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360° Connectivity

THE KEY TO THE SMART FACTORY

in the Life Sciences Industry

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360° CONNECTIVITY – THE KEY TO THE SMART FACTORY IN THE LIFE SCIENCES INDUSTRY

1 WHERE IS THE LIFE SCIENCES INDUSTRY HEADED?

Manufacturing in the pharmaceutical industry is undergoing significant transformations, driven by novel therapies, technological advancements and evolving regulatory requirements.
The life sciences (LS) sector as a whole is experiencing a shift due to the rise of personalized medicine, biologics, digitalization, regulatory compliance, and the need for supply chain resilience. To stay competitive in this evolving healthcare landscape, manufacturers must adapt to these megatrends by embracing innovation, investing in advanced technologies, and implementing agile manufacturing strategies.

The increasing prominence of biologics and biosimilars marks a shift towards complex molecules derived from living organisms. Unlike traditional small-molecule drugs, biologics require specialized manufacturing processes, such as cell culture and purification techniques. This shift necessitates investment in advanced manufacturing technologies, stringent quality control measures, and highly trained personnel to ensure product safety and efficacy.

The shift towards personalized medicine, fueled by advancements in genomics and biotechnology, has created a demand for more flexible manufacturing processes. Traditional mass production models are being replaced by smaller, more targeted production runs tailored to specific patient populations. As a result, manufacturing facilities must adapt to smaller batch sizes, increased automation, and more efficient change-over procedures.

The adoption of digital technologies and Industry 4.0 principles is a key driver behind some of these changes, simultaneously revolutionizing pharmaceutical manufacturing. Real-time monitoring and data analytics enable manufacturers to optimize processes, improve product quality, and ensure regulatory compliance. Automation, robotics, and artificial intelligence are being integrated into manufacturing operations to streamline production, reduce human error, and increase efficiency.

Sustainability is also becoming a key focus, with companies striving to reduce their environmental impact by adopting green practices and minimizing waste.
Additionally, the integration of **digital solutions**, such as Artificial Intelligence and Machine Learning, is revolutionizing drug development and manufacturing processes, enabling faster and more efficient operations. In the life sciences industry, the shift towards paperless manufacturing

represents a move to digitize and automate processes, improving efficiency, compliance, and quality while reducing reliance on paper-based documentation. Achieving paperless manufacturing requires the integration of various technical components and systems, including IT (Information Technology) and OT (Operational Technology) systems, to create a fully integrated and connected factory environment.

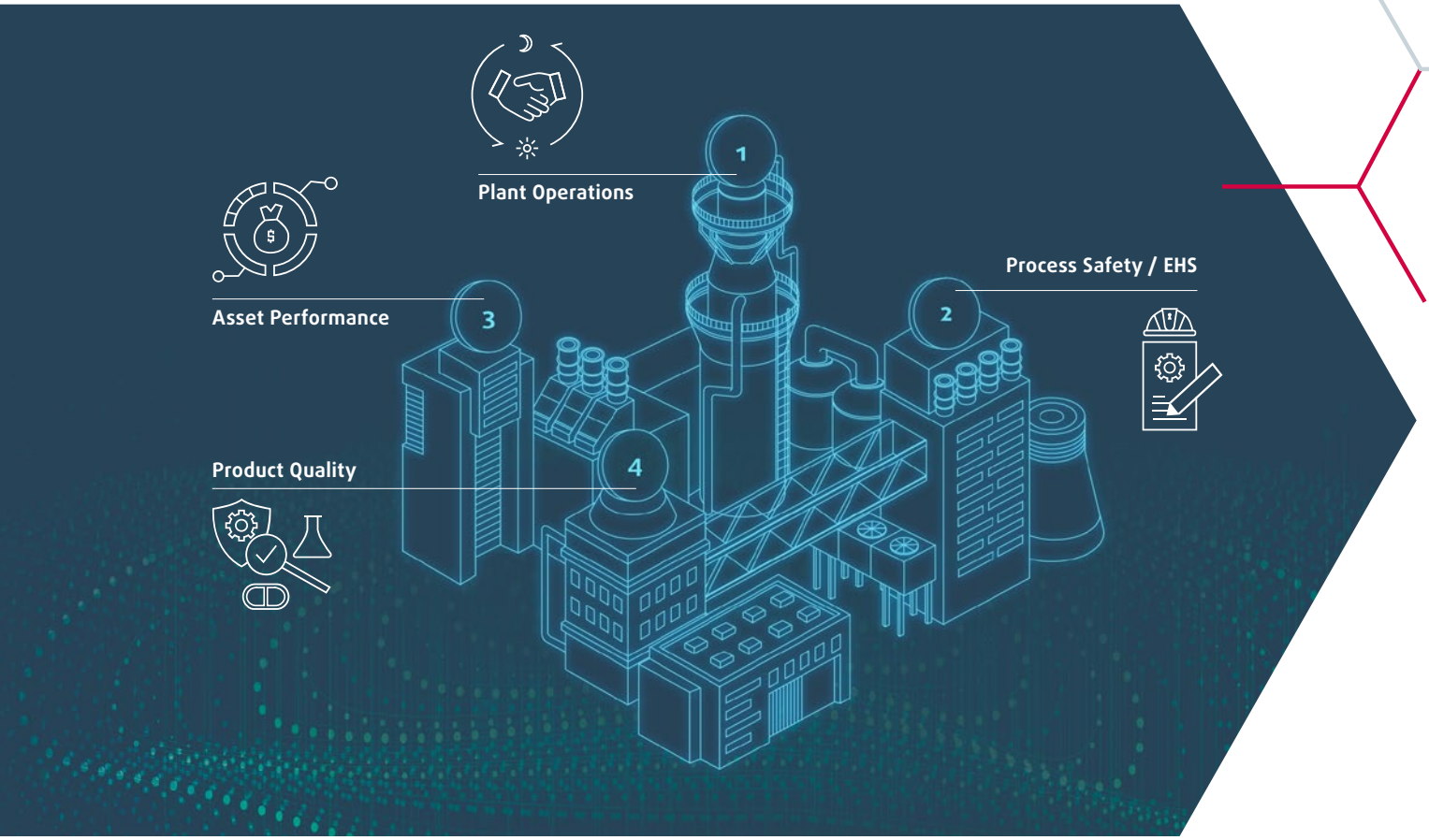
CDMOs are on the rise. Contract Development and Manufacturing Organizations (CDMOs) have become pivotal players in addressing the increasing complexity of drug development, and the need for speed in bringing innovative therapies to market. With their expertise and dedicated infrastructure, CDMOs offer the necessary capabilities to handle complex manufacturing processes. By outsourcing to CDMOs, Marketing Authorization Holders (MAHs) can leverage specialized skills and technologies without requiring significant capital investment. CDMOs provide a cost-effective alternative by offering scalable services that can be tailored to the specific needs of each project. This flexibility is particularly valuable in an industry where demand can be uncertain and the ability to scale production up or down is crucial. For MAHs, partnering with CDMOs allows them to optimize resources, reduce overhead costs, and focus on their core competencies, such as R&D and commercialization.

2 THE CHALLENGE FOR MANUFACTURING

Biopharmaceutical manufacturing faces unprecedented challenges. Novel therapies like Advanced Therapy Medicinal Products (ATMPs) offer totally new treatment options such as gene therapy, cell therapy, and tissue engineering. Treatments like GLP-1 receptor antagonists promoting weight loss and successful diabetes management promise skyrocketing sales. But they are sensitive therapies which require **specialized production processes, further emphasizing the need for flexible manufacturing capabilities.**

Pharmaceutical and biotech companies are under **pressure to reduce costs,** especially with the rising costs of drug development and the pressure to deliver affordable medicines. On the other hand, the costs of raw materials, labor, regulatory compliance, and maintaining state-of-the-art facilities are increasing.

Pressure on CDMOs is especially high. They must manage significant complexity – not only due to the number of clients with different products, but also due to the high complexity of biologics and personalized medication. Their clients expect them to deliver cost-efficient solutions as well as high quality, fast turnaround times, and flexibility. Meeting these expectations while maintaining profitability is challenging.



The concept of the **Smart Factory,** as defined by standards like ISA-95 (International Society of Automation) and MESA (Manufacturing Enterprise Solutions Association), emphasizes the integration of IT and OT systems to create a fully connected and automated manufacturing environment. Industry 4.0 principles advocate for the use of digital technologies such as IoT, cloud computing, and AI to enable real-time data exchange, interoperability, and autonomous decision-making.

In the context of pharmaceutical manufacturing, a Smart Factory integrates digital technologies such as the Internet of Things (IoT), sensors, and automation to create interconnected systems that can monitor and control the entire manufacturing process in real time. For biologics and personalized medicine, where precise control and monitoring are paramount, Smart Factories enable scientists and engineers to track critical parameters at every stage of production. This real-time data allows for proactive identification of deviations and immediate corrective actions, leading to improved process efficiency and product consistency.

A fully integrated and connected factory leverages digitalization to streamline communication and collaboration across interdisciplinary teams, from R&D and manufacturing to quality assurance and supply chain management. By breaking down silos and sharing real-time data and insights, organizations can improve decision-making, accelerate innovation, and respond more effectively to market demands and regulatory changes.

In pharmaceutical and biologics manufacturing, where complex workflows and collaborations are common, connected plants enable the sharing of data, insights, and best practices in real-time, regardless of geographic location. This connectivity facilitates collaboration, accelerates decision-making, and enhances operational agility, ultimately driving innovation and improving the time-to-market for new therapies.
A connected plant leverages digital platforms and cloud-based solutions to seamlessly integrate data from various sources across different manufacturing sites and supply chain partners.

A skilled workforce has become an increasingly scarce resource. The pharmaceutical industry requires highly specialized knowledge and extensive experience, as pharmaceutical manufacturing is a high-stakes activity. Mistakes can result in significant financial losses, regulatory penalties, and, most importantly, harm to patients. This high level of responsibility necessitates a workforce that is not only skilled, experienced and reliable, but also has access to the information required to perform their jobs effectively.

Employers are facing labor shortages in disciplines critical to the pharmaceutical industry, as well as retention challenges. Specialized workers tend to seize better career opportunities and change jobs more often than in the past. As a result, invaluable expert knowledge and experience are often lost. And still, the need for **regulatory compliance and patient safety** is paramount.

3 360° CONNECTIVITY ENABLED BY A PLANT PROCESS MANAGEMENT SYSTEM

Why 360° Connectivity?

Traditional manufacturing methods, while robust, often struggle to keep pace with developments in modern healthcare.

All components that support a digitalized manufacturing process – ERP, MES, LIMS, equipment, instruments, and also operators - require and generate vast amounts of information and data. However, these elements are very often not part of a holistic integration concept, meaning that critical data is not always available where and when it is needed.

The key challenge lies in **delivering the right information to the right people at the right time.** This is essential not only for optimizing production but also for enabling quick, accurate decisions, ensuring that patient safety and product quality are never compromised.

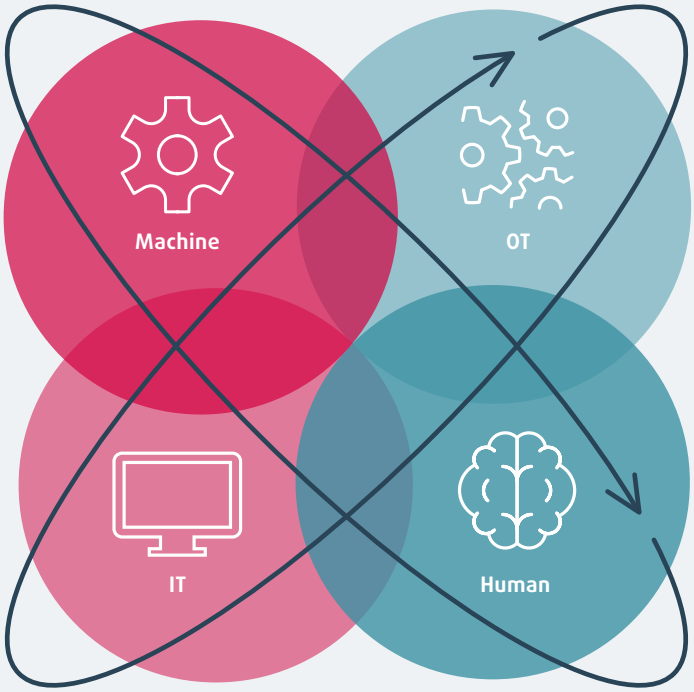
At the heart of this digital transformation is a 360° connectivity that is enabled by a Plant Process Management (PPM) solution – a holistic integration model that connects IT systems, machines, and human operators. PPM systems help manage, monitor, and optimize plant operations and production assets by providing a real-time view of work progress and tracking the status of any incidents or deviations from routine operations. This seamless integration ensures that employees, particularly those working in manufacturing, are made aware of priorities and any issues that may have occurred during previous shifts, enhancing communication, safety, quality, and productivity.

IT-to-Machine Integration: Real-time data exchange between IT systems and machines enables predictive maintenance, reducing downtime and increasing productivity.

Machine-to-Machine Communication: Automated processes where machines communicate with each other allow for synchronized production, reducing errors and waste.

Human-to-Machine and Human-to-IT Interaction: Empowering operators with real-time data and actionable insights enhances decision-making and operational efficiency.

Human to Human Communication: With increasing complexity, the seamless collaboration of different expertise between workers becomes vital and is a competitive advantage in manufacturing.



This integrated approach of 360° connectivity is enabled by PPM systems and not only supports operational excellence but also aligns with the industry's stringent regulatory requirements.

Operator Empowerment in the Digital Age

Despite the influx of technology, the role of the human operator remains crucial. Operators are no longer just task executors; they are becoming decision-makers supported by real-time data and AI. This shift towards operator empowerment is essential for maintaining control over increasingly complex manufacturing processes.

However, this evolution comes at a time when a specialized workforce has become an increasingly rare and valuable resource. The industry faces significant challenges in retaining knowledge, as frequent job changes among skilled workers and brain drain are common. Consequently, it's more critical than ever to ensure that **implicit knowledge is converted into explicit knowledge,** meaning the expertise of these operators is captured and retained within the company's systems.

Right Information, Right People, Right Time:

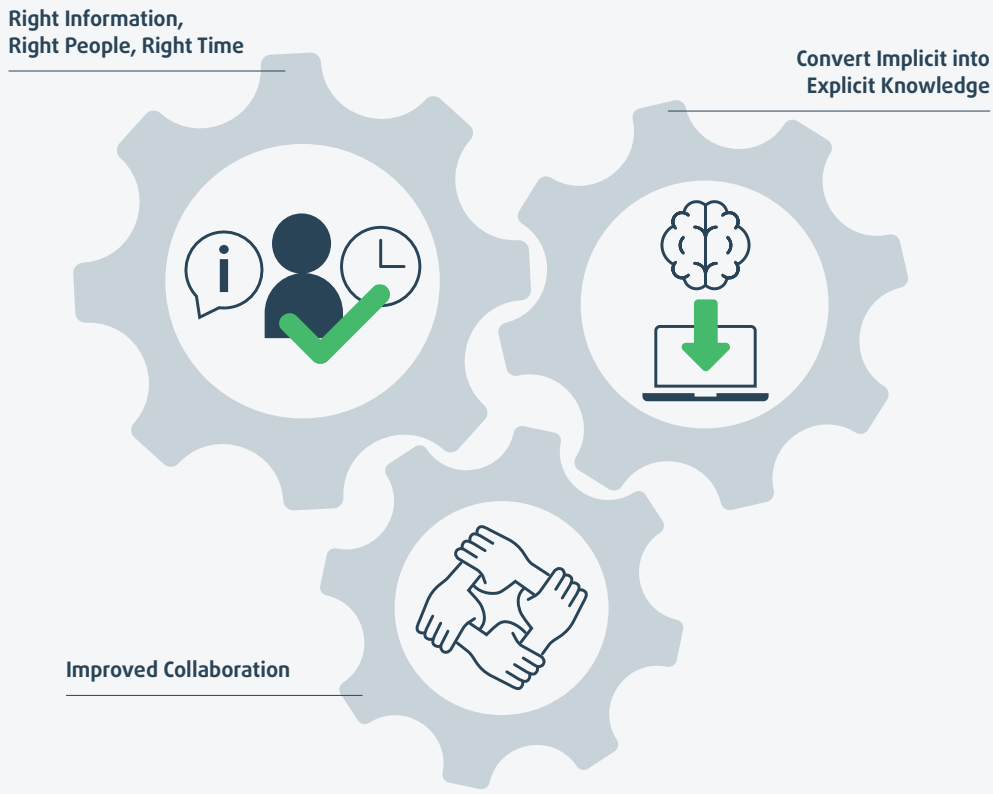
Ensuring operators have access to relevant information at the right time is critical. This approach reduces the cognitive load on operators, minimizes errors, and allows them to make informed decisions quickly. AI is empowering operators to make better decisions.

Convert Implicit into Explicit Knowledge:

By embedding essential information stored in operators' minds into systems, companies can ensure that even as the workforce changes, the expertise remains accessible, preserving operational continuity and quality.

Improved Collaboration:

Connectivity fosters better collaboration across teams, departments, and even across geographic locations. As operators are empowered with the right tools and information, they can communicate more effectively, share insights, and work together to solve complex problems. This not only enhances productivity but also helps mitigate the impact of workforce turnover by enabling seamless knowledge transfer and collective problem-solving.



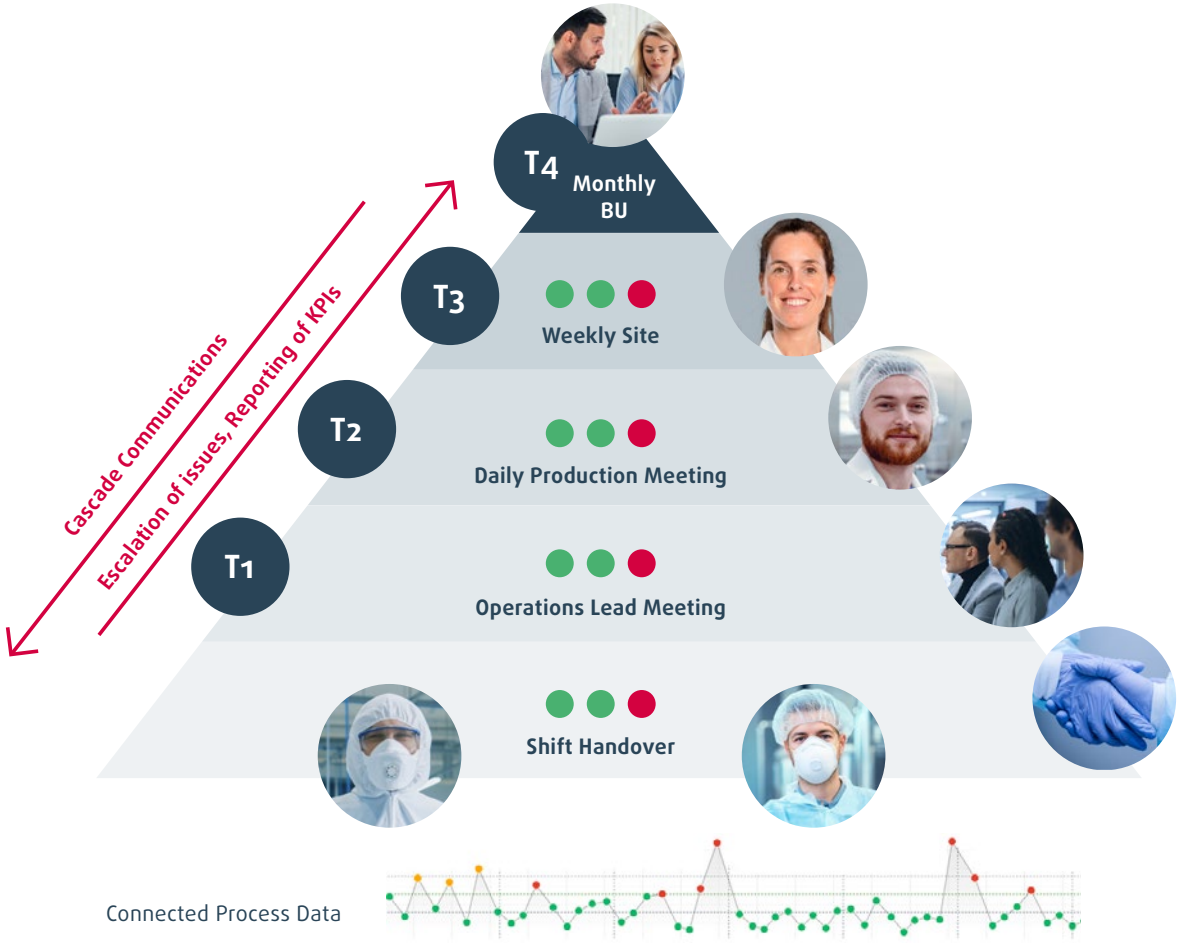
Empowering operators is not just about enhancing individual performance, but also about safeguarding the accumulated expertise and providing them with this knowledge when it is needed. By doing so, companies can navigate the challenges of a dynamic workforce while maintaining the high standards required in modern manufacturing environments.

Daily Management and Decision-Making

In the era of digitalization, daily management has evolved. Managers are now equipped with real-time dashboards, AI-driven analytics, and predictive insights, which enable proactive decision-making. This shift from reactive to proactive management ensures that potential issues are addressed before they escalate.

By leveraging predictive decision-making based on existing data from integrated systems, operators can anticipate potential issues, optimize processes proactively, and ensure smoother operations. In this context, AI acts like a process expert that guides and offers the right advice.

A PPM system digitizes shift handover activities and creates a rich historical archive with many years of collected data. However, it is difficult for operators to find relevant and usable information when it's needed. That's where AI can help. Leveraging AI-driven tools such as Smart Search, which retrieves relevant results from organizational knowledge and offers suggestions for issue resolution, significantly enhances performance.



How tier dashboards streamline manufacturing operations

A digital tier collaboration dashboard can streamline operations, improve communication, and enhance overall productivity in a pharmaceutical manufacturing environment.

Problem: During a campaign, a shift operator notices an unwanted situation in the production process that would delay the completion of the batch and the overall performance.

Using a digital tier collaboration dashboard, an operator logs the observation in the digital system, which is instantly visible to all relevant teams. In real-time, an alert is sent to the quality control team and the next shift. Teams can collaborate through the dashboard to discuss the issue, propose solutions, and implement corrective actions quickly. The dashboard tracks the issue's resolution progress and generates reports for compliance and continuous improvement.

PPM in Context of ERP, MES and Shop Floor Automation

The implementation of a PPM system must be understood within the broader context of existing manufacturing systems such as Manufacturing Execution Systems (MES), Enterprise Resource Planning (ERP) systems, and Level 2 automation systems (SCADA, Process Historian).

MES Integration: MES systems are central to the Smart Factory, providing the link between the shop floor and enterprise systems. A PPM-system enhances MES capabilities by integrating it with real-time data from machines and operators.

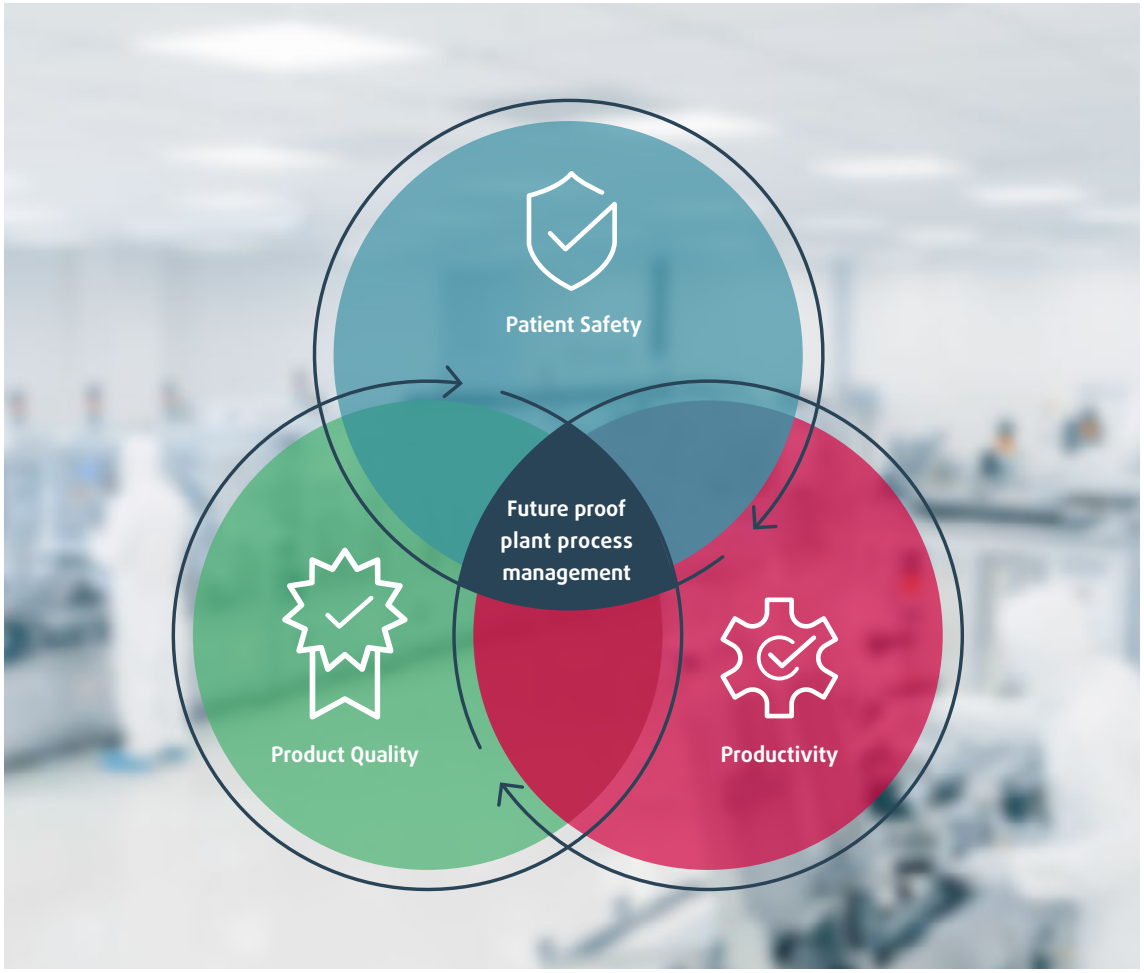
ERP Systems: ERP systems benefit from enhanced data flow from the shop floor, allowing for more accurate forecasting, inventory management, and supply chain optimization.

L2 Systems (SCADA, Process Historian): Level 2 systems provide the control and automation layer in manufacturing. PPM systems ensure these systems are not isolated but are part of the broader information ecosystem, enhancing overall efficiency and control.

PPM systems play a crucial role in providing 360° connectivity while unifying and enhancing the functionality of existing manufacturing systems like MES, ERP, and Level 2 systems. By seamlessly integrating real-time data across these platforms, it creates a more efficient, responsive, and cohesive manufacturing environment that also allows for predictive planning and decision-making.

Impact on Patient Safety, Product Quality, and Productivity

The ultimate goal of 360° Connectivity is to ensure that every aspect of the manufacturing process contributes to patient safety, product quality, and productivity.



Patient Safety: Real-time monitoring and predictive analytics allow for immediate response to out-of-specification events, ensuring that only the highest-quality products reach the patient.

Product Quality: Consistent, high-quality production is maintained through enhanced process control, reduced variability, and real-time quality assurance.

Productivity: The reduction of downtime, waste, and errors leads to higher productivity, enabling manufacturers to meet the increasing demand for biopharmaceutical products.

The Benefits of 360° Connectivity Enabled by PPM

Transparency and end-to-end visibility are among the most significant benefits of PPM solutions. By breaking down silos and ensuring that information flows freely across the organization, manufacturers can achieve greater operational efficiency, better compliance, and faster response times to market changes.

Enhanced Compliance: Real-time data and traceability ensure that all regulatory requirements are met, reducing the risk of non-compliance.

Product Quality / Patient Safety: By optimizing processes and enhancing decision-making, manufacturers can significantly improve the quality and consistency of their products. This not only ensures higher standards but also promotes patient safety across the board.

Sustainability: Increased efficiency and reduced waste contribute to more sustainable manufacturing practices, aligning with the industry's growing focus on environmental responsibility.

4 EMBRACING THE SMART FACTORY

As the biopharmaceutical industry continues to evolve, embracing 360° Connectivity is not just an option — it is a necessity. Companies that invest in this holistic approach will be better positioned to meet the challenges of modern manufacturing, ensuring that they remain competitive in an increasingly complex and demanding market.

One of the key measures to mitigate cost pressure and manage complexity is to invest in digitalization. This includes transitioning from expensive, on-premises IT operations to cloud-based solutions, which, if implemented correctly, can yield significant cost benefits in both the short and long term. Cloud-based systems can reduce operational costs by eliminating the need for extensive in-house IT infrastructure and maintenance, enabling companies to allocate resources more efficiently.

However, this shift brings with it a new set of challenges.

Is Your Organization Mature Enough for Digitalization?

A fully integrated, connected factory relies heavily on IT infrastructure and service providers. This dependency raises concerns about the reliability and security of these systems. Cyber threats, service outages, and technical issues with IT providers can disrupt manufacturing operations, potentially leading to significant downtime and financial losses.

Therefore, companies must carefully evaluate whether they are ready and mature enough to entrust critical business operations to an external IT cloud and services company.

Building a robust digital architecture requires a thoughtful approach to ensure both maturity and resiliency. **Organizations must develop a digital strategy that not only leverages the benefits of cloud computing but also safeguards against potential risks.** This involves creating a resilient system architecture that can withstand disruptions and maintain operational continuity.

Furthermore, the organization itself must mature alongside its digital infrastructure. This means developing a culture that prioritizes risk management, continuous improvement, and strategic planning. **Resiliency isn't just about preventing systems from going down; it's also about having a comprehensive business continuity plan in place for when they inevitably do.** Companies must ensure that their disaster recovery protocols are robust and well-practiced, with clear procedures for minimizing downtime and mitigating the impact on production.

In conclusion, while the move towards digitalization and Plant Process Management solutions offers significant advantages, it also requires careful consideration and preparation. By building a mature, resilient digital architecture and ensuring organizational readiness, biopharmaceutical companies can navigate the complexities of modern manufacturing, stay competitive, and continue to deliver safe, high-quality products to the market. Furthermore, the operator must be an integral part of this digital architecture, as their expertise and decision-making are crucial to fully realizing the potential of these advanced systems.

5 EMBARKING ON THE DIGITAL JOURNEY

Setting out on the road towards a smart factory requires a critical first step: assessing your digital maturity. Understanding where your company stands today in terms of digital capabilities is essential for charting the course ahead. This assessment is not just about recognizing the technology you currently have in place, but also about identifying the level of digital maturity you need to achieve in order to successfully transition to a smart factory.

Digital Maturity Assessment

The digital maturity assessment involves a thorough evaluation of your existing processes, technologies, and organizational culture. It asks crucial questions: Where are you today? What are the gaps between your current state and the desired state of digitalization? This assessment helps you understand the starting point of your digital journey and what is required to move forward.

By identifying your current level of digital maturity, you can determine the extent to which your operations are already digitized and how much further you need to go. This step is essential because the goal is not simply to achieve 100% digitalization but to reach a level of maturity that aligns with your business needs, risk tolerance, and financial constraints.

The BioPhorum Digital Plant Maturity Model (DPMM) helps you conduct single-plant and manufacturing-network assessments with a high degree of consistency. It describes five maturity levels, ranging from manual paper-based to the fully automated 'adaptive' plant of the future. Find more information about BioPhorum's DPMM here:
https://www.biophorum.com/download/digital-plant-maturity-model-3-0/

Setting Up a Digital Strategy

Once you have a clear understanding of your digital maturity, the next step is to develop a strategy that will guide you towards your smart factory goals. This is where the digital roadmap method comes into play. A digital roadmap is a strategic plan that outlines the steps and milestones needed to advance your digital maturity. It helps you move from your current state to your desired level of digitalization in a structured and phased manner.

Depending on your company's current status, this roadmap will vary. For some, the path may be shorter and more straightforward, while others may require a more gradual approach. **The key is to ask: Where are you now, and do you really need to achieve 100% digitalization immediately?** What level of organizational and technological readiness is necessary to embark on this journey, ensuring that your smart factory is resilient and capable of mitigating risks that could impact both your business and patient safety?

Balancing Ambition With Reality

In simple terms, the question becomes: What is the smart factory that you can afford? For companies operating with squeezed margins or facing the need for additional investments, capital expenditure (CapEx) constraints may be a significant consideration. It is important to determine the minimum viable investment that aligns with your business plan and ambitions. This involves finding a balance between your digital aspirations and the financial resources available.

After establishing your digital ambitions and financial realities, take a reality check. Assess your current maturity level accurately and develop a matching strategy that is both realistic and achievable. This strategy should prioritize investments in areas that will deliver the most significant impact, helping you to gradually build towards your smart factory vision.

A Journey That Can Be Taken Step by Step

Starting the digital journey requires a thoughtful and strategic approach. By conducting a digital maturity assessment, setting up a tailored strategy through a digital roadmap, and balancing your ambitions with financial realities, you can effectively embark on the path to a smart factory. This journey is not just about reaching a destination; it's about ensuring that your operations are resilient, your risks are mitigated, and your business continues to thrive in an increasingly digital world.

6 WHAT ARE THE NEXT STEPS?

After completing your digital maturity assessment, the next steps are to outline clear goals and objectives for the project, including measurable Key Performance Indicators (KPIs). What results does the organization expect to achieve? How will you know you have achieved them?

Be sure to clearly define what the PPM system will do, how workflows will change, and the expected benefits for each stakeholder group. Determine if the needs to be configured are for the entire organization or a local facility. Identify processes that correlate with teams and tasks, resulting in the PPM digitizing and creating workflows within and across several key operations:

1. **Collaboration and Workflow Management:** Creating collaboration between departments such as R&D, quality control, production, and other teams is critical to ensure that all processes are aligned and meet regulatory standards. For example, when digitalizing tier-meetings, the PPM creates a continuous communication flow across teams and provides documentation tracking. In the case of digitalizing finite production scheduling, resource allocation is optimized for each production stage, and downtimes are minimized.

2. **Operational Excellence & Efficiencies:** By maintaining an acute focus on the status of plants and equipment as well as tracking production, pharmaceutical manufacturers can ensure compliance, enhance efficiency, manage costs, mitigate risks, and track KPIs.

3. **Data Analytics and Continuous Improvement:** Data from the control room to the clean room provides essential information for pharma manufacturing operations to implement a continuous improvement process. The implementation of a continuous improvement process helps streamline processes, reduce costs, reduce defects, and helps operations gain a competitive edge.

4. **Compliance & Quality Assurance:** Real-time monitoring and tracking of routine inspections, equipment checks, and MES observations using systems that meet regulatory guidelines from the EMA, FDA and other agencies, keep pharma operations in compliance and ensures quality production results.

Digital Solutions for Pharma Manufacturing

Collaboration & Workflow Mgmt.	Operational Excellence & Efficiency	Data Analytics & Continuous Improvement	Compliance & Quality Assurance
Shift Handover & Night Instructions	Plant & Equipment Status	Continuous Improvement Mgmt.	Equipment Cleaning Use Log (FDA Part 11)
Tier-Meeting Board w. 24/7 Inteaction	Standard Work Mgmt.	Shop Floor Walk Support (Gemba)	Mobile Equipment Tracking
Task Mgmt. & Tracking	Line Loss Accounting & OTD Monitoring	Clean Room & Field Data Acquisition	Line Clearence Checklists (Cleaning...)
Mobile Task Support	Golden Batch Tracking	Manufacturing Data Control Tower	MES / Historian Based Obsevations
Expertise Mgmt.	KPI Mgmt. & Boards (SQPC)	Special Sample Tracking (LIMS Connect)	Routine Inspection Scheduler & Tracking
Finite Production Scheduling	Corrective Maintenance Notifications	Corporate Manufacturing Reporting (OTD, OEE...)	QA Review & Ovesight

Tailoring a PPM system to adapt to the dynamic systems, regulations, and goals of pharmaceutical operations is crucial for a successful digitalization journey.

Explore Our Solutions: Learn more about how our 360° Connectivity services can transform your manufacturing processes.

eschbach: Learn how leading companies in the Life Sciences industry rely on eschbach Shiftconnector for their enterprise-wide Plant Process Management system.

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eschbach, headquartered in Bad Säckingen, Southern Germany, with a subsidiary in Boston, USA, develops software for plant process management. Shiftconnector® provides a new level of team communication to ensure safety and improve plant effectiveness. The award-winning solution is trusted worldwide by leading manufacturing companies such as Bayer, DuPont, BASF and Roche. For more information visit **www.eschbach.com**.

We inspire industrial teams to work smarter.