self-adapting manufacturing capability.

Why This Is Important

Smart factories are the future of production. They offer an opportunity to leverage different technologies, such as cloud computing, AI and edge, to simultaneously minimize risk, increase competitiveness, and innovate production processes and human interactions. Ultimately, smart factories will play a role in enabling new ecosystem models, such as direct-to-consumer (D2C), or different capacity orientations, such as mobile factories, asset light or lights-out factories.

Business Impact

Smart factories have big changes to skills and processes, and have unparalleled technology intensity and disruption. Successful initiatives improve competitiveness and the customer experience by connecting different processes, information streams and stakeholders in a streamlined fashion. This can translate into improved agility and profitability.

Drivers

- Digital supply chain, Industrie 4.0 and smart manufacturing initiatives, including resiliency optimization, fuel the hype about smart factories.
- The importance of smart factories is elevated for manufacturing operations leaders and their counterparts in supply chain, engineering and IT. All want to leverage new technology options to create amazing opportunities to digitize existing processes and create newer, precise ways of working, better data access, intensified automation, and improved decisions.
- Smart factories deliver reliable supply by modernizing existing capacity to improve operational excellence and flexibility. Sites can take on more orders, meet market changes faster, or deliver newer and more complex products.

Obstacles

- Modern technologies or reference architectures (such as, RAMI 4.0) might transform the process at a site level, but not drive improvements in end-to-end process capabilities.
- Overcoming extensive backlogs of IT and operational technology (OT) upgrades, and other forms of technical debt.
- Emphasizing tactical wins at sites that are not synchronized with product supply strategy create excess costs and constraints elsewhere in the business.
- Overlooking governance beyond plant-business connections. Including aligning and converging IT, OT and engineering technology (ET) is a must.
- Failing 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 North Star of smart factories enabling profitable agility across the supply chain in focus.
- Design for scalability by combining technology, data management and workflow into use cases that support standard processes. This avoids a perilously narrow reliance on a single use case or tactical reference architecture, while adding clarity to value statements and ROI potential.
- Prepare for shifts in workforce development by creating hybrid teams that blend stakeholders across the IT, OT, ET, supply chain and HR functions. This will help with communication and upskilling, and create the alignment for both new ways of working and scale.

Gartner Recommended Reading

4 Tactics for CSCOs to Shift Manufacturing From a Cost of Doing Business to a Competitive Weapon

Innovation Insight for Engineering Technology: Why ET, IT and OT Are More Than the Sum of Their Parts

Tech Transfer Services

Analysis By: Andrew Stevens, Jeff Smith

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

Definition:

Tech transfer (sometimes called tech scale-up) services support life sciences companies in delivery of controlled, documented and systematic approaches to transfer of analytics and processing data, as well as product formulations 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. Each 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 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

The scope of tech transfer encompasses the systematic delivery across a multidisciplined set of objectives with the intent of continuous quality, learning and improvements across developmental and analytical stages of a product's life cycle. Successful tech transfers can deliver product realization either at an intracompany or intercompany level. The premise of tech transfer aligns closely to robust methods for continuous quality and process optimization and especially quality by design (QbD) principles set against the context of scale-up and knowledge transfer activities.

Tech transfer services can include:

- 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, 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 impact 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 platform are unlikely to be commonplace.
- 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 sciences project and program management and can demonstrate expertise for delivering across previous scale-up and transfer activities across all science phases of product development through to batch processing.
- Ensure that you 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

Midas Pharma; Pii; Piramal Pharma Solutions; Skyepharma; Thermo Fisher Scientific; UPM Pharmaceuticals

Digital Validation Tools

Analysis By: Andrew Stevens, Jeff Smith

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Emerging

Definition:

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

Why This Is Important

Services and tools supporting validation assist global pharmaceutical, biotechnology and contract processing organizations assure, and document process methods, protocols, equipment and operations infrastructure continually comply with requirements set out for their intended use. Gartner has observed renewed interest from manufacturers on how digital and virtual validation will transform existing best practices as companies seek to transition to paperless and more automated operations.

Business Impact

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

Drivers

- Validation tools and services help reinforce assurance and compliance across a very diverse set of process and workflow metrics, as well robustly monitor on a frequent basis to check and ratify compliance and adherence.
- Analytical and sampling methods including testing, equipment and software tools such as LIMS.
- Cleaning and sterilization cycles pre- and postmanufacturing.
- Computer system validation including testing and paperless documentation, automated services for software and hardware.
- Vendor risk assessment.
- Packaging processes and equipment.
- Mobile technology devices and supporting software applications used during manufacturing and logistics operations.
- Manufacturing systems for batch processing such as MES, serialization and quality management.
- Electronic and digital signatures for batch processing and release.
- Site validation for partnered outsourcing partners, e.g., CMOs.
- Operating instructions, work methods and training material for manufacturing associates.
- Regulatory validation — compliance.
- The increased adoption of cloud-based applications across the industry has enabled service providers to deliver enhanced ranges of digitized prevalidated documentation, templates and scripts. On the other hand, there are 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.

Obstacles

- Increased product sophistication (such as a transitioning to biologics origin products and personalized medicines) will require a more intensified and open approach to continuous monitoring and embedded levels of product excellence. Companies will need to closely monitor established (and especially developing) compliance requirements that target product differentiation as well as an increased reliance on digital and real-time tools and their alignment to best practices such as GAMP and GxP.
- Historic validation processes have overrelied on paper-based systems of records (especially operating procedure, work instructions and process methods relating to regulation and manufacturing). With important regulations such as the FDA's 21 CFR Part 11 for electronic records and systems, life sciences organization will need to ensure qualification and validation are a critical part of all discovery, development, migration and execution phases of digitalization objectives.

User Recommendations

- Establish targeted teams assigned to specific validation assignments ensuring a multidisciplinary level of representation from experts and stakeholders impacted.
- 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.
- Utilize providers who 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; Microfocus; Performance Lab; SL Controls; SSTS; Tricentis; Tx3 Services; ValGenesis

SaaS LIMS

Analysis By: Michael Shanler, Rohan Sinha

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 log-in to certificate of analysis issuance. Laboratory test data is used to support key processes, including R&D, manufacturing and clinical research. SaaS LIMS is purchased via a monthly subscription model.

Why This Is Important

Many life sciences organizations have only recently become more comfortable with having their critical laboratory data in the cloud. Newer organizations are gravitating toward pure-cloud or cloud-enhanced solutions whenever possible, which is closer to true SaaS offerings. Gartner expects the percentage of on-premises systems to continue to fall, as the cloud-based LIMS solutions improve, while cost pressures continue to drive operational effectiveness in the laboratory.

Business Impact

Many IT groups are driving “cloud first” IT strategies to better globalize lab capabilities. True SaaS-based LIMSs significantly reduce capital 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 drive collaboration, SaaS LIMSs will continue to see wider adoption and drive “digital lab of the future” strategies.
- Customers that do not have a legacy system, as well as smaller and midsize businesses and institutions, have a hunger for SaaS models as a means to lower cost and maintain a smaller IT profile.
- The trade-off of pursuing SaaS LIMS is some reduced flexibility within the laboratory as LIMS vendors, integrators and delivery firms further refine their services.

Obstacles

- Larger organizations have been slow to adopt SaaS LIMSs due to high system complexity and historical customization required for their business processes.
- Most SaaS LIMS are more amenable to nonregulated industries or lab processes that are at the lower end of the spectrum for complexity.
- While many vendors market cloud-hosted LIMS as SaaS LIMS, they typically are not fully transparent in the marketing of their cloud architecture or their subscription pricing, impeding adoption.
- SaaS technologies are becoming more popular as products get refined; however, systems that have extreme quality and integration requirements are limiting adoption.
- While cloud and SaaS are becoming more central to CIOs’ strategies for lab processes, many organizations encounter difficulties satisfying good x practice (GxP) validation, regulatory, intellectual property performance, and risk-related requirements. We place the technology near the middle of the Trough of Disillusionment on the Hype Cycle.

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 a lot of confusion within the marketplace, as most LIMS vendors sell single-tenant, managed hosted environments via partnerships, and not multitenant, shared environments.

Sample Vendors

Abbott Informatics; AgileBio; AgiLab; Blaze Systems; CloudLIMS; EuSoft; LabVantage Solutions; LabWare; LIMSABC; Thermo Fisher Scientific

Gartner Recommended Reading

Market Guide for Laboratory Informatics

Life Science CIOs’ Plans for the Lab of the Future Must Enable Digital Business

Life Science’s Lab Informatics Digital Criteria to Separate Vendor Leaders From Laggards

Enterprise Laboratory Informatics

Analysis By: Michael Shanler, Rohan Sinha

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 ELN and LIMS footprints, including inventory management, data management, billing, environmental monitoring, stability testing, process controls and analytics. Important benefits accrue with ELI such as a shared database (ELN + LIMS), shared audit trail, configuration tools and regulatory controls as well as commercial efficiencies such as simplified licensing, common support channels and shared upgrade costs.

Business Impact

Many manufacturers do not have the appetite to manage multiple laboratory informatics solutions and are moving toward systems that can be used more broadly while reducing IT complexity. As the technology is refined, leaders should take the opportunity to eliminate low-usage laboratory systems, especially if 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. This leads 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 can support a broad range of functions that extend beyond traditional ELN and LIMS footprints, including inventory management, data management, billing, environmental monitoring, stability testing, process controls and analytics.
- Therefore, we advance ELI systems to the Trough of Disillusionment 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” process 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 of Disillusionment, but should accelerate through this phase over the next two years.

User Recommendations

- Evaluate the workflows and costs for the touchpoints among different functions (e.g., 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 VBnet, which may be too risky to support LoTF strategies. Ensure vendor solution architecture is in alignment with these future focused strategies.

Sample Vendors

Abbott Informatics (STARLIMS); AgiLab; Dassault Systèmes; LabVantage; LabWare; Riffyn; Siemens; Thermo Fisher Scientific

Gartner Recommended Reading

Market Guide for Laboratory Informatics

Life Science CIOs' Plans for the Lab of the Future Must Enable Digital Business

Life Science's Lab Informatics Digital Criteria to Separate Vendor Leaders From Laggards

Digital Twin

Analysis By: Alfonso Velosa, Marc Halpern, Benoit Lheureux

Benefit Rating: Transformational

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

A digital twin is a virtual representation of an entity such as an asset, person, organization or process. The three types of digital twins are discrete, composite and organizational. Digital twin elements include the model, data, unique one-to-one association and monitorability. Digital twins are created in enabling platforms, such as analytics or simulation solutions, IoT platforms, or CRM applications.

Why This Is Important

Enterprises are using digital twins to create virtual representations of previously opaque entities or activities for process, cost or other business improvements. For instance, improved patient outcomes due to visibility of the entire patient across the siloed systems, or reductions in unplanned outages by monitoring the equipment state are now possible. Technology providers see digital twins and associated information products and services driving new customer outcomes and revenue streams.

Business Impact

- Digital twins enable business to enrich decisions — for example, to lower maintenance costs, increase asset uptime and improve performance.
- For OEMs, digital twins contribute to differentiation, new service models and obtaining customer data.
- Digital twins of people contribute to improved health monitoring, employee safety and customer transactions.
- Digital twins will help drive new business models, such as product as a service, as well as new data monetization approaches.

Drivers

- Enterprises are accelerating their adoption of digital twins to support a broad variety of business outcomes: reducing cost structure through improved remote monitoring of assets; optimization of equipment and processes by aligning asset digital twins into a range of solutions, such as predictive analytics and field service management; product differentiation via stakeholder visualization and control of assets, as well as new customer monetization strategies via digital-twin-enabled services.
- Asset-intensive industries, such as oil and gas, have leveraged lessons from their extensive digital history toward using digital twins to improve business operations.
- Military equipment and service companies on a global basis have seen a consolidated push toward using digital twins and model-based system engineering from the national ministries or departments of defense.
- Leading-edge enterprises are implementing digital twins to model IT organizations, financial exchanges, and processes such as purchase order approvals and fulfillment — for cost optimization and process improvement purposes.
- Consortia such as the Digital Twin Consortium and the National Digital Twin Programme at the Centre for Digital Built Britain contribute to digital twin visibility and business cases.
- Technology providers have woken up to the potential ways they can serve their customers and drive new revenue models using their digital-twin-enabling product portfolios.
- Improvements in models of all types employ analytics, visualization and simulation capabilities to understand, predict and automate business actions.

Obstacles

- Enterprises lack clear business objectives for digital twins. They lack consensus on the scope, structure, process or teams to start developing business-focused digital twins.
- Few enterprises have the fusion teams of skilled business, finance, and technology people and the collaboration between these people.
- These fusion teams must conceive, create and maintain the core models that are synchronized to the real entities, yet few enterprises have the budgets to do so.
- Digital twins challenge most enterprises technically due to the blend of operational and information technologies needed to develop and maintain them.
- While consortium and standards bodies are emerging, they are all generally immature, with many vendors pushing proprietary formats. We lack standards for a broad range of digital twin integration, evolution and other technical issues.
- Few vendors have a viable go-to-market strategy to build a digital twin business, creating market confusion and excess hype.

User Recommendations

- Work with business leaders to establish realistic expectations for how digital twins can support business outcomes and establish KPIs to measure success.
- Engage the business unit to identify champions, get budget support and co-create the digital twin strategy.
- Avoid digital twin projects that lack a business sponsor and objective, as they will waste resources and undermine adoption.
- Identify IT gaps and build a roadmap to drive IT organization learning opportunities, its investment plan for internal skills, and partner selection strategy.
- Build an IT digital twins technology roadmap to mitigate the hype around proprietary vendor approaches. Incorporate best practices for software asset development and management, security and privacy, and integration.
- Assess the use cases and architectural and technical implications of composite and organizational digital twins.
- Develop a long-term governance strategy.

Sample Vendors

Amazon; AVEVA; Cognite; Cosmo Tech; GE Digital; Microsoft; Thynkli; Voovio; XMPro

Gartner Recommended Reading

Use 4 Building Blocks for Successful Digital Twin Design

What Should I Do to Ensure Digital Twin Success?

What Data and Analytics Leaders Need to Know and Do About Digital Twins

Essential Product Management Practices to Monetize Data and Analytics Assets

Quality by Design

Analysis By: Andrew Stevens, Sam New

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

Definition:

Pharmaceutical 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 including systematic product and process excellence 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 delivery of more digitally connected supply chains by mapping entire product life cycles, proactively mitigating quality and regulatory issues. QbD spans product development and production to include the configuration or integration of specific patient needs, based upon robust science and quality requirements during the development of a pharmaceutical 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 and pharmaceutical sectors. QbD capabilities and services targeting this sector appeal to both large and small startup manufacturing organizations, as well as generics and virtual manufacturing life sciences companies with overarching objectives for ensuring consistent improvements for production of quality 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. For example, The European Medicines Agency (EMA) publishes guidelines and Q&A for quality; QbD capabilities can be an instrumental tool for helping companies reconfigure supply chain networks. They are configured around patient centricity and enhanced user experiences while proactively mitigating potential bottlenecks around optimization, compliance quality and validation.

- QbD capabilities include proactive mapping, and out coordination of robust and streamlined technology transfer protocols, ensuring consistency in quality and manufacturing to equivalents in generic products or geographic site processing transfer of original product. Also included are risk assessments on raw materials, ingredients, testing and analytical methods to prioritize process or knowledge gaps for further investigation. Additionally, final product continual vigilance, 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.
- Other possible barriers might include phased migration from paper-based systems of record, and the integration across layers of legacy-/custom-made processing or quality systems especially in manufacturing and packaging phases.
- QbD can play a role in supporting transitioning to new digital, collaborative and planning best practices for patient centricity and establishing product “center of excellence” hubs. Special focus will need to be paid to traditional autonomous business entities (such as manufacturing, regulatory and R&D) in change management activities, training and onboarding alongside embedding core QbD principles and tools.

User Recommendations

- Invest in solutions and services that fulfill requirements of capturing, sharing and communications of a wide range of criteria and parameters. This includes measures, risks and data points needed to be assessed as part of continuous QbD including safety, efficacy, sourcing, formulations, product stability, productivity and yield.
- Engage in enterprise wide communications of the value that QbD can deliver will increase in importance in line with greater digital connectivity and maturity. Emphasis should be placed on embedding QbD as a tool for continuous product innovation cycles and in adopting “cradle to grave” focus toward embedding product excellence across every phase of a product’s development and manufacturing life cycle.
- Ensure that QbD organizational roles and responsibilities are established at either a dedicated level or through close collaboration with representations from critical functions such as quality, IT, research, regulatory, manufacturing and distribution.

Sample Vendors

Agilent; 4Tune Engineering; MasterControl; QbDVision; QualityKick; S-Matrix; Skyepharma; Sartorius

Gartner Recommended Reading

Market Guide for Quality Management System Software8 Trends Reshaping Quality Management

SaaS ELN

Analysis By: Michael Shanler, Rohan Sinha

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

SaaS-based 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 recently invested in more sophisticated, SaaS-based ELNs to support globalization and externalization strategies. These solutions enable more collaborative approaches, making data visible, and available at a more optimized cost with simplified management. As companies become more comfortable with storing intellectual property using SaaS providers, accelerated use is expected.

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

- SaaS-based ELNs are gaining popularity due to the ease of deployment and low startup costs when compared with on-premises or hosted ELNs.
- We expect SaaS adoption to increase more rapidly as ELN technologies improve and vendors begin to either acquire (for example, Thermo Fisher Scientific acquired Core Informatics in 2017), or evolve and offer reengineered or new solutions (for example, IDBS).
- Today, Gartner estimates nearly 40% of ELNs are SaaS-based.

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 (deployed on-premises) were heavily customized, making transitions 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.
- While 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 through the Hype Cycle toward the Trough of Disillusionment.

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. While 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.
- Identify cloud-based ELNs to facilitate scientific collaboration and reduce cost, particularly the smaller companies that do not have legacy systems or deep instrument integration requirements.
- Identify 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 update 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); Dassault Systèmes; Dotmatics; IDBS; LABTRACK; PerkinElmer; RSpace; Scilligence; Thermo Fisher Scientific

Gartner Recommended Reading

Market Guide for Laboratory Informatics

Life Science's Lab Informatics Digital Criteria to Separate Vendor Leaders From Laggards

Life Science CIOs' Plans for the Lab of the Future Must Enable Digital Business

IoT Platform

Analysis By: Alfonso Velosa, Eric Goodness

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

An Internet of things (IoT) platform enables the connection and capture of data from IoT-enabled assets or endpoints to develop, deploy, and manage business solutions that improve operations such as monitoring remote assets or optimizing maintenance. Capabilities include device management, integration data management, analytics, application enablement and management, and security. It may be delivered as edge or on-premises software, or cloud IoT platform as a service, or a hybrid combination.

Why This Is Important

Enterprises continue adding IoT capabilities to assets and products, seeking benefits such as cost optimization, process optimization, improved customer experience, and new opportunities such as product as a service. The sophistication, scale and business value of these interactions call for specialized technology resources, most often implemented as an IoT platform. While all verticals are deploying IoT, spend is highest in asset intensive industries such as manufacturing or oil and gas.

Business Impact

IoT platforms are usually required to implement IoT-enabled assets in order to make better business decisions from the data and information generated by connected products. Goals include:

- Differentiated smart products
- Cost optimization strategies centered on improved maintenance
- Process improvement by using assets at their best state
- Opportunities to sell new services and data products

Drivers

- Proliferation of IoT projects since IoT is widely proven across many industries to improve business outcomes — see Survey Analysis: Focus on Practical Outcomes for IoT Projects.
- IoT platforms are fit-for-purpose PaaS and on-premises software offerings that specifically help software teams to accelerate and improve the quality of IoT products while consolidating and structuring the data.
- Enterprises leverage their IoT assets to drive differentiation, lower costs, improve processes and enhance worker safety.
- Technology providers are driving marketing and sales efforts to engage their customers with IoT platforms. In parallel they invested in improved ecosystems and channel partners to make it easier for companies developing IoT enabled solutions to achieve business value.
- In parallel, technology providers continue to invest in their IoT platform technology to ensure they can deliver business solutions at scale for their customers.

Obstacles

- IoT platforms require extensive customization to achieve business outcomes for large-scale deployments, driving up cost and schedule.
- Many enterprises approach IoT projects as technology projects, instead of as business projects that use IoT platforms to achieve business outcomes.
- Many enterprises operate in siloed fashions, adopting different IoT platforms for each use case, limiting their ability to scale, and adding complexity.
- Projects that use IoT platforms drive greater volumes of data, complicating existing processes and overwhelming employees and other stakeholders. They often lack training or process changes to absorb this new data — leading existing systems and people to reject the output of the IoT platform.
- IoT technical complexity, security and integration challenges remain barriers to scale at enterprises.
- Technology providers have yet to develop a clear value proposition and sales strategy that helps their customers leverage their platforms on scaled up levels.

User Recommendations

- Start with smaller IoT projects that help the business unit and IT organization acquire implementation lessons, identify IoT platform strengths and weaknesses, and verify alignment to business and finance KPI requirements.
- Identify the range of IoT projects for your enterprise, and segment them by their focus (internal vs. external), complexity and business objectives. Use these insights to establish a distributed deployment and a platform of platforms architecture.
- Use a skills gap for IoT projects and IoT platforms to build a plan to improve the IT organization's capabilities such as integration or digital twin model development.
- Prioritize vendors you already work with for their IoT platform. Evaluate candidate vendors on their fit-to-your-business objectives and technology. Key evaluation criteria include: proofs of value projects (for tech and business), the ability to drive operational-scale deployments, vertical market expertise and a partner ecosystem.

Sample Vendors

Alibaba Cloud; Amazon Web Services; AVEVA; ClearBlade; COVACSIS Technologies; Detechtion Technologies; Knowledge Lens; Microsoft; Siemens

Gartner Recommended Reading

Magic Quadrant for Industrial IoT Platforms

Critical Capabilities for Industrial IoT Platforms

Use the IoT Platform Solution Reference Model to Help Design Your End-to-End IoT Business Solutions

Use 4 Building Blocks for Successful Digital Twin Design

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. FDA's 21 CFR Part 11 and 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, manufacturing and supply chains to more easily leverage the benefits of 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 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.
- Large enterprises benefit from flexibility and economies of scale, and enable small and midsize businesses lacking expertise and resources to maintain these environments.

Drivers

- Life science organizations are continually focusing on reducing costs, resource use and complexity, so the need for GxP support on cloud platforms will increase. 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 for 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 that have expertise in previous deployments (such as for managing HIPAA compliance or 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.

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, 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 been traditionally resistant to change from on-premises approaches. As a result, we see this profile in the Trough of Disillusionment, poised to begin progress up the slope.

User Recommendations

- Factor in the total cost of ownership for the system delivered via GxP cloud services versus internal approaches. Take into consideration the fully loaded costs required for ongoing upgrades, 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 Group; OdysseyVC; Validated Cloud

Gartner Recommended Reading

Accelerate Digital Capabilities by Migrating Validated Life Sciences Applications to the Cloud

Four Types of Cloud Computing Define a Spectrum of Cloud Value

Strategic Life Science Regulatory Information Management: From Fragmented to Holistic

Life Science Top Actions for 2021: Prioritize Composability in Digital Trial Operations

2021 Business Drivers for Life Science CIOs

Predictive Analytics

Analysis By: Noha Tohamy

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Predictive analytics is a form of advanced analytics that examines data or content to answer the question, “What is likely to happen?” It includes techniques such as regression analysis, multivariate statistics, pattern matching, predictive modeling and forecasting.

Why This Is Important

By anticipating future trends, predictive analytics allows organizations to make informed decisions when responding to evolving business environments. Predictive analytics is required to support the vision for automated decision making. Predictive analytics leverages internal and external data, historic sales or weather patterns. Today, there are many successful examples of the use of predictive analytics, spanning demand forecasting, risk monitoring or predictive maintenance.

Business Impact

Predictive analytics improves organizations’ ability to anticipate further conditions. These can range from better predicting demand, supply variability or disruptive events. Predictive analytics can result in supply chain process redesign. Processes that fully relied on human judgment can now be heavily powered with predictive analytics. The adoption of predictive analytics requires additional investment in technology or technical data science talent.

Drivers

- Supply chain organizations that have heavily relied on human domain experience are now looking to rely on data and analytics to understand trends and anticipate future environments.
- Supply chain talent shortage is driving the need for automating processes such as demand forecasting or supplier risk predictions. The goal of automation is to free up human users to focus on qualitative priorities, such as collaboration with trading partners or team communication.
- Predictive analytics has traditionally targeted problems in the strategic and tactical time horizon like long-range forecasting or demand planning. Now, with more advanced techniques, predictive analytics can be deployed in real time or the near-real-time horizon in areas such as dynamic pricing, product quality testing and demand sensing.
- Recently, interest and adoption of predictive analytics has enjoyed a significant increase thanks to corresponding interest in machine learning techniques that are capable of generating more accurate predictions with little human intervention.

Obstacles

- Data availability and quality. As with other advanced analytics techniques, the timeliness and accuracy of the data will determine the accuracy and usefulness of the output of prescriptive analytics.
- Lack of analytics maturity that can drive further adoption of predictive analytics. Many organizations are still focused on answering “what has happened?” without a forward-looking focus on “what might happen?” and “what can we do about it?”
- Lack of technical talent to build and maintain prescriptive analytics models.
- Lack of transparency of more complex predictive models resulting in users’ resistance.
- Lack of predictive analytics capabilities in current supply chain applications.

User Recommendations

To take advantage of predictive analytics, supply chain leaders responsible for analytics strategy must:

- Identify the supply chain processes that can benefit from predictive analytics and clarify how predictive analytics’ output will be embedded in the process and incorporated in users’ decision making.
- Plan to allocate significant time and resources to preparing the data to conduct predictive analytics.
- Build a foundation of descriptive and diagnostic analytics. Without understanding what is going on and what might be the problem, it is unrealistic to accurately predict future outcomes.
- Educate your organizations on new predictive analytics technologies that can handle more dynamic data sources and satisfy requirements for faster response times.
- Secure the internal or external skill sets to create and deploy predictive analytics solutions.

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 support managing end-to-end manufacturing processes with a view to optimizing production. These application suites extend traditional manufacturing execution systems (MES) beyond production-execution management to include detailed production scheduling, production resource management (materials, assets, labor), process and product reliability (quality), and manufacturing data analytics.

Why This Is Important

The impetus for MOM application suites is based on the premise that built-for-purpose capabilities across the manufacturing plant spectrum provide product plants more flexibility and agility. They accomplish this by minimizing the need for communication with upstream systems (ERP/PLM/SCM) to make better decisions and respond in near real time on the plant floor.

Business Impact

- MOM application suites are enabling process optimization across manufacturing process 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 foster manufacturing operations process optimization rather than requiring them to master multiple disparate applications from different vendors.

Drivers

- Users have recognized that they need capabilities beyond core MES to continuously improve upon efficiency, quality and cost. Seamless integration with capabilities such as material handling/warehouse management system (WMS), detailed plant-level scheduling, quality management and intra-plant 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 to data from multiple manufacturing disciplines. This can be enhanced by MOM application suites that support a more diverse set of manufacturing functions.
- The impetus for MOM application suites is based on the premise that extended MES capabilities (built-for-purpose) across the manufacturing plant spectrum provide product plants more flexibility and agility.

Obstacles

- By their very nature, 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 level of functionality as the built-for-purpose applications in production scheduling, resource management, quality or data analytics, their value comes in providing an integrated, manufacturing plant specific suite of tools.
- Additionally, the preferred vendor approach to building MOM application suites involves adopting yet another platform that can add complication and cost integration points between the MOM platform and enterprise applications.
- Supply chain and manufacturing operations convergence are hampered by site/plant specific duplicative functions such as scheduling, inventory management and quality management.
- Emergence of composable solutions, may threaten the viability of MOM suites.

User Recommendations

- Ensure implementation success by aligning the MOM application suites to your proven manufacturing operation processes and systems.
- Build out MOM capability by examining the need in each solution area, and defining 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.
- 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; iBASEt; iTAC Software; Rockwell Automation; SAP; Siemens Digital Industries Software

Gartner Recommended Reading

Critical Capabilities for Manufacturing Execution Systems

Magic Quadrant for Manufacturing Execution Systems

Supply Chain Brief: Modernize Production Systems to Unlock Manufacturing Operations and Support Agility Imperatives

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

SaaS-Regulated CSP

Analysis By: Jeff Smith, Michael Shanler

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

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

CIOs have increasingly adopted newer SaaS and cloud vendors over on-premises systems, to benefit from the increased robustness, security and cost advantages. This transition has been uneven across life science domains, with commercial areas leading the way, followed by clinical, regulatory, manufacturing and labs. However, SaaS-regulated CSPs are maturing quickly and include some of the most mature cloud offerings, providing a robust and flexible browser-based environment for content storage.

Business Impact

Adopting SaaS-regulated CSPs can help simplify deployments and reduce support resources, especially when content services platform as a service (csPaaS) capabilities are used. 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

- The COVID-19 pandemic has accelerated life science companies' push to SaaS-regulated CSPs, thus moving this profile further along toward the Slope of Enlightenment.
- 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 to explore 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 permeating regulatory and quality areas, taking advantage of more powerful csPaaS capabilities and robust global implementations supported by multitenant cloud deployments.
- As many of the initial obstacles to acceptance of SaaS-regulated CSPs have evaporated, and real gains begin to be realized, we place this profile moving up the Slope of Enlightenment toward the plateau.

Obstacles

- Some larger life science companies are challenged in adopting SaaS-based solutions in niche areas due to over complex processes resulting 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 then the 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 QA 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 cost projections reflect application growth under new licensing models.
- Review solutions that address all overlapping components of development, including clinical trials, quality, regulatory and contract management, when considering pure CSP deployments.

Sample Vendors

ArisGlobal; Box; DXC Technology; Ennov; Generis; M-Files; OpenText; Veeva

Gartner Recommended Reading

Life Science Top Actions for 2021: Prioritize Composability in Digital Trial Operations

Accelerate Digital Capabilities by Migrating Validated Life Sciences Applications to the Cloud

Electronic Trial Master File Strategy Alignment

Market Guide for Life Science E-Clinical Platforms

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

Climbing the Slope

Asset Performance Management

Analysis By: Nicole Foust, Kristian Steenstrup

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

APM are business applications for optimizing reliability and availability of operational assets (such as plant, equipment and infrastructure) essential to the operation of an enterprise. It uses data capture, integration, visualization and analytics to improve asset maintenance activities. APM includes capabilities and functionality to support asset strategy, risk management, predictive maintenance, reliability-centered maintenance, and financially optimized maintenance activities.

Why This Is Important

APM has become an important core competency for asset-intensive and asset-centric organizations. Organizations invest in APM tools and technologies to reduce unplanned repair work, improve asset availability and safety, minimize maintenance costs, and reduce the risk of failure for critical assets. Realizing the business can move beyond the key use case of equipment reliability, organizations are leveraging APM to improve overall business operations.

Business Impact

- APM is an important investment area for asset-intensive industries, including manufacturing, mining, oil and gas, transportation, telco, and utilities.
- Successful APM deployments can deliver measurable improvements in availability, as well as reduce maintenance and inventory carrying costs.
- Benefits such as improved uptime and cost savings can be substantial, typically delivering benefits measured in millions of dollars per year.

Drivers

- Organizations need better solutions to deliver enhanced asset insights.

- Those that depend significantly on availability of their assets, such as manufacturing, utilities and natural resources industries, tend to be further along in their asset management capabilities and strategy, and invest more heavily in APM.
- Innovation in enabling technologies such as cloud, IoT and AI/ML are widening the scope and decreasing the deployment cost, aiding more awareness and use of APM.
- As operations take advantage of newer sensors (e.g., acoustic), drones and bots, APM has access to increased data volumes of better quality and granularity (or reduced latency) and accuracy yield richer use cases and more robust capabilities.
- Business processes supported by APM software are becoming an important core business capability for asset-intensive organizations. CIOs are increasingly realizing benefits which aid the market transition beyond the use of APM focused on equipment reliability to increasingly leveraging APM to also help improve overall business operations.
- Most APM projects are executed on the premise that data-driven decisions will improve equipment reliability and, therefore, reduce operational risk.
- The potential of reduced maintenance cost and downtime, coupled with higher levels of operational reliability is attracting other industries, however, all are progressing at a varied pace.

Obstacles

- Limited availability of good-quality and consistent asset data to support a more advanced maintenance capability.
- Limited adoption of asset management standardization such as ISO 55000.
- Digital business immaturity constrains organizational ability to support advanced asset maintenance capabilities.
- Market confusion from conflicting vendor claims overlaps with complementary products. These comprise Industrial Internet of Things (IIoT) platforms, EAM systems that also provide CbM and beyond, APM included as a part of digital twins, and OEMs including predictive analysis support.
- Whether the vendor and product have proven capabilities for your desired asset maintenance activities and classes of assets within your industry, and if they align with your asset management strategy.

- Importance of EAM in APM success: (1) there must be an interface to your EAM to be able to execute APM recommendations directly in the transactional EAM system; (2) your EAM systems must have good quality data; (3) some EAM vendors also have APM capabilities which may require significant customizations or may limit use with only their offered EAM product.

User Recommendations

- Assess the maturity of your EAM system and have a sustainable integration plan with your APM before investing in APM. Although newer EAM products include APM capabilities, CIOs should not expect to get all APM capabilities from the EAM vendors themselves.
- Identify a combination of asset maintenance capabilities to support a variety of asset types and situations across the business through a toolbox approach. Most vendors do not offer all levels of APM maintenance capabilities, across all industries and asset types. Thus organizations may need more than one APM product, depending on the complexity of their businesses, the types of assets and their asset maintenance goals.
- Ensure IoT and operational technology (OT) systems compatibility with the technical and process needs of reliability systems by getting involved in the planning of IoT monitoring of plants and equipment.
- Source good data — that is, historical service and operational data — organizations looking to invest in APM should also expect to make investments in information management infrastructure to capture operational data where it doesn't exist today.

Sample Vendors

AspenTech; AVEVA; Bentley Systems; GE Digital; Hitachi ABB Power Grids; IBM; SAP; SAS; Uptake

Gartner Recommended Reading

Market Guide for Enterprise Asset Management Software

Top Practices for Utility CIOs Evaluating Enterprise Asset Management Software

Market Guide for Asset Performance Management Software

Optimize Utility Capital Expenditures With Asset Investment Planning Solutions

CSOS

Analysis By: Andrew Stevens

Benefit Rating: Moderate

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

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

Why This Is Important

CSOS supports the U.S. federal government's Controlled Substances Act (CSA) across classes of scheduled drugs in conjunction with the DEA's proposed final rule (21 CFR Parts 1305 and 1311).

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 to consider are elimination of process waste that comes with the paper-based systems like delay, errors and costs, enhancing B2B relationships, faster delivery times and customer validation.

Drivers

- With a global approach to controlling and/or regulating controlled substances still a long way away, the potential remains on the value CSOS solutions could deliver. Longer-term benefits may 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 leverage CSOSs in the future.
- CSOSs use digital certificates transmitted via electronic files that use a digital signature to bind together a public key with an identity.
- In October 2019, the DEA introduced a new single-sheet format for 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 1 and 2 substances with a supporting DEA 222 form following the electronic order. The final rule allows for electronic orders for Schedule 1 and 2 controlled substances using digital signatures. The DEA regularly reviews schedules based on global reported incidents on controlled drugs. Valid digital signatures through encryption allow secure electronic verification of controlled substances.
- Available solutions are either hardware and client-based or software as a service, with a focus on the facilitation of DEA and PKI requirements.

Obstacles

- While U.S. compliance is critical the broader benefit and potential for CSOS solution maturity is limited subject to further updates to the mandates and broader adoption of similar process requirements globally.
- The positioning on the Hype Cycle on the Slope of Enlightenment reflects maturity for addressing the specific needs of the U.S. mandates, and their overall ability to create broader opportunities for integration, governance and digitalization across high risk/profile product categories.
- The position on this year's Hype Cycle and subsequent market penetration reflects that CSOS solutions currently map to just one country regulation.

User Recommendations

- Assess the cost of deployment versus immediate supply chain benefits (for example, 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.
- Scope the wider compliance and IT-business-enablement capabilities across the longer terms than a CSOS can deliver.
- Identify applicability and scalability for 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 (for example, cannabis).
- Identify regulatory proposals and existing mandates for electronic registry and security for controlled substances across other regions and countries and their viability for integration to the emerging solutions marketplace.

Sample Vendors

Axway; Blue Link; CuraScript SD; Legisym; Liaison Technologies (nuBridges); McKesson; nCipher Security; Omnicell

QMS Applications

Analysis By: Sam New

Benefit Rating: High

Market Penetration: More than 50% of target audience

Maturity: Early mainstream

Definition:

Quality management system (QMS) application software represents the business information management system that houses quality policies and standard operating procedures (SOPs). This may include, but is not limited to, customer requirements, quality documents, 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, house quality documents, protect version control, 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

- New SaaS platforms include many low-code features to support ease of configuration and to limit required technical expertise.
- SaaS QMS more easily integrates with product life cycle management (PLM), manufacturing execution systems (MES) and ERP platforms.
- Integrated platforms provide seamless connections between document authoring and deployment, issues management, and other features.

Drivers

- Key drivers for this replacement and upgrade activity, coupled with the movement toward cloud-hosted solutions, include a desire to harmonize and add common structure to the various methods and procedures that have traditionally been enforced on a functional or localized basis. In some industries, this has driven a replacement market.
- 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.
- The QMS market is active with new product launches, enhanced functionality, and with many vendors building new SaaS solutions that include enticing, business-facing features and low-code accelerators for quality processes.

Obstacles

- General absence of a disciplined approach to “enterprise” quality architecture that balances standard processes and regulatory requirements has delayed QMS adoption.
- 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 for 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, but mainstream offerings and widespread user adoption remain limited.
- QMS providers also have begun to incorporate emerging technologies into their offerings. These include ML, IoT, AI and predictive analytics. Although such nascent technologies are increasingly a component of product roadmaps, movement to widespread adoption has been slow.

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 early in the vendor identification phase. Consider compatibility and availability of APIs for ERP, product life cycle management (PLM) and MES, as well as laboratory information management system (LIMS) and learning management system (LMS) platforms.
- Evaluate the industry depth, geographic reach 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

ETQ; Intelex; MasterControl; Oracle; QAD; SAP; Siemens; Honeywell (Sparta Systems); Veeva Systems

Gartner Recommended Reading

Market Guide for Quality Management System Software

Ensure Success in Quality Management System Software Selection

Toolkit: RFP for Quality Management System Software

Tool: Quality Management System Software Vendor Evaluation Model

Pharma PLM

Analysis By: Michelle Duerst, Michael Shanler

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Pharma product life cycle management (PLM) is the discipline of guiding products from an original concept through to retirement for pharmaceutical manufacturers. Pharma PLM emphasizes compliance with rigorous regulations and quality control requirements.

Why This Is Important

While engineers using PLM in other industries have already reached the Plateau of Productivity, PLM in pharma has been finding its place. The slower adoption in this industry is due to life science manufacturers having greater difficulty speeding the time to market, as they must strictly adhere to more stringent Good X Practice (GxP) regulations across phases with longer duration.

Business Impact

- PLM can mitigate the risk of noncompliance, as well as save time and money through efficient workflows.
- Pharma PLM provides advanced governance for the most critical issues: compliance, quality, time to market and potential loss of exclusivity.
- A digital PLM platform provides the traceability required by government agencies, as well as the capability to generate audit logs through product specifications.

Drivers

- Pharmaceutical companies are among the most heavily regulated industries with the most significant long-term investments in their product pipelines.
- CIOs should be aware that many PLM vendors have capabilities that meet specific aspects of quality and document control, with the majority being able to provide greater capabilities in the final market phase. For example, event-driven notification, coupled with batch reporting, can provide alerts to generate documents to extend exclusivity rights. These universal capabilities should definitely be considered, even though they may not be specifically marketed to the pharmaceutical industry.
- Over the past few years, PLM has moved beyond scope for 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 in the Slope of Enlightenment.
- Instead of focusing on expedition, life science manufacturers now focus on “cradle to grave” in terms of business processes, governance and traceability.
- Several large pharma organizations have spent nearly a decade performing POCs, and attempting to use PLM to improve R&D and portfolio efficiency. After several years of trials, the role of PLM has become more defined. Several of those large projects are finally moving into production.
- Food and beverage and pharma manufacturers can use compliance tools within PLM, but the regulatory implications and development timelines are significantly greater in pharma than they are in food and beverage manufacturing.

Obstacles

- Pharma R&D groups typically use science-centric, not engineering-centric systems. PLM in pharma has often been blocked out of portfolios at the expense of heavily customized ERP environments and a patchwork of scientific software.
- Pharma manufacturers are progressing more slowly in implementing PLM than other process manufacturing industries. In comparison, food and beverage manufacturers have adopted PLM to govern product data across the entire life cycle for multiple product lines. They use PLM to expedite R&D to reduce time frames and costs, while increasing success rates.
- The pharmaceutical industry has kept PLM to a relatively narrow footprint, and its adoption is still relatively new.

User Recommendations

CIOs should prioritize the following capabilities:

- Quality assurance.
- Clinical trials. Document trials and results, while ensuring patient privacy as part of an experimental group.
- Documentation. Generate template-driven documentation with a single source of truth database.
- Portfolio management.
- Bill of materials (BOM).
- Labeling. Manage content blocks and track-and-trace capabilities.
- Intellectual property rights. Create granular secure access and documentation, and create event-driven notification for expiring exclusivity rights.
- Forecasting. Generate semiautomated profit/loss (P/L) statements, which provide more accurate forecasting that can be integrated with sales and operations planning (S&OP) processes.
- Scenario modeling and leveraging formulations. Mine past data for alternate therapeutic uses, simulate results and optimize formulations with new delivery mechanisms.

Sample Vendors

Dassault Systèmes; Infor; Neo PLM; Oracle; SAP; Siemens

Gartner Recommended Reading

Proving the Value of a Digital PLM Ecosystem: B2B Recipe-Based Manufacturers

Proving the Value of a Digital PLM Ecosystem: Recipe-Based Consumer Goods

Healthcare and Life Science Business Driver: Medical Technology Innovation

Tool: Life Science CIO's Executive Presentation for Building the Composable "Digital Therapeutech"

Infographic: Artificial Intelligence Use-Case Prism for Life Science Manufacturers

Track and Trace

Analysis By: Andrew Stevens

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early 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 continue to develop globally. For phased mandates in more established regulations, companies have already run pilots, small-scale implementations, or are already in production. Solution stacks have evolved in areas such as serial number generation, data governance and data capture capabilities. Data is frequently integrated and communicated across enterprises, and via 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. Supplier networks may also come into future scope, especially in other regulated industries such as food and beverages and cosmetics.

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 or virtual organizations 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. Other areas and degree of impact are:

- 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.

- 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 sciences specific or dedicated. The market is significantly fragmented as providers translate or expand their capabilities into other industry verticals.
- 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 further regulations.

User Recommendations

Assess the key differentiators and enablers of track-and-trace and serialization solutions including;

- Enterprise level for global integration of common datasets, emerging standards and links to central repositories.
- Interoperable communication networks, including end-patient connectivity.
- Data management solutions for governance, aggregation, randomization, data storage and encryption.
- Operational-line level for material flow, automation, scanning, routing and data capture through vision systems.
- Last-mile logistics and customer fulfillment aligned to specific regulatory or trade. management mandates and specific logistics or network communications infrastructures.
- The 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.

- Strategic collaborative initiatives and deployments focused on risk mitigation, especially for counterfeit or falsified products.

Sample Vendors

Advanco; Navitas Life Sciences; SAP; SEA Vision; Softgroup; Supply Chain Wizard; TraceLink; TrackTraceRX; Vimachem

Gartner Recommended Reading

Market Guide for Track-and-Trace and Serialization Providers in Life Sciences and Healthcare Value Chain

Toolkit: Vendor Selection for Track-and-Trace and Serialization Providers in Life Sciences and the Healthcare Value Chain

An Assessment of Global Regulations Across the Healthcare Value Chain Requiring Track and Trace With Serialization

An Assessment of Global Regulations Across the Healthcare Value Chain Requiring Product Authentication and/or Verification With Serialization

Serialization Regulatory Outlook for Anticounterfeiting and Fake Medicines Across the Healthcare Value Chain

Process Analytical Technology

Analysis By: Andrew Stevens

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early 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, 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 as well as 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 postpandemic global events, with 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 significant 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.

- Companies can consider PAT in assisting life sciences companies 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 multimillion-dollar revenue opportunity, but also 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, pH or temperature.

- 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 as well as

legacy and planned IT infrastructure supporting manufacturing batch processing, technical and quality specifications, and automation systems, such as manufacturing execution system (MES) applications, errors through continued monitoring and close to real-time process business intelligence.

Obstacles

- Most processes are designed to operate without PAT. The position on this year's Hype Cycle represents solution maturity with its value proposition well-positioned for integration and deployments supporting a future shift to biologics and large molecule processing.
- As 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 process, or product parameters that cause serious quality issues and look for ways to utilize PAT to reduce them.
- Avoid being cajoled into believing that a feedback loop from a single special sensor or an investment in a process historian will deliver potential value. A mature structure for data acquisition, integration and organization necessitates a broad look at 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.
- 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

Camo Analytics; Eurotherm; IRIS; METTLER TOLEDO; Panacea Technologies; synTQ; Sartorius Group; Siemens; Thermo Fisher Scientific

Electronic Batch Records

Analysis By: Andrew Stevens

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early 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/continuous products) or large extended volume production runs. Across life science companies, EBRs align to 21 CFR Part 11 requirements to be accepted by the U.S. Food and Drug Administration (FDA) in place of paper-based records.

Why This Is Important

Electronic batch records 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, promote the elimination of errors and manufacturing downtime incidents and enhance levels of interoperability across manufacturing, engineering, technical and quality stakeholders.

Business Impact

EBR systems integrate across systems such as manufacturing execution systems (MES), laboratory information management systems (LIMS), process control systems (PCS), quality management systems (QMS) 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 EBR content alone.

Drivers

- Several providers, especially those making newer investments for EBRs realize the need to build an architecture that also complements closely aligned solutions, such as automation and quality systems. EBR evolution also aligns closely to emerging or innovative technologies supporting visibility, predictive analytics, collaboration and traceability.
- The benefits that EBRs provide depend heavily on how the data required to drive them is captured and governed. The method of recording and communicating batch data varies according to the solution implemented and products/markets in question. These limitations directly impact the ability of EBRs to provide adequate reporting on product manufacture control.
- EBRs provide a clear path to improving batch release times regulated processes. They can significantly reduce the time spent on manual data cleansing and approving product release reducing the risk of an FDA warning or, even worse, a recall.
- EBRs deploy process engines to guide tasks and instructions for operations. This makes them well positioned for consideration against further initiatives focused on change management or greater needs for integration or collaboration.
- They also act as a data hub 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 error in production areas that have traditionally been reliant on paper-based records and systems.
- Successful deployments will rely on robust data feeds of regulatory business intelligence.
- EBR can promote expectations for process improvement, automation and reliability, as well as quality and data integrity release times.

Obstacles

- As EBR solutions typically do not map specifically to compliance mandates, this could limit their impact for prioritization in less mature organizations.
- Planning around architecture is critical to EBR success given the large number of systems that may be capturing, tracking identical or distinct datasets related to batch or lot processing.
- Workflows and tracking of key processing phases can be achieved only when a broad range of solutions and services integrate seamlessly and begin to extend connectivity outside of the manufacturing footprints.
- EBR's true potential will be reliant on its ability to cleanse and extract critical batch-related data from across the supply chain for responsive decision making.

User Recommendations

- Select one small-volume product and review EBR requirements for each process stage from start to finish. Reinforcing time to value on investment in starting compact assessments can help reinforce continued scale up around EBR.
- Be realistic about the role of EBRs in assessing its integration and optimization attributes, but also understanding its limitations, especially across specific batch- or quality-related mandates and legacy systems deployed to meet batch related compliance objectives. EBR should not be viewed as a panacea for process issues, but rather as a progressive hub that bridges operations, process and technical support IT infrastructures
- Review the integrated product supply architecture that is needed to sustain quality levels if you are a client looking to implement an effective EBR solution that drives "right first time" and operational excellence.

Sample Vendors

BIOVIA; Emerson; Informetric Systems; Lonza; LZ Lifescience; MasterControl; POMS; Siemens; Verify Technologies

Gartner Recommended Reading

Magic Quadrant for Manufacturing Execution Systems

Critical Capabilities for Manufacturing Execution Systems

Entering the Plateau

ELN

Analysis By: Michael Shanler, Rohan Sinha

Benefit Rating: High

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,” especially in light of COVID-19, improving quality, creating knowledge platforms and driving collaboration, ELN adoption continues to expand. As ELNs become easier to maintain and deploy, they are becoming more integral in enabling evolving scientific and experimental data capture.

Business Impact

ELNs have a high impact on laboratory productivity in R&D and QA/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 offer an opportunity to replace paper-bound notebooks and disparate electronic systems. Some ELNs can be augmented with scientific plug-ins (e.g., chemical formulations), as well as 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 replacing paper-bound notebooks. In fact, ELNs have much deeper functionality spanning biology, chemistry and quality assurance (QA)/quality control (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 replace traditional paper notebooks.
- Therefore, we advanced the ELN profile to the Plateau of Productivity stage in the Hype Cycle, and expect mainstream adoption in two years.

Obstacles

- Many organizations support multiple ELN environments (e.g., biology, chemistry, QA/QC, formulation, 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 also have overengineered customized environments, which has damaged some of their credibility with clients.
- Some ELN companies overreached with the messaging on their capabilities.
- Many scientists are in the habit of using paper notebooks and are reluctant to adopt new electronic recording systems.

User Recommendations

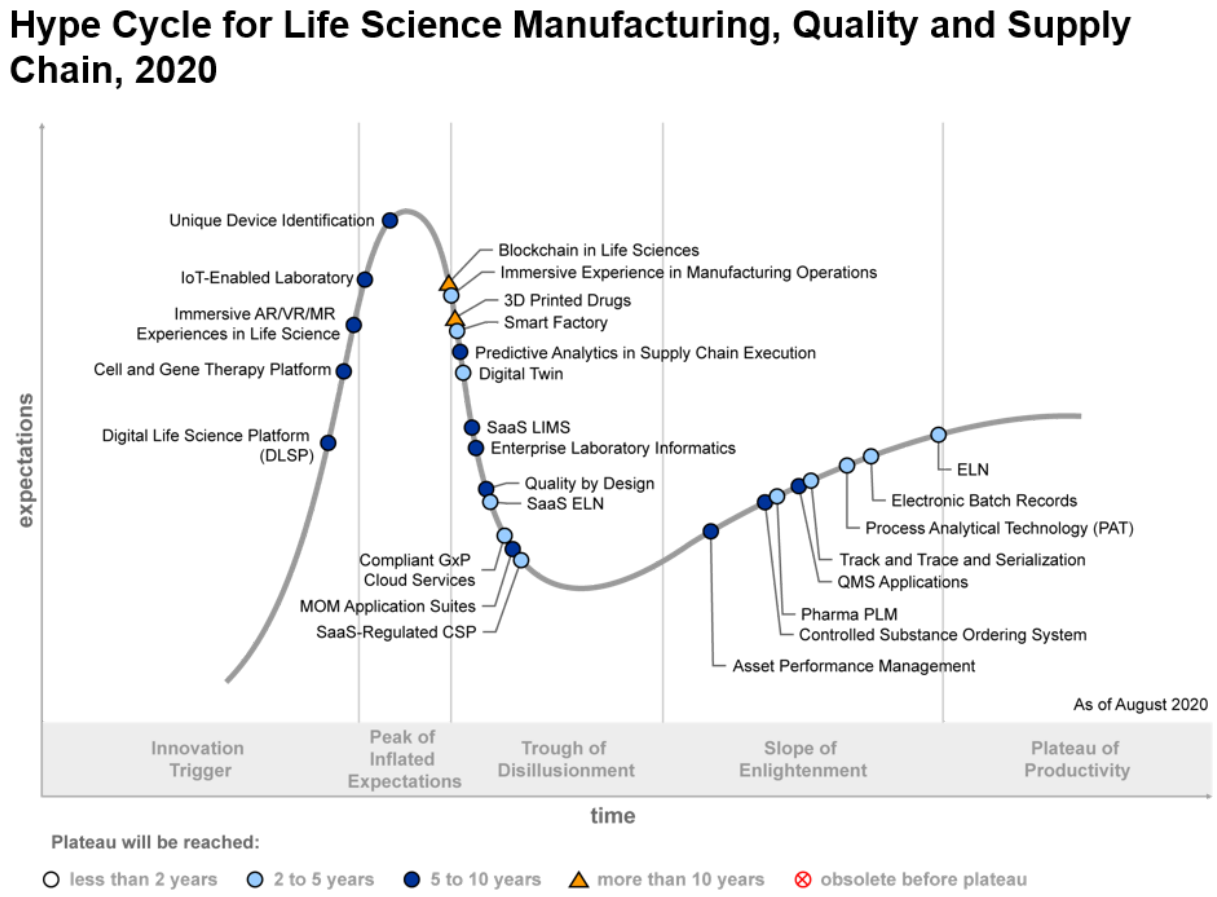
- Collaborate with decision makers who are familiar with laboratory processes when selecting a system. Different disciplines and research labs have divergent needs.
- Know that an R&D-centric ELN will not function well in a quality/operations environment, and a QM-oriented solution may not operate well in an R&D area.
- Consider ELNs with enhanced bioinformatics, analytical and reporting capabilities in organizations that conduct drug discovery or therapeutic research.
- Look for 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; Benchling; Dassault Systèmes; Dotmatics; IDBS; Labguru; LabVantage Solutions; LabWare; PerkinElmer; Thermo Fisher Scientific

Appendixes

Figure 2. Hype Cycle for Life Science Manufacturing, Quality and Supply Chain, 2020



Source: Gartner
ID: 467845

Gartner

Source: Gartner (August 2020)

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 2021)

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 2021)

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 2021)

Document Revision History

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

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

Table 1: Priority Matrix for Life Science Manufacturing, Quality and Supply Chain, 2021

Benefit	*Years to Mainstream Adoption*			
↓	***Less Than 2 Years*** ↓	***2 - 5 Years*** ↓	***5 - 10 Years*** ↓	***More Than 10 Years*** ↓
Transformational		Digital Twin Smart Factory	Cold Chain as a Service Digital Life Science Platform Generative Design Immersive XR Life Science	Blockchain in Life Sciences Cell and Gene Therapy
High		Electronic Batch Records ELN Immersive Experience in Manufacturing Operations IoT Platform MOM Application Suites Pharma PLM Process Analytical Technology QMS Applications SaaS ELN SaaS-Regulated CSP Track and Trace	Asset Performance Management Digital Validation Tools Enterprise Laboratory Informatics IoT-Enabled Laboratory Predictive Analytics Quality by Design Tech Transfer Services UDI	
Moderate		Compliant GxP Cloud Services	Bioprocessing Informatics CSOS SaaS LIMS	3D Printed Drugs

Benefit	Years to Mainstream Adoption			
↓	Less Than 2 Years ↓	2 - 5 Years ↓	5 - 10 Years ↓	More Than 10 Years ↓
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Phase ↓	Definition ↓

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