Expanding the strategic power of MES in pharma

Closing post-launch MES gaps to unlock future business value

Capgemini

The pharmaceutical industry is at an inflection point: regulatory expectations are rising, product complexity is increasing, and the pace of technological change is accelerating. In this environment, MES must be more than compliant, it must be intelligent, agile, and aligned with strategic business goals.

Avoiding the MES post-launch plateau

Many pharma organizations face a critical challenge post manufacturing execution system (MES) deployment: value delivered at the time of launch is often limited to technical functionality, falling short of the broader, business-aligned impact the system is capable of delivering.

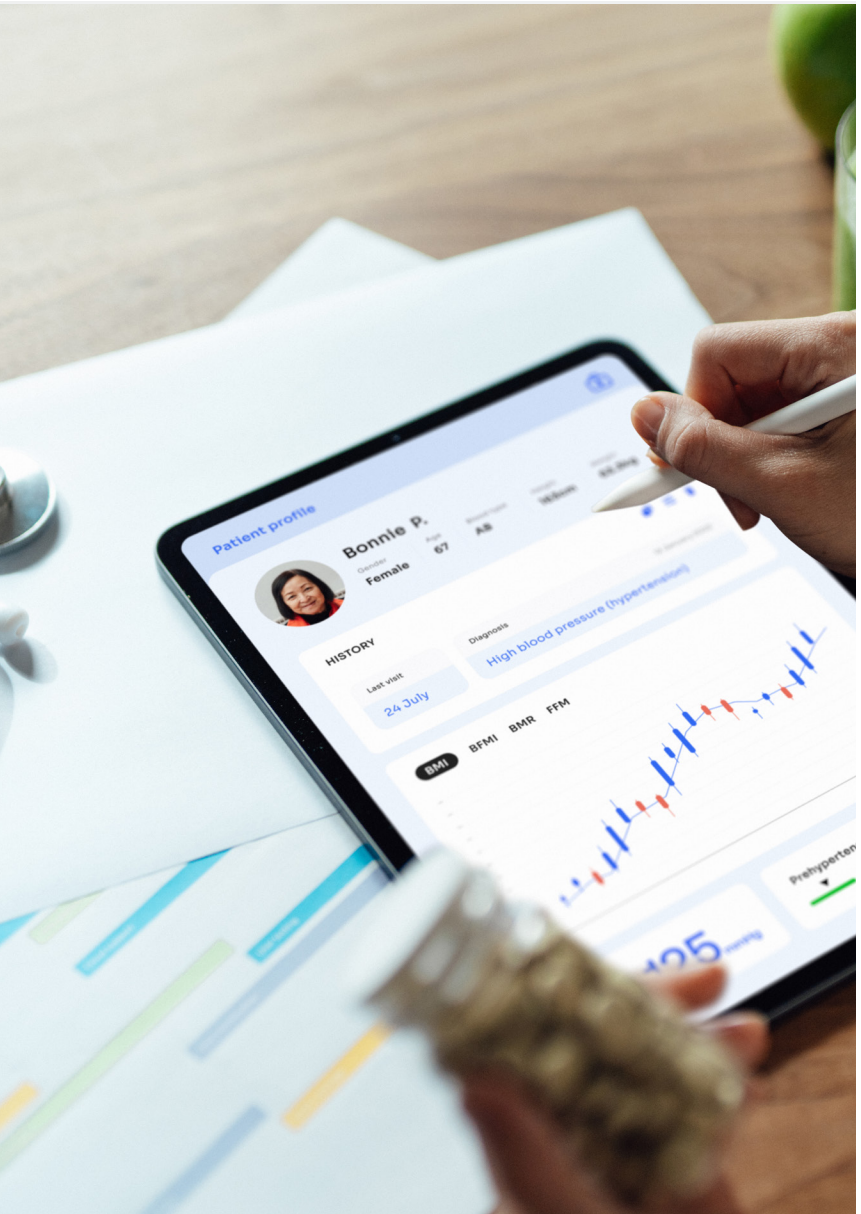
This gap is often the result of an implementation plan that ends at go-live, as well as an insufficient measurement system. While the initial MES deployment is often well-resourced, the post-implementation phase is frequently underemphasized, leading to underutilized features, limited user engagement, and missed opportunities for operational improvement.

At the same time, the role that MES plays in the business is evolving. Once seen as a static IT system that ensures compliance and manages execution, the application of advanced technologies and integration with other core business systems enables MES to become a strategic asset that can drive efficiency, agility, and innovation.

To unlock MES's full potential, pharma organizations must rethink the system's role, applications, measurement, and possibilities: Deployment is not the finish line—it's the starting point. MES is not a static IT tool or compliance checkpoint, but a driver of operational excellence and a catalyst for innovation. The purpose of MES is not just to stabilize systems, but to actively create value across the business.

In this paper, our experts examine how pharma companies, as well as biopharma and other life sciences organizations, can embrace this new vision of MES to avoid the post-launch plateau and harness the full power of their investment.

Beyond uptime: Turning MES into a performance engine with strategic KPIs



The true measure of MES success lies not in its deployment, but in the value it continues to generate over time. Yet, many organizations lack a standardized approach to measuring this value.

For example, organizations focus on system uptime or compliance metrics, overlooking the operational and strategic indicators that truly reflect MES impact. This reinforces the limited role of MES as a static compliance tool rather than a dynamic driver of business performance. It also makes it difficult to demonstrate return on investment or to justify further optimization efforts.

Effective MES governance begins with identifying the right metrics—meaning those that align with business goals and reflect the system's role in driving performance. Some strategic KPIs may include: batch release cycle time, right-first-time rates, deviation frequency and resolution time, operator productivity and recipe or MBR change cycle time.

For example, one of the most frequently cited metrics is **batch release cycle time.** In many pharma organizations, this process can take days or even weeks due to manual review, incomplete data, or fragmented systems. A mature MES implementation, especially one integrated with the quality management system (QMS) and laboratory information management system (LIMS), can significantly reduce this cycle.

For example, by enabling real-time data capture and contextualized batch records, manufacturing sites can cut batch release times substantially, freeing up QA resources and accelerating product availability.

Deviation reduction is another high-impact area. Modern pharmaceutical quality systems leveraging MES technology have been shown to reduce investigation cycle times by 45-60% and decrease overall quality deviations by 25-40%.[1]

For example, MES can help prevent deviations by enforcing procedural compliance, flagging anomalies in real time, and providing structured data for root cause analysis. However, this potential is only realized when the system is actively monitored, and its data is used to drive continuous improvement. Manufacturing sites that have implemented MES dashboards to track deviation trends see significant reduction in repeat deviations shortly after implementation.

Generating sustained value from an MES needs to be seen as a continuous process, supported by regular audits, user feedback loops, and agile enhancements. KPIs should also be reviewed regularly at the leadership level and used to inform decisions about system enhancements, training needs, and integration priorities.

Unlocking the value of MES

When paired with other digital systems and advanced technologies, MES can accelerate production, improve quality, cut costs, and reduce errors. But, without the right metrics and a structured measurement approach, these gains often go unquantified or even unrealized. Embedding strategic KPIs into MES performance tracking enables pharma organizations to capture and maximize the full value this system can deliver.

Estimated MES benefits when executed in conjunction with other technology and process improvements:

50%
reduction in manufacturing lead time

25-45%
overall equipment effectiveness (OEE) gains

75%
reduction in documentation time

25–30%
drop in quality-related costs

35%
improvement in right-first-time metrics

95%
fewer documentation errors

Source: *European Journal of Computer Science and Information Technology*

MES maturity: Unlocking long-term value with 5 critical enablers

Achieving MES maturity is the key to unlocking its full, long-term value. Beyond simply keeping the system stable, it requires an intentional approach that drives continuous improvement, fosters user engagement, integrates data seamlessly, and builds a future-ready architecture. Here we explore the five interconnected enablers that turn MES from a static tool into a strategic asset that delivers compounding returns.

1 Operational maturity and continuous improvement

Generating sustained value from a MES is a continuous process driven by regular audits, user feedback loops, and agile enhancements to uncover underutilized features, process inefficiencies, and skill gaps. Leadership should routinely review KPIs to guide decisions on system upgrades, integration priorities, and training needs. This ongoing improvement cycle helps ensure MES evolves with the business, supporting emerging requirements rather than just legacy processes.

2 Change management and user adoption

Even the most technically sound MES implementation can fall short if users are not fully engaged. A robust management strategy, featuring role-specific training, super-user networks, and clear communication of MES benefits, is essential.

In good manufacturing practice (GMP) environments, usability is especially critical. Technologies like voice recognition and augmented reality (AR) can enhance operator interaction, reduce training time, and improve accuracy[6]. For example, a MES integrated with AR smart glasses could guide operators through step-by-step batch processes hands-free, ensuring compliance while reducing errors and speeding execution.

Industry reports show that pharmaceutical companies adopting MES have achieved notable gains in GMP compliance, with maturity scores rising from levels 1–2 to levels 4–5 on a five-point scale within just three years of implementation.[1]

Case study

Biologics manufacturer: Application support services

Sustaining MES value through smart support and optimization

A biologics manufacturer implemented a comprehensive application support model covering 31 systems, including MES, LIMS, and other digital manufacturing tools. The support structure included 24/7 Level 1 and Level 2 services, incident and problem management, root cause analysis, and continuous service improvements. Monthly volumes included over 140 incidents and 260 service requests; all tracked through SLA-based reporting.

The support model incorporated minor enhancements, automation accelerators, and proactive issue resolution, enabling the MES to remain aligned with evolving operational needs. This approach helped avoid the common post-go-live plateau and ensured the system continued to deliver measurable value over time.

3 Data governance and seamless integration

MES must operate as a central node in the digital manufacturing ecosystem, not as a siloed application. Strong data governance ensures traceability, consistency, and contextualization across systems. Integration with ERP, LIMS, QMS, and IoT platforms, using standard APIs, OPC-UA protocols, and unified namespace architectures, enables real-time visibility, predictive analytics, and advanced capabilities like digital twins.

4 Scalable, future-ready architecture

To futureproof MES, ERP and other critical systems, organizations should adopt modular, cloud-native platforms with containerized deployment and low-code extensibility. This approach supports rapid rollout, reduces infrastructure costs, and enables site-specific customization without compromising global standards.[2] This helps MES avoid common challenges related to scalability and adaptation.

5 Centralized governance

A mature governance model also includes a lean, centralized team or Change Control Board responsible for overseeing MES evolution, maintaining version control, and ensuring strategic alignment. This group ensures that changes are harmonized across sites, aligned with the global functional core model, and evaluated not just for compliance, but for business value. This shift is essential for ensuring MES remains a living, strategic asset.

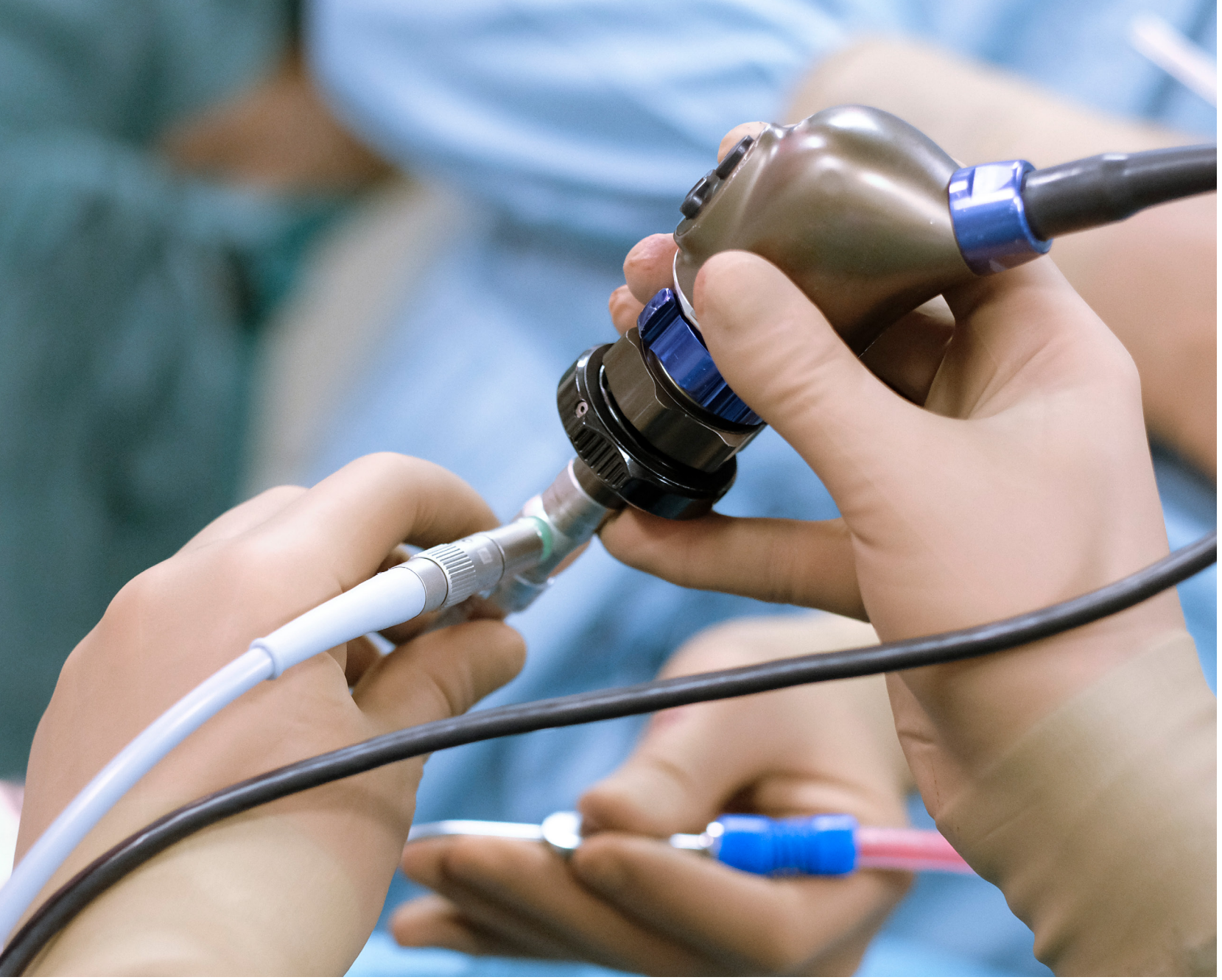
Case study

Network control tower for biologics

Turning complexity into clarity with real-time visibility

A biologics manufacturer with a rapidly expanding R&D and manufacturing network developed a digital control tower to coordinate operations across internal and external production nodes. The solution provided real-time visibility, predictive analytics, and decision support for technical transfers, capacity planning, and product launches.

The control tower design accounted for varying levels of digital maturity across sites and CMOs, using standardized data models and integration protocols. MES data was integrated in the architecture design with ERP, QMS, and LIMS systems to enable consistent, high-quality data flows and support network-wide orchestration.



Case study

Global eBR transformation

Scaling MES across 52 sites through standardization

A top 5 pharmaceutical company executed a global MES transformation across 52 sites in two years. The program used a centralized MES factory model to accelerate configuration, deployment, and validation. Key components included machine connectivity audits, SOP updates, operator training, and a harmonized governance structure.

The architecture supported rapid rollout through standardized templates and offshore development, while allowing site-specific configuration. This approach reduced deployment timelines and verification overhead, while also ensuring consistent compliance, improving system reliability, and enabling faster realization of MES value across all sites.

What's next: Unlocking a new era of pharma manufacturing with next-gen MES

As pharma organizations look beyond stabilization, the next frontier for MES lies in its transformation into a flexible, intelligent, and scalable platform. The MES of the future will not simply support operations, it will anticipate, adapt, and optimize them.[3]

Companies can build MES maturity and adopt these advancing technologies in parallel, ensuring that system capabilities evolve alongside business needs. These innovations are not speculative; they are already being piloted across the industry and will soon define the standard for MES excellence.[4]

Here we explore three key areas of evolution and how they are enhancing value realization in mature pharma organizations.

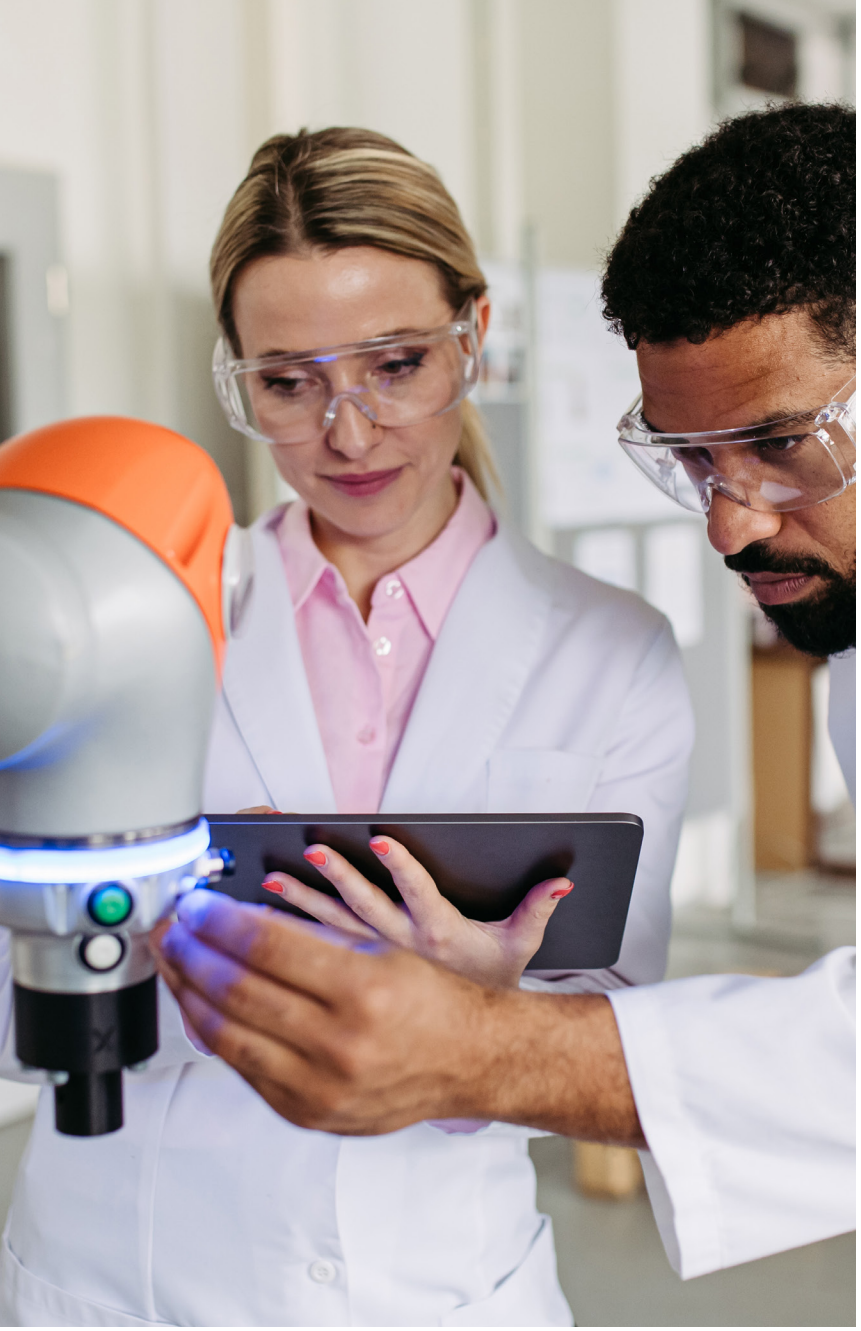
Modular, cloud-native, low-code MES

The next generation of MES will be defined by its architecture: modular, cloud-native, and extensible through low-code platforms. This shift is not just a technical upgrade—it's a strategic transformation that addresses many of the limitations of legacy MES systems.

Traditional on-premises deployments are often rigid, costly to maintain, and difficult to scale across multiple sites. In contrast, cloud-native MES platforms offer centralized management, elastic scalability, and the ability to deploy updates and enhancements with minimal disruption, which is essential for centralized deployment and global harmonization.

Modularity is key to enabling agility. By breaking MES into discrete, containerized components, organizations can implement or update specific functionalities without overhauling the entire system, enabling rapid upgrades and site-specific customization through low-code development environments. This supports faster time-to-value and reduces the burden of validation.

Low-code development environments further enhance flexibility by allowing site-specific functionality to be configured rather than custom-coded. This empowers local teams to adapt MES to their unique needs while also preserving the integrity of a global core model. It also reduces reliance on scarce technical resources and accelerates the pace of innovation.



AI-driven MBR creation and validation

One of the most transformative developments in MES is the integration of artificial intelligence into master batch record (MBR) design, testing, and lifecycle management. Traditionally, MBR creation has been a labor-intensive process, heavily reliant on subject matter experts and prone to inconsistencies across sites.

AI is poised to change that. AI-powered assistants can now support the creation and modification of MBRs by analyzing existing records, applying global design standards, and generating updates based on predefined conditions. These AI tools don't just assist with design, they also perform automated regression testing, simulating both successful and failure scenarios around the clock. This enables faster validation cycles, reduces the burden on QA teams, and improves the consistency and quality of batch records. In the event of a system upgrade or process change, AI can also initiate a regression test, analyze the results, and even suggest corrections, dramatically reducing the time and effort required for revalidation.

The implications are significant: faster time-to-market, reduced compliance risk, and a more agile response to product or process changes. AI-driven MBR management also supports the broader shift toward lean MBR design, where the focus is on harmonization and process quality rather than manual detail entry.

Case study

MES CoPilot: Redefining execution

Accelerating MBR design with AI and automation

To address delays and inconsistencies in MBR development, Capgemini is partnering with manufacturers to pilot an MES CoPilot solution that uses generative AI to create functional specifications and RPA to automate configuration and testing. The solution can reduce reliance on SMEs, standardized input documentation, and enable 24/7 design cycles.

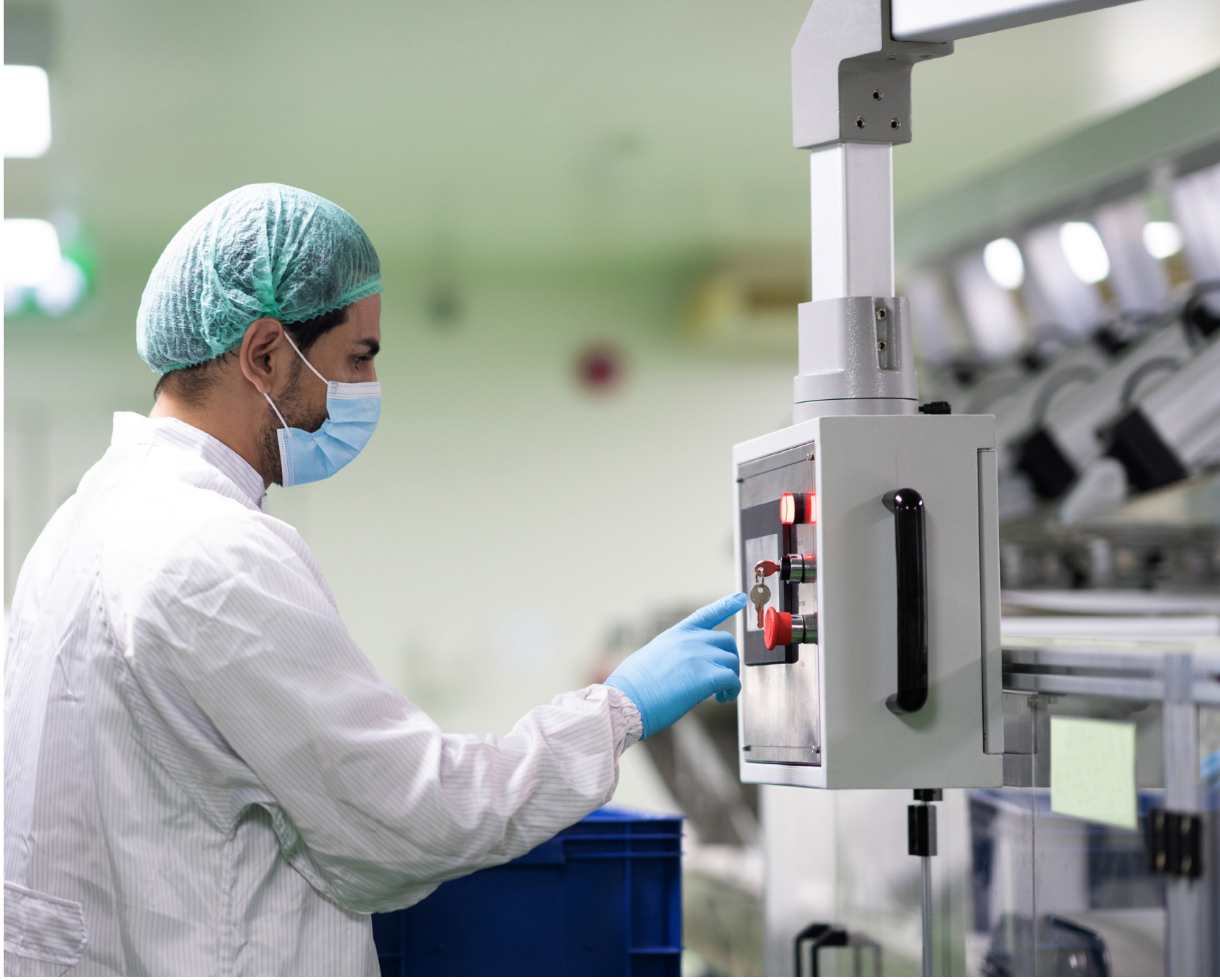
This combination of AI and automation has the potential to shorten MBR lifecycle times, improve design consistency, and reduce manual effort. The approach also supports knowledge reuse and streamlined validation processes.

Digital twins, predictive analytics, and AR/UX

The future of MES is not just smarter, it's more immersive, predictive, and proactive. Digital twins, for example, emerge as powerful tools for simulating production environments and testing process changes before they are implemented on the shop floor. By creating a virtual replica of the manufacturing process, MES can support "what-if" scenario planning, impact assessments, and optimization strategies without disrupting live operations. This capability is especially valuable in highly regulated environments where change carries significant risk.

Predictive analytics, powered by real-time data and AI, will further enhance MES by enabling early detection of anomalies, forecasting deviations, and recommending corrective actions before issues escalate. Industry 4.0 is a concept based on data and MES must evolve from a system of record to a system of insight. This shift transforms MES from a reactive tool into a proactive partner in quality, compliance, and performance.

At the same time, the user experience is undergoing a revolution. Operators in GMP environments face unique challenges, such as gloves, goggles, and protective gear make traditional interfaces cumbersome. Augmented reality (AR) and voice-enabled interfaces offer a solution, projecting instructions, SOPs, and key metrics directly into the operator's field of view. These technologies not only improve usability but also reduce training time and error rates. In the MES of the future, the interface will adapt to the user, not the other way around.



From system stabilization to sustained value creation

5 strategic recommendations to accelerate MES maturity and drive continuous value

For pharma leaders, the post-implementation phase of MES is a critical window of opportunity, one that requires deliberate prioritization to ensure long-term success. Here is where leaders should focus to generate the most value from their system today and ensure future returns.

1 Shift the mindset from project completion to value realization.[5]

MES is no longer just about executing instructions, it's about enabling flexibility, scalability, and intelligence. This means moving beyond technical go-live metrics and focusing on those related to business outcomes: reduced batch release times, improved right-first-time rates, fewer deviations, and increased operator productivity. These outcomes should be tracked through clearly defined KPIs and reviewed regularly at the executive level; they should also be used to guide investment decisions, architectural choices, and integration priorities.

2 Align and connect MES with the long-term digital strategy and tech ecosystem.

ensure MES remains a strategic enabler, not just a compliance tool, organizations must align it with their broader digital transformation agenda. This means embedding MES into enterprise-wide initiatives such as Industry 4.0, smart factory programs, and data-driven decision-making frameworks. MES should not operate in isolation; it must be part of a connected digital ecosystem that includes ERP, LIMS, QMS, IoT platforms, and advanced analytics.[6]

3 Establish a governance model that balances global standardization with local flexibility.

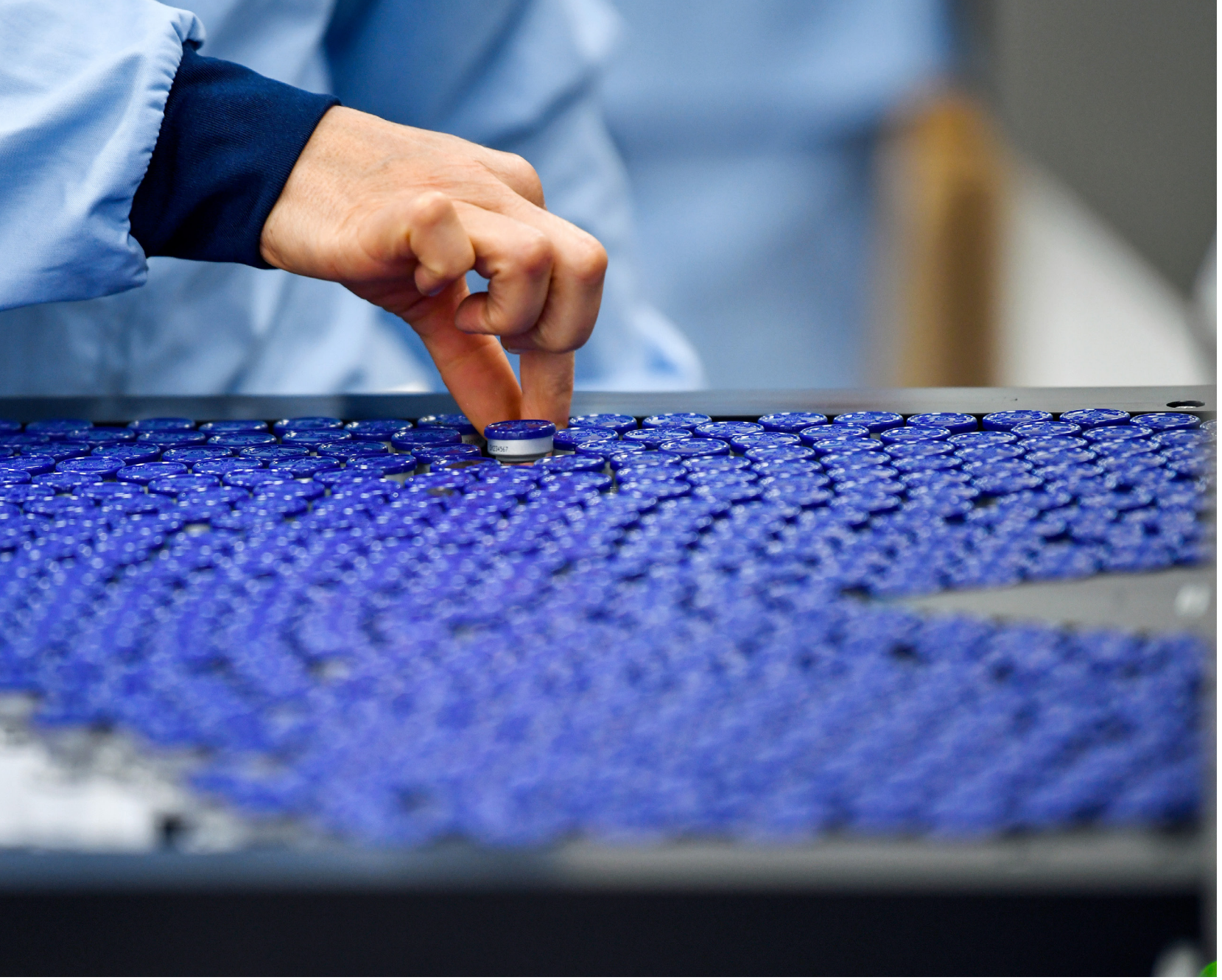
A centralized team should oversee the core MES solution, supported by a cross-functional CCB that includes representatives from production, quality, IT, and site operations. This structure ensures that enhancements are aligned with strategic goals and implemented consistently across sites.

4 Prioritize investments in MES usability and integration.

As the pace of innovation accelerates, the organizations that succeed will be those that stay ahead of the technology curve, treating MES not as a static system, but as a continuously evolving platform for digital transformation.[2] This includes enabling seamless data flow across systems, adopting low-code platforms for rapid configuration, and exploring technologies like AR and AI to enhance the user experience and system intelligence.

5 Foster collaboration across functions to unlock the full potential.

Aligning MES with digital strategy requires cross-functional collaboration. IT, manufacturing, quality, and business leaders must work together to ensure MES capabilities are prioritized based on business value, not just technical feasibility. This includes adopting modular, cloud-native platforms that can scale with the business, leveraging AI to automate routine tasks, and ensuring that MES data feeds into enterprise analytics platforms.



Case study

Building the Future of MES

Advancing CAR-T manufacturing with next-gen MES

A global biopharma company launched a next-gen MES initiative to digitize CAR-T and engineering processes as part of its 2030 vision. The program included modular MES deployment, integration with smart factory accelerators, and the creation of a global MES and MBR factory.

The initiative began with a single MBR modeling resource and expanded to a global, multi-partner team supporting both base business and innovation programs. The MES was aligned with enterprise-wide Industry 4.0 goals and supported by AI, low-code platforms, and global delivery models.

The shift from implementation to innovation

While MES implementation is a significant milestone, the real opportunity lies in what comes next: transforming MES from a transactional system into a platform for innovation.

This shift requires a fundamental change in mindset: MES should no longer be viewed as a static tool for enforcing compliance, but as a dynamic engine for operational excellence, continuous improvement, and digital transformation.

Companies must also recognize that innovation in MES is not limited to technology—it also involves rethinking how the system is governed, used, and evolved. This is critical for ensuring that MES supports new requirements, as opposed to simply reflecting old ones.

As pressure mounts for organizations to accelerate time to market, lower costs and support more personalized medicines, MES holds great potential for value creation. Organizations that succeed in this landscape will be those that embed MES into their strategic planning, invest in user experience, and continuously align the system with emerging business needs.

It's time to embrace the future of MES. The tools are available. The vision is clear. The opportunity is now.

Ready to unlock the next era of pharma manufacturing? Capgemini can help.

Capgemini is an end-to-end transformation partner that works with pharma organizations to assess their current MES maturity, identify gaps in value realization, and define a roadmap for future capabilities. This includes investing in scalable architectures, embracing AI and automation, and fostering a culture of digital ownership across functions. It also means breaking down silos between systems, teams, and sites, to create a truly integrated digital manufacturing ecosystem.

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Capgemini is a global business and technology transformation partner, helping organizations to accelerate their dual transition to a digital and sustainable world, while creating tangible impact for enterprises and society. It is a responsible and diverse group of 340,000 team members in more than 50 countries. With its strong over 55-year heritage, Capgemini is trusted by its clients to unlock the value of technology to address the entire breadth of their business needs. It delivers end-to-end services and solutions leveraging strengths from strategy and design to engineering, all fueled by its market leading capabilities in AI, cloud and data, combined with its deep industry expertise and partner ecosystem. The Group reported 2024 global revenues of €22.1 billion.

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