WHITE PAPER

Pharmaceutical and life sciences report 2025

How leading manufacturers cut costs, drive compliance and scale innovation

FORRESTER®

A commissioned study conducted by Forrester Consulting on behalf of Octave

Contents

The new demands on pharma manufacturing

Pharmaceutical manufacturing is entering a period of unprecedented complexity and opportunity. Global demographics and rising regulatory demands are reshaping the market, compelling organizations to embrace digital transformation strategies that foster resilience, efficiency and innovation.

The market is expected to experience significant growth (6.5%) in the next decade,[1] fueled by the ageing population in the West and China. At the same time, several factors have pointed to the limitations of the current manufacturing model.

The companies that thrive in the next decade will be those that manage to evolve because they face significant challenges.

Steep “patent cliffs”

are putting pressure on margins, pushing drugmakers to reconsider their R&D and manufacturing costs.[2]

Supply chain disruptions

are calling into question the centralized production model that has made companies more exposed to shortages and tariffs, etc.

New modalities

(RNA/DNA-based drugs, cell and gene therapies and antibody-drug conjugates) are raising new challenges such as smaller batch sizes, more complex processes and rising costs.

Digital and cyber resilience

is becoming critical as manufacturing, research and clinical data move to the cloud and data breaches become more frequent and severe.

Future growth is almost entirely dependent on facing and overcoming these challenges

The vision: intelligent manufacturing

To thrive in this new environment, leading organizations are shifting toward intelligent manufacturing, a model characterized by seamless data integration, advanced automation and proactive quality management. Moving beyond isolated digitalization efforts, intelligent manufacturing leverages connected systems to drive value at every stage of the product lifecycle.

Going deeper: pharma's information management woes show the importance of the lifecycle view

When analyzing research, some of the most interesting findings are the apparent paradoxes

In a recently commissioned study conducted by Forrester Consulting on behalf of Octave,[3] one of the most intriguing findings lies in the way respondents describe their organizations.

For the study, "Transforming pharmaceutical manufacturing: overcoming hurdles with digital innovation," Forrester surveyed 160+ manufacturing technology decision-makers based in Europe. The participants were at manager level and above, and responsible for manufacturing processes, quality assurance and testing within pharmaceutical organizations boasting at least US$1 billion in annual revenue. Those questioned reported high levels of digital maturity. **More than 70% said that production or maintenance is data-driven and over three-quarters (78%) stated that asset management is integrated with real-time monitoring systems.**

However, when asked about outcomes and realized value, the picture changes. Two-thirds stated that data silos still hold their organizations back. Half consider their digital transformation efforts to be at an early stage. The other half cites internal data sharing and collaboration as one of their most pressing challenges.

This disconnect is familiar to anyone working in asset-intensive industries: the gap between digitization and actual value delivery. **The more mature an organization becomes digitally, the harder it is to generate clear, incremental value.**

The paradox that isn't

The contradiction between capabilities and perceived maturity is just that – a perception.

Firstly, the rapid advance of technologies such as AI can make every organization feel like it's moving too slowly, particularly in highly regulated environments.

Secondly, silos can make the path from capabilities to value much steeper. When operations, quality, engineering, IT and capital projects are siloed and operate on different systems, workflows and metrics, the data often exists but the value remains constrained.

Capital project teams may deploy digital solutions to manage cost and schedule, but without integration with operations or QA systems. Quality teams may digitize deviation tracking, while maintenance teams optimize asset data. Pharma needs a way to break those silos—not through centralization for its own sake, but through a shared asset-centric perspective.

Moreover, pharma is experiencing a lack of centralized procedures to remedy the high turnover of long-tenured retirements.

The industry must transition from compliance-driven digitalization to a value-driven approach. This shift empowers stakeholders to realize business outcomes—not just implement technology for its own sake.

The case for asset lifecycle thinking

A digital approach to capital projects and asset lifecycles connects the dots from design and procurement through commissioning, operation, maintenance and retirement. It focuses on traceability, performance and quality across every phase of an asset's use through connected tools.

This view enables digital investments to reinforce one another. Data collected during project execution becomes the foundation for operations, and insights from operations feed back into maintenance and reliability improvements.

Three signs your organization needs lifecycle thinking:

01	**An ever-expanding set of point solutions kills productivity** Industry-wide, duplicate manual entries, lack of integration and frequent context switching all have negative effects.
02	**Technology first, value later** A new technology is selected before use cases are identified; feedback loops are not in place to measure long-term adoption and value.
03	**Teams focus on optimization rather than impact** A common situation is maturity myopia, where teams pursue advanced capabilities or metrics that are disconnected from business value or simply lack the foundational building blocks (stakeholder engagement, optimized processes, access to valuable data) to realize tangible value.

The path forward: value-driven digitalization

So how does an organization avoid these pitfalls and escape the spiral of no-value digitization? Transformation requires a strategic, holistic approach. Organizations that succeed do so by adopting practices that focus on measurable and tangible values at each stage.

Start with value

Discovery

Work together to identify a transparent, defensible business case that aligns with organizational objectives.

Delivery

Match the business case with the adoption of the right technology solution.

Realization

Measure and track the actual value created by the technology adopted and measure those results against the expectations created during the value discovery phase.

Build feedback loops

Success hinges on combining executive vision with field expertise, fostering feedback loops that ensure solutions deliver best-in-class benefits.

Favor interoperable tools that can grow and evolve

Solutions built with flexibility and interoperability in mind allow for growth, adaptation and long-term value capture. Prioritizing interoperability enables organizations to adopt solutions that evolve and mature at their own pace, enabling them to capture value even when it emerges in unexpected ways.

The challenge: overcoming barriers

Research by Octave and Forrester reveals five weak points that prevent pharma companies from realizing full value from their digital investments and using technologies to become more efficient and agile versions of themselves:

1. The weight of compliance, sustainability and documentation is compounded by data silos and document management challenges

Stringent and evolving government regulations (e.g. Annex 11 in the EU / FDA 21 CFR part 11 requirements in the US for the keeping of electronic records) make maintaining clean, attributable and timestamped records across systems critical. 66% of European decision-makers agree that increasing regulations have made compliance more complex and costly.

However, manual entries, uncontrolled spreadsheets and disconnected tools represent major obstacles to demonstrating data integrity during audits or inspections.

Documentation activities consume up to 30% of staff time,[4] a situation due in part to the large volume of manual entries, while manufacturers struggle to digitize and integrate key data sources like maintenance records and IoT inputs.

The sustainability imperative. Top sustainability benefits include a reduced carbon footprint (39%) and minimized waste through efficient resource use (34%), highlighting the sector's growing focus on environmental responsibility.

Ensure expertise and continuity. Retaining knowledge and attracting talent are key challenges. Cloud-based platforms, AI and collaborative tools provide secure knowledge repositories, which 67% of respondents expect will improve retention.

54%

of pharma manufacturers are prioritizing data management and organization

53%

of are prioritizing demonstrating compliance

2. Difficulties automating and scaling-up key work processes that make it difficult to replicate technology and best practices

57% of businesses are looking to scale up processes from one manufacturing plant to another.

This problem can hide a range of causes. Different plants may use different equipment, systems, procedures or naming conventions, which makes any attempt to replicate best practices challenging and trial-and-error. Additionally, process knowledge can be tacit, undigitized and tied to specific individuals. Lastly, each site must demonstrate control, traceability and consistency through validation, documentation and potentially local regulatory engagement.

80%

of manufacturers identify implementing tools to facilitate data sharing and collaboration as a top data priority.

Regulatory compliance and audit readiness are similar concerns for

80%

of manufacturers, according to Forrester research.

3. Challenges in AI adoption related to pharma's unique constraints in Good Manufacturing Practices (GMP) environments

While the use of AI in areas like discovery or clinical trial design has become commonplace, adoption in GMP-regulated production (e.g. batch release, deviation investigation, process control) is cautious, exploratory and immature.

GMP compliance demands transparency, repeatability and validation. AI models, especially black-box algorithms, don't easily align with these requirements. Regulators such as the FDA and EMA have started to engage with the topic, but clear frameworks for validation, change control and audit readiness are still evolving.

There is clear interest in using AI more extensively in the manufacturing environment, with cybersecurity automation (68%), AI for predictive maintenance (65%), or AI in native language interfaces (61%) emerging as key investment areas.

53%

of manufacturers have identified the need to manage change with auditable traceability as a strategic priority.

82%

of respondents believe that real time monitoring and analytics is a top data priority.

4. Lack of efficiency and control over capital project management

Pharma's manufacturing footprint is changing. As is the industry's handling of capital projects.

The traditional way, marked by rigid and linear project planning, silos between capital and operational teams and a low focus on capital efficiency, is giving way to more adaptive and risk-averse approaches.

From a tooling perspective, digital twins, model-based design and integrated project controls are now being used in large capital programs for faster design iterations, better risk tracking and smoother handover to operations. 79% of European decision-makers say they plan to use project digital twins and advanced modeling tools to create precise and efficient designs, reducing errors and rework.

5. Cybersecurity concerns

The pharmaceutical sector is increasingly vulnerable to cyberattacks. This is reflected in the fact that cybersecurity automation is cited as the top use for AI and that 79% of decision-makers view it as critical to reinforce security measures to protect sensitive information from cyberthreats and unauthorized access.

The pandemic also revealed that cyber risks have changed. While ransomware remains a major concern, espionage or sabotage via operational technologies is an underestimated risk.

The challenge: emerging cybersecurity threats

68% of decision-makers in large companies named cybersecurity automation as a top investment priority for the next twelve months, putting it ahead of more high-profile technologies like the IoT or natural-language AI.

Two factors can explain this result. Firstly, a similar number (67%) believe their organization's vulnerability and risk management practices could be improved. Secondly, the pharmaceutical industry and the healthcare sector have emerged as focal points in geopolitical tensions, which make them a primary target for hacktivists and state-affiliated actors, all of which pose risks for intellectual property.

1. Ransomware epidemic

Ransomware attacks are highly visible: by encrypting critical systems, they can cause prolonged operational disruptions and significant financial losses. Regulations such as the SEC's cyber incident reporting rule and the EU's NIS2 directive encourage this visibility by requiring large or listed companies to disclose material cybersecurity incidents and describe their timeline, scope and effect.

2. Third-party risks

Many ransomware groups are opportunistic in nature and target whichever company offers the easier entry point. In the pharmaceutical ecosystem, pharmaceutical wholesalers, distributors and specialized software vendors are overrepresented among victims.

This makes third-party risk especially acute. According to recent findings, 98% of pharmaceutical companies have experienced negative impacts from cyber incidents linked to external partners.[5]

3. Operational technology (OT) threats on the rise

With tensions between geopolitical blocs rising, cyber operations are now part of state toolkits. Pharmaceutical manufacturers face state-backed actors with capabilities and motives beyond profit. These groups target IT and OT alike—the systems that run physical processes, equipment and manufacturing environments.

A validated environment means that systems such as HVAC or lighting can be legitimate targets: an outage of any one of them can stop production.

4. State-nexus actors

An OT attack typically originates on the IT side and sees attackers attempt to gain permissions and move through the network, which can take months or years. Unlike traditional attacks that will install scripts on the target systems, some state actors will therefore rely on native, legitimate tools that are already present. This practice, known as 'living off the land' or LOTL, attacks in a way that traditional tools cannot detect.

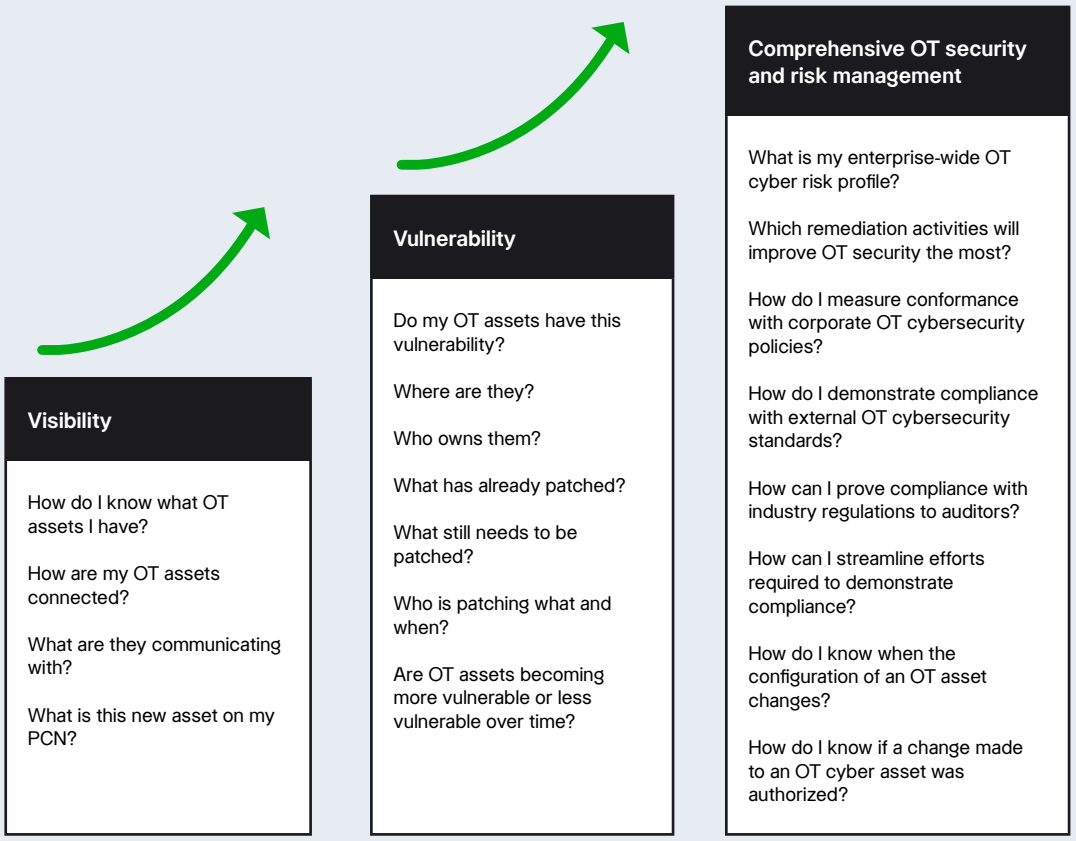
Infiltrating the OT environment can serve a number of purposes, including financial extortion, intellectual property theft, espionage or process manipulation. State-affiliated groups are increasingly developing malware that specifically target industrial control systems (ICS).

5. Lack of skills and visibility

Cybersecurity problems are compounded by several factors. The first is lack of skills, acknowledged by 77% of decision-makers in the study conducted by Forrester Consulting on behalf of Octave.

Without dedicated skills, it is not uncommon for cybersecurity practitioners lacking OT competencies to take an IT-only approach. For example, this could be by limiting their inventory to IP-addressable devices. Because of this, they could miss out on critical control systems and important vulnerabilities. Developing this complete visibility is the crucial first step to developing a solid security program.

Fig. 1: Example of maturity levels for an OT security program



6. Beyond prevention

The SANS Institute's Five Critical Controls for ICS/OT Cybersecurity notes that common cybersecurity frameworks are often focused on preventing an attack rather than responding to it: "Between 60-95% of the most well-known and utilized security frameworks focus on prevention but lag in detection and response capabilities. As a result, many organizations invest as little as 5% of their resources in detecting, responding to and operating through an ICS/OT attack."[6]

Against sophisticated threat actors who leverage trusted tools and excel at hiding in plain sight, preventive approaches will fall short. Instead, pharmaceutical manufacturers should devote greater resources to incident response and business continuity, by developing comprehensive OT security baselines and configuration management.

Chapter 5

The practice: scalable pharma operations

Modern pharmaceutical operations demand connected platforms, adaptable processes and resilient infrastructure. Here is some actionable guidance that will allow your organization to leverage these enablers for maximum scalability and operational excellence.

1. Solving information management pain points with enterprise asset management

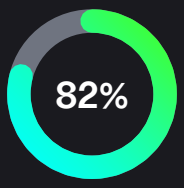
Pharmaceutical manufacturing rests on several complementary tools, such as Quality Management Systems (QMS), Quality Management Systems (QMS), Manufacturing Execution Systems (MES), Enterprise Asset Management (EAM) and Laboratory Information Management Systems (LIMS).

Among pharma companies that manage to successfully transform and achieve scalable operations, EAMs are becoming a foundational layer that ensures effective integration, powers autonomous operations and AI adoption and simplifies compliance.

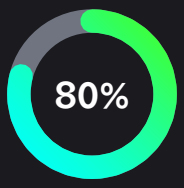
The reasons for this growing importance are threefold.

01	**Reliable assets are a prerequisite for GMP compliance** If equipment isn't performing as expected, neither is the process. A modern platform like Octave Attune EAM (formerly HxGN EAM), is built to become a record of truth for asset status, calibration, maintenance history and deviations. It underpins batch integrity, qualification and audit readiness.
02	**An EAM platform has built-in integration capabilities with other key platforms and data sources** such as ERPs, QMS, MES, SCADA and IoT systems. This eliminates silos for a clearer view into real-time asset data, better operational performance and data-driven decisions.
03	**It provides a launchpad for AI implementation at scale and new approaches** such as asset performance management that help identify risk and opportunities.

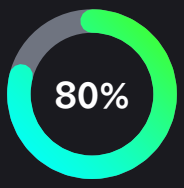
An EAM platform is the perfect tool to address the top information management challenges cited by pharma decision-makers:



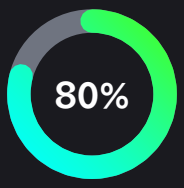
Real-time monitoring and analytics



Tool implementation to facilitate collaboration and data sharing among employees, regardless of their location



Data and document accuracy and accessibility



Regulatory compliance and audit readiness

Defining essential EAM capabilities

To deliver a platform for future success, an EAM must offer these capabilities:

Single source of truth

Having all equipment, parts and instrumentation data available through a single pane of glass is essential for real-time visibility and smarter decision-making. An effective EAM will integrate instrumentation assets into the overall asset hierarchy and interact with assets for maintenance, traceability, controls and performance. Centralizing parts and standards management in the same system ensures that every downstream process, from maintenance planning to procurement, draws from one authoritative source.

Traceability, cause determination and reporting

Calibration errors must be identified quickly to mitigate and limit effects on production. Your ideal EAM platform will maintain a history of calibration activities to support reverse traceability for investigations and analysis. You should also be able to track test results such as calibration sequences. Test-point data, tolerances, process control limits, as-found results, as-left results, action taken and calibration status can all be captured digitally. A digital twin type system logs calibration work orders against specific items of equipment, allowing you to roll up costs and maintain historical tracking of work completed, corrective actions taken, root-cause analysis and out-of-tolerance work orders.

Smart reporting, both inside the system and as exported documents, is intrinsically tied to this capability. The ability to share clear, auditable reports with the right stakeholders strengthens accountability and accelerates decision making.

Mobility

Capturing data immediately ensures quality and accuracy. Using mobile devices to record, view, edit and transfer calibration information to the EAM database is vital. Adding electronic signature standards to mobile devices will enable you to further optimize workflows.

Electronic signatures and workflow approvals

An EAM system must be able to verify that electronic signatures are unique, secure and valid. By introducing routine and a sequenced approval of signatures on revisions of PMs, tasks and material lists, you can ensure process execution. Introducing workflow approvals directly in the same system where users already do their work eliminates the friction of switching between dozens of disconnected applications. This integration also provides a valuable audit trail showing when and by whom documents were altered, making the EAM a critical compliance tool.

Granular, secure user and access management

Effective EAM platforms must provide the ability to control access down to specific functions, data sets and workflows. Granular user rights management protects sensitive data, reduces risk of error and ensures compliance with regulatory requirements while supporting teams to work efficiently.

Optimized scheduling

Crew and technician schedules need to be optimized across maintenance windows, skill sets and equipment priorities. An advanced scheduling capability ensures the right people are assigned to the right tasks at the right time, reducing downtime and improving asset reliability.

Asset investment planning

Financial resources are limited. The right EAM platform helps organizations allocate those resources toward the most critical equipment. By linking condition, risk and performance data with investment decisions, companies can prioritize upgrades and replacements that will deliver the greatest impact.

Asset performance management

Beyond maintenance tracking, an EAM should enable prescriptive maintenance strategies, detecting failures before they occur and recommending corrective action. By integrating condition monitoring and predictive analytics, organizations can reduce unplanned downtime, extend equipment life and optimize asset performance over time.

Introducing electronic signatures also provides a valuable audit trail, showing when and by whom documents were altered. Your EAM becomes an important tool for demonstrating compliance.

Complementary to the EAM platform, a modern Quality Management System (QMS) enables pharmaceutical firms to move beyond compliance toward consistent, scalable operational performance. The QMS serves as a single point of control for quality-related events—deviations, CAPAs, audits and change management—across all sites.

Centralizing these processes reduces variation and supports a more uniform response to regulatory expectations.

Three key QMS functionality requirements:

01	Quality data flow across functions in real time, such as ERP, MES and HR. QMS integration increases transparency, ensures traceability and improves response time during audits or inspections.
02	Automation eliminates the delays and risks associated with paper-based processes. Data entry errors are reduced, cycle times shrink and records are always inspection-ready.
03	Configuration flexibility is key: systems must adapt to business needs without excessive customization.

Integrated quality systems play a key role in advancing digital transformation. A recent Octave case study highlights how one of Europe's largest pharmaceutical companies harmonized and automated its change management process, moving from a manual, paper-based system to a fully digital one. Change data captured online reduces the risk of data loss and improved data quality.

Octave's flexible platform enables the organization to configure the solution to their specific business needs and apply intelligent business rules to streamline workflows. The system is integrated with SAP and other business applications, making Octave a central hub for all compliance-related events. The result? The company has improved visibility, shortened lead times and strengthened inspection readiness across global operations.

Case Study

Digitizing quality management to overcome silos compliance

Read more

3. The AI imperative: how to leverage AI in pharma's GMP environment

Recent research surveying large pharmaceutical companies, conducted by Forrester Consulting on behalf of Octave, shows that two-thirds of European decision-makers believe data silos are limiting their organization. Even businesses that consider themselves data-driven face disconnected systems and fragmented workflows. This prevents teams from gaining a full understanding of any given situation.

Around 80% of respondents reported issues with data and document accuracy or accessibility. Often this stems from poor integration between key systems such as quality management, maintenance and production. In other cases, it is due to gaps in software coverage such as the inability to manage both traditional assets and instrumentation within a single platform.

Silos also exist in physical form, where information remains undigitized or lacks context. This is especially common at the interface between projects and operations. Essential documents like P&IDs or engineering records are frequently unavailable or not linked to operational data.

While data silos can hinder the implementation of AI, they also represent one of the areas where AI can deliver the most value.

AI is renewing interest in digital twins by improving the ability to process large volumes of information in various formats and to contextualize unstructured data. Information that was previously siloed due to being undigitized, unindexable or requiring intensive human review can now be quickly processed and put to use. This provides a collaborative environment and one single source of truth.

Another example is maintenance optimization. AI can unify diverse data streams—real-time asset data, work schedules, budgets and spare parts availability—to improve work allocation, identify risks and protect critical assets. In these cases, data was often already digital but scattered across documents, applications and formats. AI brings it together in a meaningful, actionable way.

Using AI to reduce workloads

Over half of the respondents in the Forrester-Octave study cited they struggle to maintain operational efficiency during audits and 53% reported difficulty demonstrating compliance. AI assists with both.

According to the European Federation of Pharmaceutical Industries and Associations (EFPIA), current GMP frameworks already support the integration of AI, particularly in areas such as quality control, process monitoring and deviation management. The EFPIA notes that even in GMP environments, where processes are tightly controlled, AI can be applied safely within existing quality management systems.

AI is especially useful for continuously monitoring data, flagging anomalies in real-time and ensuring traceability across systems. By analyzing both historical records and live inputs, AI surfaces trends and identifies deviations from standard procedures. This also supports faster response times, for instance, by pinpointing when and where a calibration may have been incorrect. This enables teams to isolate affected products and conduct reverse traceability for investigation and analysis.

AI can also cut down the time spent on documentation tasks, which can consume up to 30% of staff time. By structuring and organizing records for quicker access, compliance activities.

Where to start with AI, automation and digital twins?

AI, automation and digital twins should only be deployed where they add value. A common trap is adopting a tool before clearly defining the problem. This often leads to retrofitting it into workflows for negligible gain.

While most firms say they have invested in cloud infrastructure or asset monitoring tools, more than half report that their digital transformation is still in the early stages. This suggests that digital tools are in place but not yet delivering real value.

Interoperability and data continuity is essential for getting results from AI or automation. When choosing an EAM platform to automate and optimize maintenance, it must establish digital swim lanes between core systems to support advanced capabilities. Data from ERP, capital planning, quality management and predictive or prescriptive sources— such as sensors and building management systems—should flow into the EAM to enable the full execution of reliability and maintenance activities.

As a highly regulated industry, the pharmaceutical sector faces unique challenges that must be considered in any technology decision-making process. Ensuring traceability of GMP assets through configured workflows, electronic records and change control approvals is critical. As is the ability to set up distinct processes for nonGMP assets based on classification. These features should be built from the start, not something to struggle with during implementation.

4. Digital twins and EPP transform capital project management and deliver higher project performance

McKinsey reports that only half of large pharma companies have a dedicated capital management function.[7] Historically, the industry focused disproportionately on large greenfield builds, while most capital spending—routine upgrades, equipment replacements, capacity adjustments—was handled locally and with limited central oversight. These small and mid-size projects, which can account for up to 70% of total capex in mature operations, were rarely assessed through a portfolio lens.

The result is missed value. Poor prioritization, cost variability and redundant investments are common. Some firms pursue expansion projects at sites with idle capacity. According to McKinsey, improving capital project planning and governance could unlock up to $200 million annually in savings for a typical large pharmaceutical company.

Case Study

Quality global pharmaceutical leader partners with Octave Sequence Enterprise (formerly EcoSys) to support scalable growth across its manufacturing network

Read more

Where do pharma capital projects go wrong?

Premature commitments and late changes

Compared to other industries, pharma projects have been found more likely to have budgets and timelines locked in before completing sufficient front-end loading (FEL). This leads to underdeveloped scopes and late-stage changes. With major capital projects coming with a four to six year timeline, the problem can be compounded by changes in needs or regulations.

Late commissioning and validation planning

Pharma projects require significant time and effort to complete IQ/OQ/PQ under GMP. Treating commissioning as a late-stage activity rather than a parallel workstream from design onward can lead to delays and burden of quality teams. This is an outcome that can be avoided with solutions like Octave OnSite Completions (formerly Intergraph Smart® Completions), which run commissioning and qualification in parallel to design by keeping a single tag register, generating digital IQ/OQ/PQ packs with e-signatures, linking checks to the schedule and capturing punch items in the field.

Limited integration between capital and operational stakeholders

Capital projects are still too often treated as isolated engineering efforts, with input from operations, QA, IT and digital teams brought in late. Handover issues are also a concern. Project digital twins can consolidate information across disciplines, provide a shared model that fosters collaboration and eliminates information loss during handovers.

Limited use of project data and project controls

Without integrated project controls, teams face difficulties managing scope creep, vendor delays or cost escalations, especially across multi-year timelines. Approaches such as Enterprise Project Performance (EPP) provide real-time visibility into budget, forecast and actuals across the portfolio. They help project owners monitor earned value, enforce change governance and make earlier interventions based on reliable performance data.

How better projects lay the groundwork for better plants

The case for improving capital project capabilities goes beyond efficiency. Done well, these projects lay the foundation for better information management across the asset lifecycle.

Projects that enable structured, digital handover from design through commissioning into operations are better positioned to deliver value and ensure access to accurate data. This is already pushing some pharma firms to mandate the software and data environments used by EPCs, mirroring the developing practice in other industries, like oil and gas.

Eight scenarios facilitated by accessible, up-to-date engineering data

01	**Planned maintenance and shutdowns** Operations teams use P&IDs to locate valves, boundaries and instrumentation, which ensures safe isolation and efficient execution. A digital twin streamlines planning through current, verified data.
02	**Deviation investigations or root cause analysis** To trace faults or contamination, teams review flow paths and sensor locations. Diagrams help visualize system behavior and a digital twin can overlay alarms or history to guide analysis.
03	**Commissioning, Qualification and Validation (CQV)** Operations teams use P&IDs to locate valves, boundaries and instrumentation, which ensures safe isolation and efficient execution. A digital twin streamlines planning through current, verified data.
04	**Change control and engineering review** For proposed changes, teams assess impacts using up-to-date diagrams showing affected systems. A digital twin highlights dependencies, helping prevent compliance risks.
05	**Emergency response and troubleshooting** For proposed changes, teams assess impacts using up-to-date diagrams showing affected systems. A digital twin highlights dependencies, helping prevent compliance risks.
06	**Training and knowledge transfer** P&IDs and 3D models help new staff understand system layout and flow. Operations teams use them to explain real-world practices and risks.
07	**Regulatory inspections and audits** Auditors may request proof of system layout or changes. Controlled, validated drawings provide clear evidence of compliance and change history.
08	**Facility expansion or modification planning** Teams review 3D models to assess space, routing and utility tie-ins. Digital twins reduce rework by grounding design in trusted, current data.

To consolidate and organize information across projects to operations, decision-makers are increasingly looking to digital twins. In a 2025 Octave-commissioned study, Forrester found that 79% of European pharma decision-makers saw implementing digital twins as a high priority, with the ambition of reducing errors, rework and the ensuing delays and costs.

This interest is also a reflection of the sector's persistent information management challenges. In the same study, 80% saw it as a high priority for their organization to improve data and document accuracy, and 77% wanted better information practices overall.

Capital project information often remains fragmented across project delivery, IT and operations, which undermines transparency. A more integrated approach, one that connects the design and engineering phase, the project data centralized in an EPP platform and the long-term asset performance provided by an EAM, can help close that gap.

Greater control over project execution reflects a wider shift in how pharma manages infrastructure and capital. In the current context, continuing with business-as-usual means greater vulnerability to external factors and translates to weaker performance. By contrast, companies that strengthen capital project capabilities will be more agile, efficient and able to scale faster, three critical advantages in a time of patent cliffs and geopolitical risks.

The proof: four lessons from Pfizer on using asset management to transform operations

Mike Tomasco, who served as vice president at Pfizer Digital, overseeing the digital transformation of Pfizer Global Supply (PGS), provides insights and learnings from his experiences.

Start with empathy and solving problems for the end-user

The measure of digital transformation is that it frees up time, energy and resources, particularly for end-users. Achieving this requires understanding what obstacles they face in their work and avoiding "technology-first thinking."

"It started with empathy, walking in the shoes of the people who do the work. They often ask, 'Why do I have to log into 27 different things every day to do my job? Why can't we have a better experience?' That concept of end-to-end experience design is really important, especially when applications don't talk to each other. So, having a layer of continuity or abstraction through data becomes really important."

Strike the right balance between agility and control

In domains like asset management or AI, it can be easy to fall into two opposite traps: trying to deploy fast and failing to meet needs for control, traceability and explicability, or spending years building a solution that meets rigid specifications only to realize needs have changed.

"Our first EAM deployment to Sweden involved 5,000 pages of test scripts and months of validation, yet it didn't do what users needed, only what we told it to do. We realized that process was inefficient and non-value adding. This prompted an agile transformation, where we eventually chose a structured framework like Scaled Agile Framework. This provided structure, allowing us to codify processes and make anything we were doing potentially validatable, ensuring everything meets a required level of rigor, explainability and traceability."

Mike Tomasco
Former VP of Pfizer Digital

"It all starts with governance, leadership and vision. There must be ownership and a clear vision, with tangible commitment to execution... through procedures, process and consistency, and with a governance team to drive it to make things successful."

Use asset management to power growth and standardization

As an acquisitive company, Pfizer employed a strategy of implementing core solution capabilities, such as global maintenance and calibration management, to enhance efficiency in newly acquired businesses.

"Our strategy as a company is part of the growth of Pfizer. Pfizer would buy companies and a lot of our job was to consider how we can help them become more efficient. One of our strategies was to put in core solution capabilities, such as maintenance management and calibration. This capability set was one of the first global models."

Don't underestimate the importance of governance and leadership

Successful transformation hinges on robust governance, strong leadership and a clear vision, supported by a culture that fosters growth, consistent procedures and dedicated oversight.

On-Demand webinar

Digital evolution with Enterprise Asset Management: an in-depth discussion with Mike Tomasco

Watch now

About our research

This publication is partly based on the results of a Forrester Opportunity Snapshot, "Transforming pharmaceutical manufacturing: overcoming hurdles with digital innovation," published in March 2025.

This custom study, commissioned by Octave, provides key insights into the digital transformation trends reshaping the pharmaceutical manufacturing industry in Europe.

Forrester surveyed 161 manufacturing technology decision-makers at the manager level and above, responsible for manufacturing processes, quality assurance and testing within pharmaceutical organizations boasting at least 1 billion USD in annual revenue.

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About Octave

Octave is a leader in enterprise software, turning data into decisive action and intelligence into your edge. Our software solves for and simplifies complexity, from the design and build to operations and protection of people, property, and assets– for any scope, at any scale. For decades, we've partnered with customers to sharpen performance, elevate efficiency, and amplify results. From factory floors to entire cities, our solutions are tuned to scale up what's possible from day one onward.