

HOW A MANUFACTURING EXECUTION SYSTEM SUPPORTS YOUR BUSINESS CONTINUITY DURING AN ACUTE CRISIS

Remote services and digital manufacturing keep your pharma & biotech operations running, even in a situation of severe crisis

MES PROVIDE STRATEGIC RESILIENCE THROUGH FLEXIBILITY AND DIGITIZATION

Business continuity relies on resilience: the ability to successfully deal with crisis situations like COVID-19, to keep core manufacturing and supportive business processes alive and to adapt to new, threatening environmental changes. Pharmaceutical and biotech manufacturers who invest in their resilience gain a competitive advantage over organizations that are less prepared for unforeseen events.

Resilience does not only mean enduring sudden crisis situations. Threatening change tends to unfold much more slowly, like an emerging major competitor, shortage of skilled workers or even global warming. True resilience, in a business context, is "strategic resilience": the capacity to anticipate and adjust, to react quickly to changing conditions, to turn threats into opportunities and to seize those opportunities – in due time, but not in crisis mode.

In this context, Manufacturing Execution Systems (MES) play a pivotal role and prove to be true game changers. **By digitizing production processes, MES provide the basis for the necessary flexible process design and adaptation**, for automated real-time production and quality control, and for fast and informed decision-making – ensuring GMP-compliant production processes from clinical trial to commercial manufacturing.



MES SAVE TIME & EFFORT AND AVOID RISK IN YOUR FACTORY



Enabling remote operations

Digitization not only creates the basis for automation and Pharma 4.0, but also enables remote operations and services in a crisis situation. The online services offered by an MES allow a large part of the workforce to **work remotely and access data from home**. For example, Master Batch Records (MBRs) can be designed, reviewed, tested, verified and approved in a completely remote way. Electronic equipment logbooks are accessible from home. Furthermore, executed batch records can also be reviewed and approved remotely by production personnel and quality professionals from homeoffice using electronic signatures.

In the case of self-inspections or health authority audits, batch records can be quickly accessed in electronic format and presented remotely. It is no longer necessary to waste time searching for indexed paper records in physical archives to find specific documents that inspectors ask for.

Pharma 4.0 automation concepts even enable **"lights-out manufacturing"** minimizing the on-site presence of operators. In this case, the orchestration of production is managed automatically by the MES – including regulatory documentation.

As a matter of course, the MES itself can also be maintained remotely – from implementation to on-going configuration.



MES as a service: remote delivery of manufacturing IT

With MES as a service dedicated providers bring their **MES into the cloud**. Rather than setting up infrastructure locally, pharma and biotech manufacturers can turn this time and resource-consuming responsibility over to the remote MES supplier. The production data is stored in a dedicated data center. Pharma companies can thus focus on their core business – manufacturing vital, often life-saving pharmaceutical products.

MES as a service is a good choice for pharma and biotech companies that are currently unable to implement an MES – for instance, because **access to the facility is limited** or because they don't have any production-grade IT infrastructure in place.

What is MES?

Manufacturing Execution Systems (MES) enable the integrated, detailed, real-time control of a manufacturing process. They act as the central connecting platform between ERP and process control systems (SCADA, DCS). MES in pharma and biotech introduce electronic batch recording to the pharmaceutical production. They take care of batch execution and GMP-compliant documentation of every process step.



Offering remote visibility to processes at a fingertip

With paper-based processes, it is not possible to monitor workflows, detect errors, integrate and share information in real time and ensure data integrity. This makes it difficult to react promptly and appropriately in a crisis situation when certain information is needed quickly and access to premises may be hindered.

In an MES, **critical batch status information is available anytime and anywhere** – with just one click. Continued Process Verification (CPV) as well as Ongoing Process Verification (OPV) enable digital transparency and real-time process control. Moreover, the analysis of the available production data provides valuable insights and allows for near real-time decision support – even remotely. Weak points can be identified and problems can be avoided in advance.



Increasing process efficiency and flexibility

Flexible business processes enable rapid adaptation to changing circumstances. MES increase process flexibility in various ways, for example with regard to supply chains, process design, scheduling and execution, resource management and allocation, or workforce mobility. At the same time, MES reduce dependencies by making **process knowledge available to everyone**. Operators or quality professionals can use online repositories of all relevant data, e. g., for batch record release.

Using MES, business processes ultimately become more efficient. Previous paper-based business processes are not just replicated into an IT application and made digitally available. Instead, these processes and the relevant documentation are thoroughly reviewed, streamlined and may be harmonized to a high extent. This includes process and equipment Standard Operating Procedures (SOPs), quality documents, forms and paper sheets. Automated checks of process steps and sequences, electronic formulas and calculations, automated assignment of process data to process events, electronic attachments from sub-processes, reduction of overall manual entries (i.e., date and time stamps), and review by exception are just some of the evident examples that **leverage process efficiency with MES**. In addition, manufacturing and quality data is permanently examined by the MES for critical process exceptions. Deviations, e. g. out-of-spec production parameters, are automatically detected; only then, manual reviews are necessary.

Doing things right the first time on the shop floor by giving clear, robust and intuitive operator instructions in MES, product throughput times can be significantly optimized and potential write-offs may be avoided. Furthermore, a high MES utilization on the shop floor positively impacts quality performance such as the On Time Batch Approval by faster batch record approvals (review by exception), the Batch Right First Time Rate by robust process execution, and the reduction of product backlogs by avoiding or detecting exceptions on the spot. Also, supply chain metrics like the On Time In Full (OTIF), inventory levels, and stock-out rates may be positively affected by a high MES utilization.





Speeding up time to market

Strategic resilience is as much about mitigating the impact of crisis situations – such as the COVID-19 pandemic – as it is about seizing the opportunities they present. Time to market is crucial here.

MES shorten time to market by providing end-to-end, **integrated knowledge management around the control strategy**, starting in-process development for the drug substance and the drug product via clinical trials up to technology transfer and commercialization. No knowledge from earlier stages will be lost because the manufacturing control strategy is preserved in the electronic MBRs which are developed step-by-step to commercial maturity.

Manufacturers can further shorten time to market by identifying specific MES functions that directly address their biggest pain points. The right MES allows companies introducing it to start with one or a few functions and expand the system later: **“start small, scale up later”** ensures the fastest time to value.

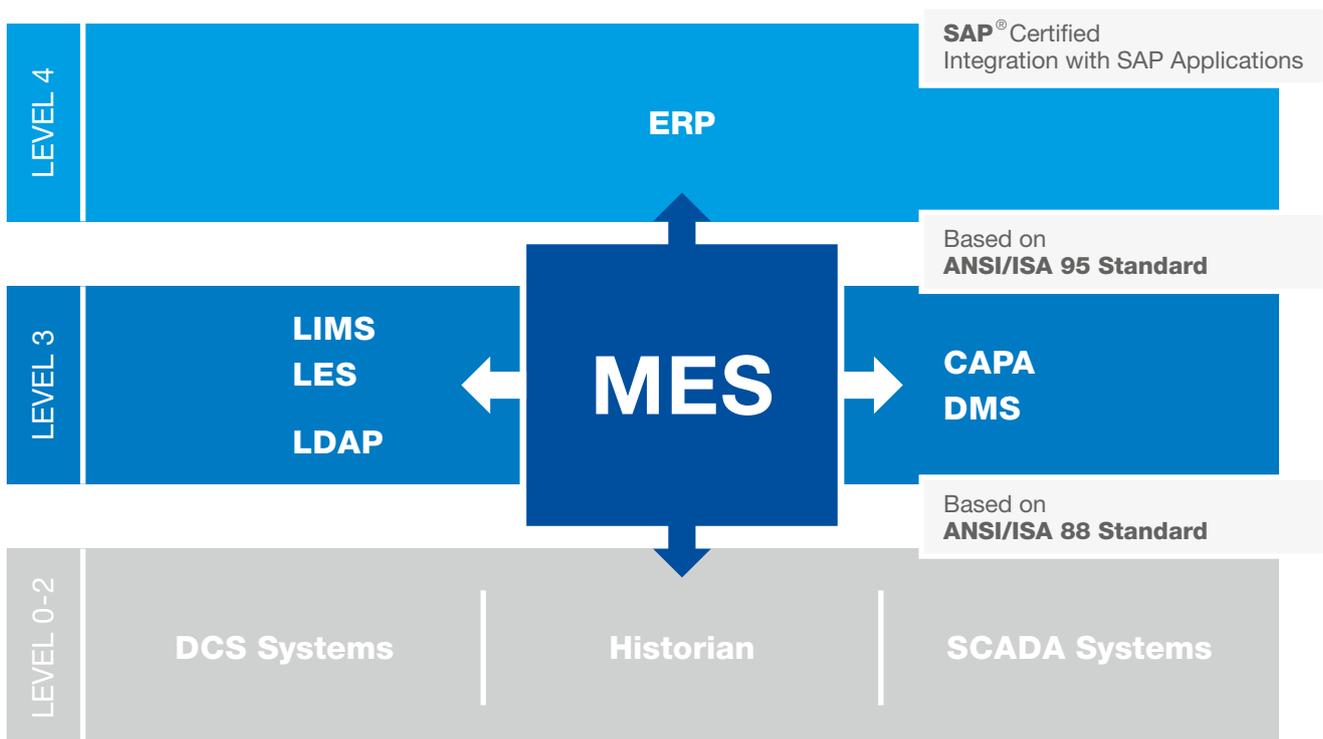


Safeguarding regulatory & patient quality expectations

Especially when it is necessary to react quickly to increased demand, effective quality assurance is essential. Insufficient quality increases production costs and prevents on-time delivery. According to the FDA, quality issues account for two thirds of drug shortages in the U.S.

The **MES helps ensure compliance** with the International Council of Harmonization (ICH) quality guidelines, FDA, EMA and cGMP quality assurance regulations by guiding the operator through approved process steps. It thus reduces repetitive human errors and provides real-time control of Critical Process Parameters (CPPs) by accurate decision-making based on precisely captured shop floor data to control the Critical Quality Attributes (CQAs) during quality-critical process execution.

MES IS THE BACKBONE OF PRODUCTION AND A PREREQUISITE FOR PHARMA 4.0



What is Pharma 4.0

With Pharma 4.0, the focus is no longer on pharma production according to fixed specifications. It is more about an intelligent and networked system for real-time monitoring, simulation and control of manufacturing processes. The basis of all processes is data from interconnected systems. With a high-tech system, the manufacturing processes can constantly adapt themselves and offer a high degree of automation. MES is a prerequisite for implementing various Pharma 4.0 solutions.



Digitizing manufacturing processes

One of the lessons learned from the COVID-19 crisis is that many pharmaceutical and biotech manufacturers must replace paper-based processes in their process development, launch and production facilities with digital processes which have built-in principles of process data lifecycle data integrity. **MES enable the digitization** of production-related processes, thus greatly increasing process transparency, flexibility and speed.

Processes depending on paperwork require the physical presence of documents, available storage capacities, record management systems and people who handle them. Moreover, they have a high data integrity risk. This slows down processes, increases the probability of human error or total loss of a batch record, and impairs production quality and compliance. Digital processes, by contrast, are not only faster, but they can also be **monitored and controlled remotely** and much more efficiently.

CRUCIAL BUILDING BLOCK FOR YOUR BUSINESS CONTINUITY MANAGEMENT

An MES is only one building block for effective business continuity management – but a decisive one. Therefore, it must, of course, be effectively protected against failures. Modern MES systems are able to meet high-availability requirements. They also offer functions for constant remote monitoring, system health checks, and improvement.



ABOUT WERUM IT SOLUTIONS

Werum IT Solutions is the **world's leading supplier of manufacturing execution systems (MES) and manufacturing IT solutions** for the pharmaceutical and biopharmaceutical industries. Its **PAS-X software** product is run by the majority of the world's top 30 pharmaceutical and biotech companies and also by many mid-sized manufacturers. Werum's manufacturing IT solutions help pharma manufacturers to **increase efficiency, improve productivity, and meet regulatory requirements.**

Founded in 1969, Werum is headquartered in Lüneburg, Germany, and has many locations in Europe, America, and Asia. Werum is part of Medipak Systems, the Pharma Systems business area of the international technology group Körber with around 10,000 employees all over the world.

www.werum.com

GLOBAL HQ

Werum IT Solutions GmbH, Germany
Wulf-Werum-Str. 3 · 21337 Lüneburg, Germany
T +49 4131 8900-0 · www.werum.com
info@werum.com

ASIA PACIFIC HQ

Werum IT Solutions Ltd., Thailand
Liberty Square Building, 14th FL.
Unit 1405, 287 Silom Rd.
Silom, Bangrak, Bangkok 10500, Thailand
T +66 2 0205720 · www.werum-asia.com
info@werum-asia.com

NORTH AMERICA HQ

Werum IT Solutions America, Inc.
5 Sylvan Way · Parsippany, NJ 07054 · USA
T +1 973 644 4000 · www.werum-america.com
info@werum-america.com

LATIN AMERICA HQ

**Werum IT Solutions represented by
Körber Medipak Systems América Latina**
Edifício Corporate Plaza
Rua Alexandre Dumas, 2100 – 1º andar
Chácara Santo Antônio São Paulo, SP 04717-004, Brazil
T +55 11 4349-0100 · www.werum.com.br
info@werum.com



IMPRINT: Werum IT Solutions GmbH (Global HQ) · Wulf-Werum-Str. 3 · 21337 Lüneburg · Germany
T +49 4131 8900-0 · F +49 4131 8900-200 · info@werum.com · www.werum.com

