

TECHNICAL GUIDE

# Advanced MES Critical Capabilities for Medical Devices

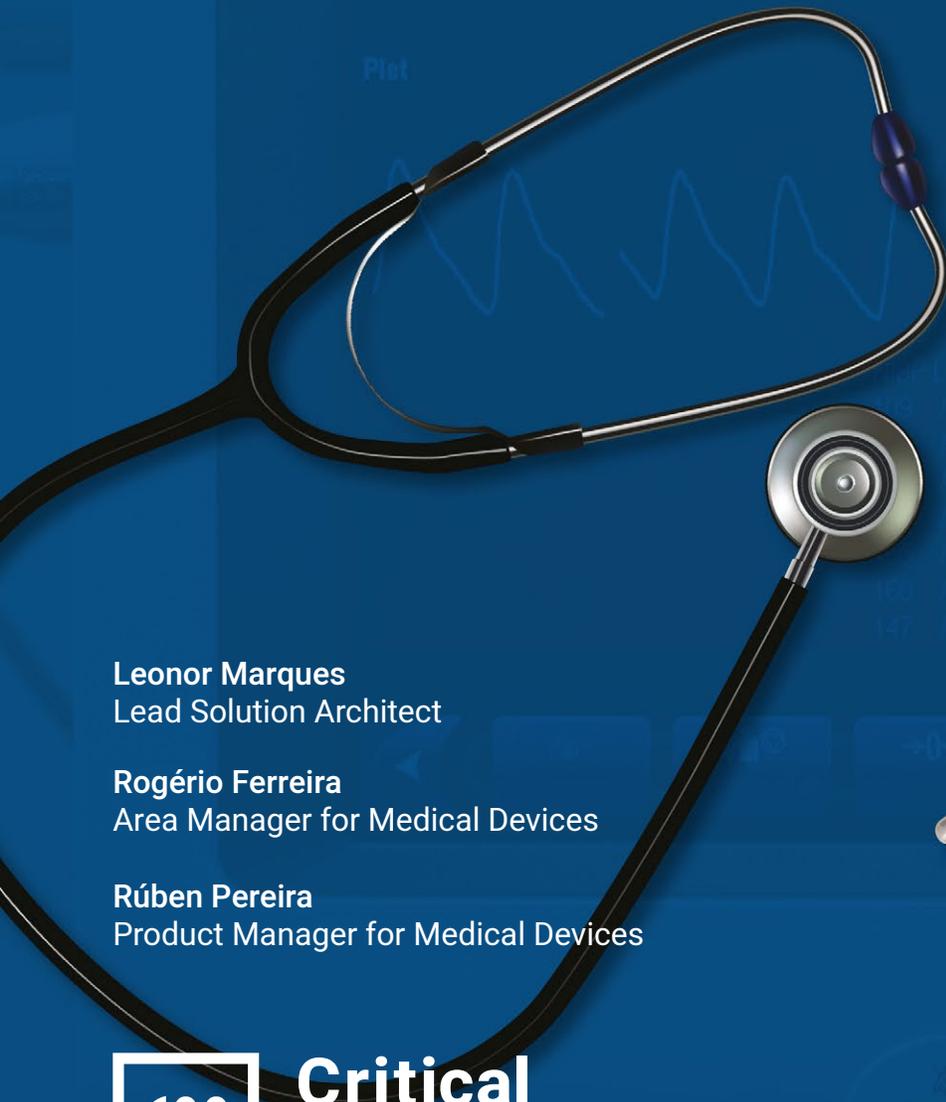
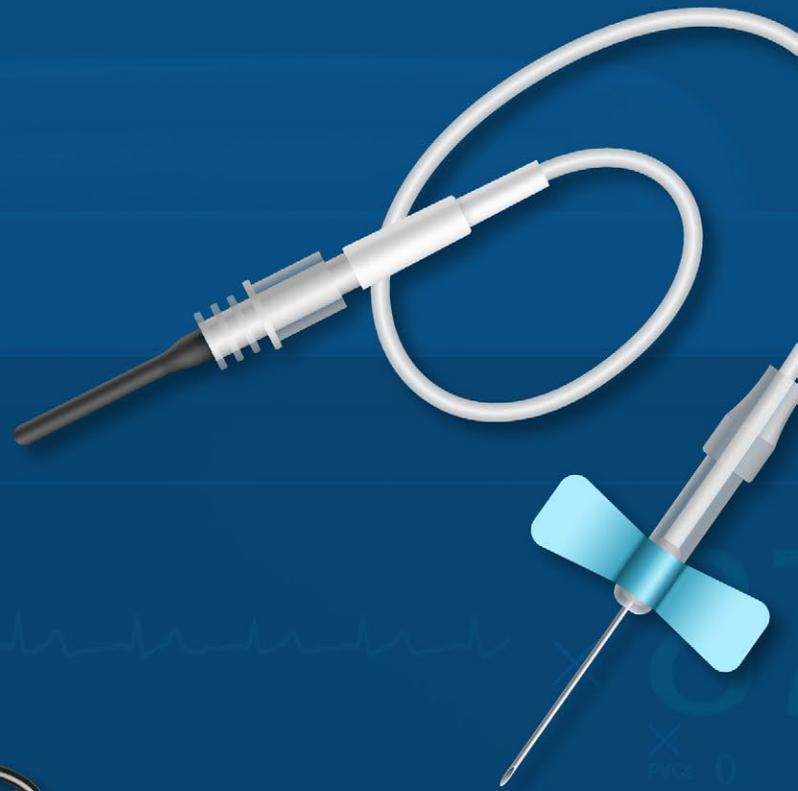
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**Critical**  
manufacturing  
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# Introduction

New business opportunities are emerging rapidly in the medical devices industry. With the increasing demand for personalized healthcare, data analytics, etc., the scope of innovation is immense. However, the MedTech industry also presents substantial challenges, including working across multiple geographies with their own regulatory complexities, product lifecycles, and stringent safety and quality standards.

MedTech manufacturers must achieve both quality and cost-effectiveness. A single device may involve hundreds of components and multiple manufacturing steps. Having detailed traceability of each device, in a way that every step of the manufacturing process is properly documented, from raw materials to the final product, is imperative.

To meet these demands, modern MedTech manufacturers are turning to specialized software solutions designed to streamline production, and maintain compliance with strict regulatory standards, while ensuring complete traceability. This guide will explore the key manufacturing scenarios, challenges, and advanced capabilities that a modern Manufacturing Execution System (MES) must support in the MedTech industry.



# Regulatory Compliance: Non-Conformance Management

## The Challenge

Regulatory compliance and non-conformance management are crucial components in a MedTech company, due to the stringent requirements imposed by health authorities and regulatory bodies. Ensuring patient safety and product efficacy are key to gaining approval to market and sell medical devices in different regions. Non-compliance can lead to delays or recalls. Adhering to international standards facilitates entry into global markets, expands the company's reach, and business opportunities.

Regulatory frameworks mandate rigorous quality assurance processes, thus ensuring consistent product quality and reducing variability. Regular audits and reviews, as part of compliance, help to identify areas for improvement and they can also drive continuous enhancement in quality management systems.

Comprehensive documentation is required for all processes, including design, manufacturing, testing, and distribution. By doing so, traceability and accountability are ensured. Moreover, detailed records facilitate readiness for regulatory audits and inspections by guaranteeing that the company can demonstrate compliance at any time.

## The Solution

To ensure regulatory compliance and support non-conformance management, MES provides the following capabilities:

- 1. Automated Compliance Monitoring**  
MES offers real-time monitoring of production processes, thus ensuring continuous compliance with regulatory standards. Automated generation of audit trails and electronic records facilitate easy access to compliance documentation.
- 2. Streamlined Non-conformance Handling**  
MES can trigger immediate alerts when a non-conformance is detected, which enables prompt action. It can also integrate Corrective And Preventive Actions (CAPA) processes that ensure corrective and preventive actions are tracked and implemented efficiently.
- 3. Enhanced Traceability**  
MES ensures end-to-end traceability of materials, components, and processes, which are crucial for managing recalls and regulatory reporting. MES helps maintain comprehensive and organized documentation and simplifies compliance audits and inspections.
- 4. Data-Driven Insights**  
MES analytics provide insights into non-conformance trends by aiding in the identification of underlying issues and driving continuous improvement. Automated reporting features in MES enable timely and accurate submission of mandatory reports to regulatory bodies.

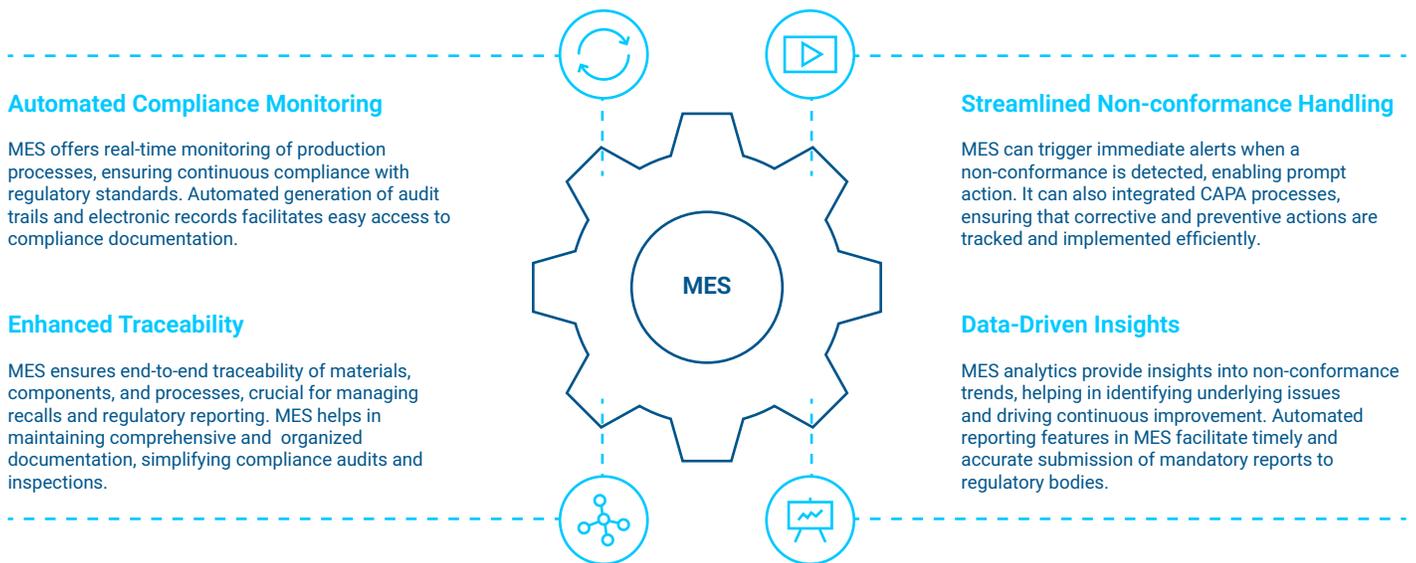


Figure 1 MES Core capabilities for regulatory compliance

# Sampling

## The Challenge

For regulated industries, compliance with standards such as Food Drug Administration (FDA) and International Organization for Standardization (ISO) is a mandatory requirement for manufacturers to ensure the correct level of quality and safety of their products. However, inspecting thoroughly each unit of each product increases manufacture time and costs, and sometimes, it is impossible when destructive tests are required. This is where sampling comes to the rescue: supported by statistical rules, one can infer the quality of a batch or lot based on the quality of a sample. By using sampling techniques, manufacturers can significantly reduce the risk of defective products reaching the market without examining each unit (cost/effectiveness).

Acceptable Quality Level (AQL) is a specific sampling technique that is based on standardized tables supported by statistical analysis, and which predefines the sample size as well as the maximum allowed number of defective items in that sample. An acceptable number of defects is key to ensure product quality and safety, thus balancing quality with the possible costs of testing every item in a batch. AQL tables consider different levels depending on the criticality of the product and its regulatory requirements. A lower AQL level (stricter quality requirements) requires a larger sample size and/or fewer allowable defects. AQL also establishes clear Acceptance/Rejection criteria by type of defect, and this ensures consistency.

Despite the advantages of AQL, its implementation on the production floor is challenging. Collecting accurate data manually is time-consuming and error-prone and requires continuous monitoring and training. Products and processes variability complicates the application of consistent sampling and inspection plans especially when facing high-volume and fast pace productions. Additionally, resource allocation for sampling and inspection can be demanding in terms of personnel, time, and equipment.

## The Solution

An MES providing sampling and AQL capabilities takes production, quality control, and traceability to another level, as it:

- Ensures sampling procedures are triggered automatically, thus guiding the operator so that specified sample sizes are respected, and correct test parameters are gathered.
- Helps to gather data in real time, especially when equipment integration is considered, making the sampling results more reliable and less error prone.
- Provides automatic AQL criteria application that guarantees consistent and data-driven decisions regarding acceptance or rejection of batches.
- Enables quicker quality deviation detection, which improves response and resolution times.
- Guarantees thorough traceability, offering detailed documentation, necessary for regulatory adherence, to be integrated with the Electronic Device History Record (eDHR).
- Enforces the adherence to SOPs (Standard Operating procedures), since sampling and inspection procedures are extra to normal procedures enforcing and guiding its execution, and helping to ensure the quality of the product.
- Facilitates root cause analysis by providing detailed historical data on production and quality issues, helping to identify, categorize, and address underlying causes of defects.
- Optimizes the use of resources by streamlining sampling processes and ensuring that inspections are conducted efficiently, without unnecessary redundancy.
- Can issue alerts and notifications when quality issues are detected, ensuring that the responsible workers are immediately informed and, that way, reaction time can be reduced.

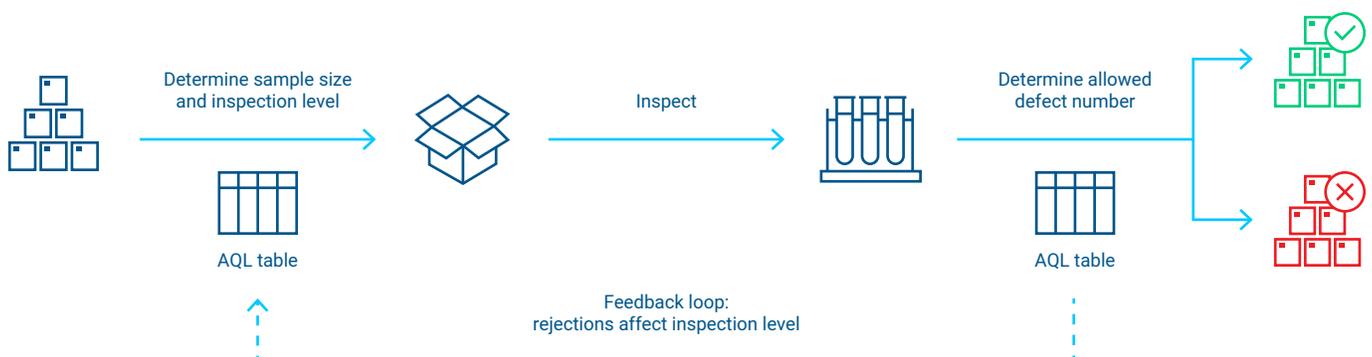


Figure 2 Example of an AQL diagram

# Exception Management

## The Challenge

During manufacturing operations, it's inevitable that some problems, exceptions, and deviations occur. However, in the MedTech industry, it's critical to address these problems quickly and systematically, find the root cause, assess the impact, take containment actions, and define measures to mitigate the risk of the issues if they re-occur.

Procedures can be defined and standardized for addressing the known possible problems. Nevertheless, planning for unknown issues requires extra flexibility on the quality processes to adapt to new exception scenarios. These processes need to be strictly enforced and corrective and containment actions need to be immediately reflected in the production operations, to minimize impact and ensure compliance of the final product.

## The Solution

The MES control of operations must be integrated with exception management handling, so that all potentially affected materials are flagged while the issue investigation is in progress. The system must track the status of the exception handling procedure, which is responsible for following up and keeping comprehensive history records of findings and actions taken – all incident data (who, when, what) must be captured, and any resulting escalation procedures need to be tracked.

Problems that fall within defined patterns and pre-defined workflows should be integrated in the MES to guide users on their resolution, for example, Statistical Process Control (SPC) violations which can be addressed by Out-of-Control Action Plans (OCAPs). Other problems need a more thorough analysis to address the issue, such as Corrective And Preventive Actions (CAPA) procedures.

The system should be flexible enough to allow defining or extending any exception handling process, but at the same time, it must ensure strict control of process changes and approvals, so that it is clear which procedures are active at any time.



Figure 3 CAPA workflow

# Electronic Device History Records (eDHR)

## The Challenge

The eDHR is crucial in the medical device industry for complying with regulatory requirements such as FDA (21 CFR Part 820) and international standards like ISO 13485. These records ensure that every device meets safety and effectiveness standards.

An eDHR must provide detailed traceability of each device, in a way that every step of the manufacturing process is documented, from raw materials to the final product. These records are crucial for identifying and addressing issues whenever a defect is discovered, and they are also essential for quality monitoring for both processes and products.

EDHRs are part of the documentation reviewed in audits and external inspections which MedTech industries are subject to. Having a comprehensive and organized eDHR facilitates those processes. In the event of a product recall or investigation, eDHRs provide the right level of detail to thoroughly investigate past events and analyze what occurred during the manufacturing process. This helps in identifying root causes, other affected batches, and supports the development of corrective and preventive actions.

## The Solution

An MES is a significant aid in overcoming the challenges associated with obtaining a comprehensive and complete eDHR:

- May integrate several sources of information in a centralized system, ensuring all data is accessible from one place and simplifying the generation of the eDHR.
- Can capture data in real-time from different stages of the manufacturing process, ensuring that records are up-to-date and accurate.
- MES provides guidance to the operator through a predefined process, tracking detailed information of each step. This ensures products are produced according to specifications, and traceability and accountability information are recorded.
- MES should be designed to scale and be flexible enough to accommodate changes in the production process without requiring the whole eDHR generation to be revised.
- Provides an organized and easily accessible eDHR, simplifying and accelerating the audit and inspection processes, for both the manufacturers and regulators.

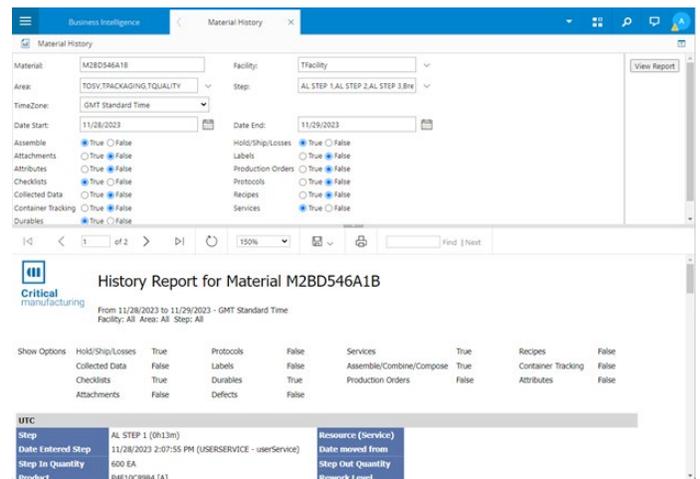
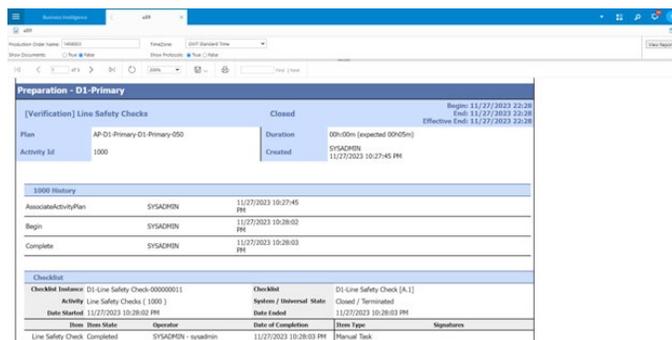


Figure 4 Example of an eDHR record

# Automation: Environment Monitoring

## The Challenge

The environment where medical devices are manufactured has a straight relation with product quality. MedTech companies should have in place mechanisms to ensure that the final products are released within the required quality standards. However, more than ensuring the product is within specification, preventive measures should be in place to reduce the number of bad pieces produced. Constant monitoring of control parameters must be ensured, to be able to react fast and avoid scrap.

Environmental control systems have been adopted to ensure more control of critical parameters, such as:

### 1. Sensors and Monitoring Devices

- Temperature and Humidity Sensors: Ensure that environmental conditions are within specified limits.
- Particulate Monitors: Measure airborne particles to maintain cleanroom standards.
- Pressure Differential Sensors: Monitor pressure differences to prevent contamination between areas.

### 2. Control Systems

- HVAC Systems: Automated Heating, Ventilation, and Air Conditioning systems maintain optimal temperature, humidity, and air quality.
- HEPA Filters: High-Efficiency Particulate Air filters in HVAC systems help achieve and maintain cleanroom standards.

### 3. Data Acquisition and Management

- SCADA Systems: Supervisory Control and Data Acquisition systems collect data from sensors and control equipment to monitor and manage environmental conditions.
- BMS Systems: Building Management Systems integrate various subsystems (HVAC, lighting, security) to optimize the overall environment control.

### 4. Alarms and Alerts

- Real-Time Alerts: Automated systems can trigger alerts for immediate attention when parameters deviate from set points.
- Remote Monitoring: Allows for off-site monitoring and control, enabling rapid response to issues even when staff is not on-site.

## The Solution

The Internet of Things (IoT) connectivity enabled through the MES can ensure complete control of manufacturing parameters, including:

### 1. Enhanced Compliance and Reporting

- Automated Documentation: continuous monitoring and automatic logging of data provides an easy access to compliance reports and historical data for audits.
- Regulatory Reporting: automated systems can generate and submit reports required by regulatory bodies.

### 2. Improved Product Quality and Yield

- Consistent Conditions: maintaining stable environmental conditions ensures that products are manufactured under optimal conditions, reducing variability and defects.
- Reduction in Contamination Risks: automated control of air quality and cleanroom conditions minimizes contamination risks, leading to higher product quality.

### 3. Advanced Analytics: IoT devices can provide additional data points, that can be used for SPC, to identify patterns, prevent failures, and identify process improvement opportunities based on historical data.

### 4. Remote Monitoring: IoT integration enables remote monitoring and control, improving response times and operational flexibility.

There are also significant advantages to following this complete integrated approach. One of the key benefits is cost savings, achieved through energy efficiency and reduced waste. Automated systems optimize HVAC and other environmental controls, leading to substantial energy savings. Additionally, consistent environmental control minimizes product defects and waste, ultimately improving overall yield.

Another major advantage is increased operational efficiency. Automation reduces the need for manual checks and interventions, allowing staff to focus on more value-added activities, thereby saving time. Furthermore, predictive analytics derived from environmental data enable proactive maintenance scheduling, which helps reduce unplanned downtime.

# Maintenance

## The Challenge

Working in a highly regulated industry, as MedTech, requires visibility, command, and control over shop floor operations which is not seen in other industries since the cost of poor quality could be life-threatening. A complete understanding of the supply chain, equipment maintenance, and document control is the bare minimum, but the bare minimum doesn't increase competitiveness. However, a paradigm shift in your factory will have a significant positive impact. Embracing digital transformation and Industry 4.0 involves IIoT and quality management.

Proper maintenance of equipment is critical to maintain the health and performance of manufacturing assets to reduce unplanned downtime. Manufacturers schedule maintenance or parts replacement based on time or usage. With the large amount of data collected, analytical tools can predict maintenance needs and schedule machine activities based on time or usage patterns.

## The Solution

An MES can support the following types of maintenance : corrective (performed for unplanned downtime), preventive (based on pre-defined time and usage schedules), condition-based (triggered when certain conditions are observed) and predictive (estimates the remaining useful life and failure probabilities).

The MES ensures that maintenance plans are followed as defined and keeps track of the maintenance history for every equipment or other asset to which the plan is applied. The equipment usage counters are fully integrated in the system and are automatically increased as material is processed. They also prevent equipment from being used if maintenance is due. Moreover, the system also checks the certifications of maintenance technicians and updates the inventory of spare parts as they are consumed. The Scheduling module is alerted of planned maintenance downtimes to ensure that that equipment is unavailable.



# Certification Management

## The Challenge

The validation of qualifications and certifications of manufacturing personnel is paramount to ensure product safety, efficacy, and compliance with regulatory standards. As a highly specialized and regulated industry, MedTech companies require that all employees, from engineers to assembly line workers, possess the necessary skills and knowledge to perform their duties accurately and consistently.

Worker certification programs provide structured training that covers critical aspects such as manufacturing operations, equipment maintenance, quality control, emergency procedures, etc. By validating such certifications, manufacturers ensure that their staff is qualified in handling sophisticated equipment, adhering to stringent protocols, and executing precise processes that are vital to producing safe and effective medical devices. This not only minimizes the risk of errors and product defects, but also ensures compliance with regulatory entities such as the FDA and ISO.

Tracking and enforcing employee certifications per manufacturing operations and equipment poses challenges, particularly in coordinating shift schedules to ensure that enough qualified personnel are consistently available to maintain uninterrupted manufacturing operations.

## The Solution

For effective enforcement of worker certifications, an MES must go beyond basic user-role assignments and track the actual qualifications and certifications of each employee. The system should know that some certifications expire and need to be renewed periodically, whereas others can be achieved just with on-the-job experience time. Integrating with corporate Learning Management Systems (LMS) enhances these capabilities, ensuring a single source of truth for training and certification data management.

In terms of process Master Data, the MES must maintain which certifications are required to execute certain operation steps, operate specific equipment, or perform a set of maintenance activities. This needs to be cross-checked with the user's certifications at runtime to ensure compliance.

Production scheduling must also take certifications into account, as manufacturing throughput can be reduced if there are not enough qualified workers available in all process steps. The MES scheduler should assist planners in identifying labor qualification and certification bottlenecks, feeding into shift planning to balance the availability of employees for each required certification.

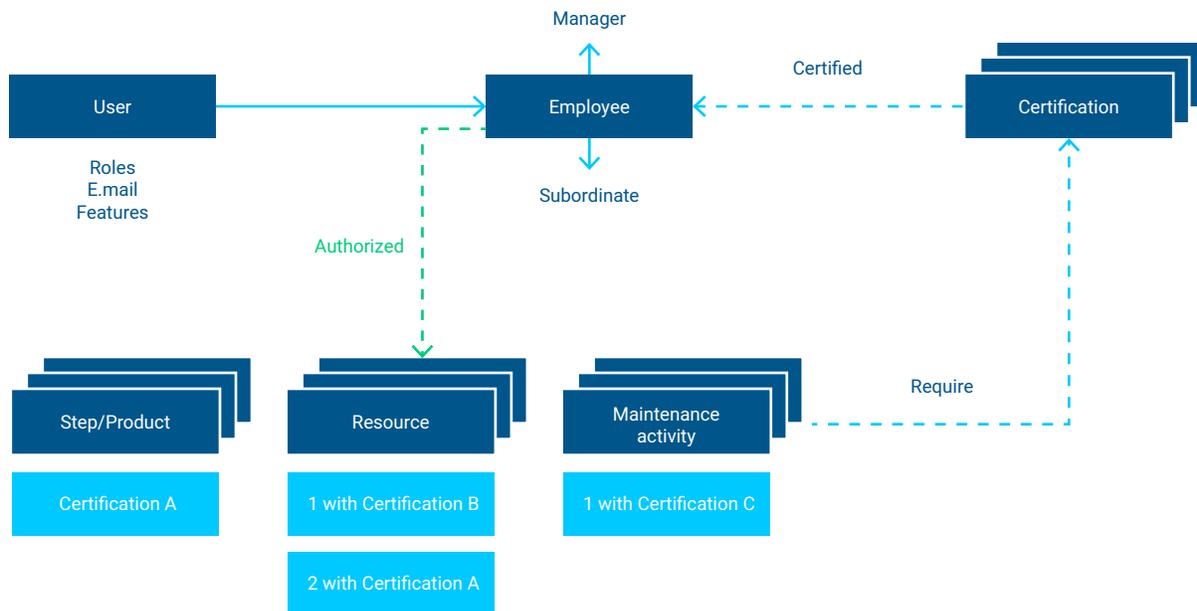


Figure 5 Certification process

# Time Constraints

## The Challenge

Depending on the nature of medical devices being manufactured, certain production processes may be time-sensitive and compromising quality is possible the time between two process steps is exceeded or not enough wait time between steps.

Production operations need to be aware of all materials reaching the process time limit, to promptly react and shift priorities to avoid reaching the point where materials need to be scrapped. In addition, there may be multiple time constraints active at the same time for the same lot, making production planning more complex. In the case that a time constraint is exceeded, it is essential to ensure the identification of the affected materials in a timely fashion and ensure they are properly dispositioned.

Time constraints are not limited to the direct manufacturing processes, but also to raw materials and consumables preparation cycles, which can require specific conditioning wait times before being used.

## The Solution

The MES must support the definition of process queue time constraints between any process step and trigger business rules when a warning time or error time is reached. The system must enforce that the process queue time constraints are not violated and prevent production from proceeding in case of non-conformity.

MES operations scheduling should be optimized to reduce the risk of missing critical time windows and plan for any required waiting times.

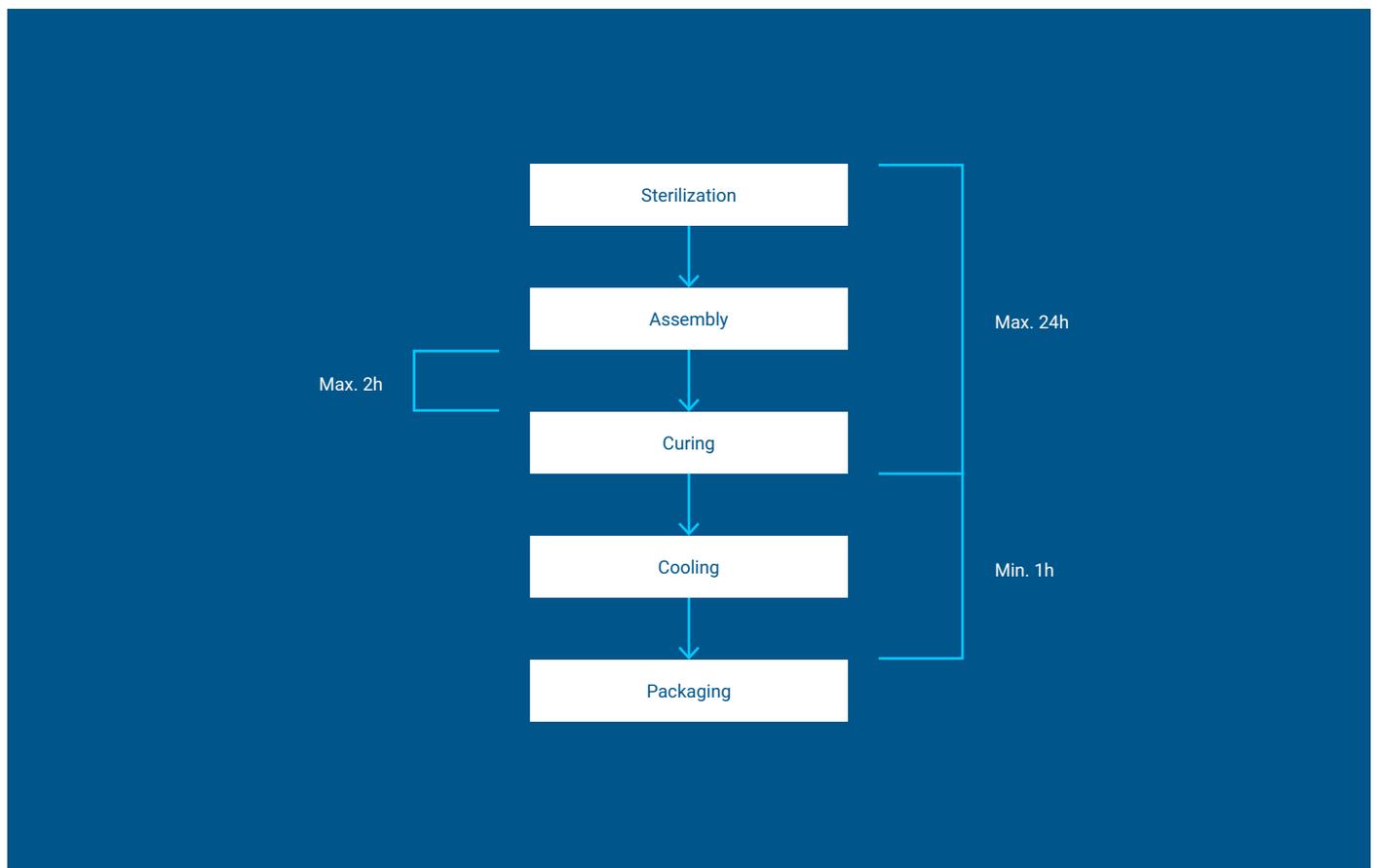


Figure 6 Time Constraints flow

# Extensibility

## The Challenge

An MES that provides flexibility to adapt to the specific working mode of the production shop floor, accommodating all quality and manufacturing processes, represents a major advantage for any kind of industry.

The MedTech industry has specific characteristics that make MES flexibility and extensibility factors even more critical such as regulatory requirements, demanding traceability needs, and specific quality procedures to ensure product quality control.

In a world where the evolution of products, demanded quality and velocity of data-driven decisions is growing to unprecedented levels, having an MES that can adapt to reality swiftly and cost-effectively is a major benefit.

## The Solution

Having an MES with adequate flexibility and extensibility mechanisms will ensure that manufacturers are able to quickly and efficiently adapt the system to the required changes. Here are some examples of how flexibility of an MES has a direct impact:

- **Regulatory compliance:** regulatory requirements are frequently changing. So, manufacturers need to implement changes both in their internal and manufacturing processes. Having an MES facilitates these process changes avoiding non-compliance issues, potential fines, and damage to the company's reputation.
- **Handling specialized processes:** in this industry, it is common to have specialized processes for quality control. The lack of extensibility in the MES can prevent correct representation of manufacturing and quality processes.
- **Integration Challenges:** an MES is often called the "brain of the shop floor", but there are other imperative systems one needs to consider, for instance, Enterprise Resource Planning (ERP), Product Lifecycle Management (PLM), Quality Management System (QMS) and the processing and testing equipment. Without proper integration capabilities in the MES, the adoption of innovative solutions through new systems may be jeopardized.
- **Limited user adoption and training:** a system that is not able to adapt to different roles and responsibilities becomes less intuitive and harder to use, leading to lower adoption rates and higher training requirements. Opting for an MES with GUI flexibility to create specific operator interfaces is vital, as it accelerates adoption and reduces the learning curve, leading to cost-effectiveness.

# Conclusion

MedTech manufacturers are continuously innovating to meet evolving healthcare demands, and their manufacturing systems must keep pace with these advancements. Companies require software that not only supports critical production processes, but also ensures the smooth operation of the entire manufacturing ecosystem.

To manage the full operation, MedTech manufacturers need to ensure compliance in every step of the way. That is why having eDHR records is important to ensure that the produced device is meeting safety and effectiveness standards. To reduce costs and ensure the correct level of quality, it is also important to have sampling techniques as well as proper maintenance of equipment, so unplanned downtime can be avoided. Additionally, Exception Management is also imperative since it allows manufacturers to tackle any deviations and quickly find the root cause.

Innovation in medical devices is not limited to product development – success on the shop floor is equally crucial. By equipping both people and processes with advanced tools, manufacturers can achieve the agility and precision needed to lead in their market segments.

When selecting an MES, manufacturers need to consider the solution maintenance cost as part of the cost of adoption. For any kind of industry, deviating from standard features will imply higher costs of maintenance. In MedTech, besides any normal maintenance cost, manufacturers also need to consider the validation process, increasing the importance of opting for the right MES with the best off-the-shelf capabilities.



# About the Authors



## **Leonor Marques** Lead Solution Architect

Leonor Marques is a Lead Solution Architect at Critical Manufacturing, supporting and guiding project implementation teams when designing solutions in Critical Manufacturing MES. Before joining Critical Manufacturing, Leonor gained valuable experience working with MES systems in different manufacturing settings.

During her 15-year career at Critical Manufacturing, Leonor was part of the Critical Manufacturing MES development team, managed implementation projects for multiple clients and has participated as a Solution Architect in several MES projects in different segments (electronics, semiconductor, medical devices, industrial equipment).



## **Rogério Ferreira** Area Manager for Medical Devices

Rogério Ferreira is the Area Manager for Medical Device implementation projects at Critical Manufacturing. Rogério started his career as a software consultant, and has worked with MES systems in different manufacturing industries, such as semiconductor, and different management positions.

For the past 15 years he has been working at Critical Manufacturing, and more recently his focus has been on projects related to medical devices, where he makes sure that they meet the expectations of their customers. He likes working with projects in the medical devices sector because he gets to see, and experience firsthand, how Critical Manufacturing contributes to the final product, which he knows will benefit the health of all.



## **Rúben Pereira** Product Manager for Medical Devices

Rúben Pereira is a Product Manager for Industrial Segments at Critical Manufacturing, helping industries take full advantage of the MES while driving continuous improvements to best fit the system to each industry's specific needs. With over 20 years of experience in MES architecture and implementation, he has deep expertise in industry requirements and how to effectively address them.

## ABOUT CRITICAL MANUFACTURING

**Critical Manufacturing** provides the most modern, flexible and configurable manufacturing execution system (MES) available. Critical Manufacturing MES helps manufacturers stay ahead of stringent product traceability and compliance requirements; reduce risk with inherent closed-loop quality; integrate seamlessly with enterprise systems and factory automation and provide deep intelligence and visibility of global production operations. As a result, customers are Industry 4.0-ready. They can compete effectively and profitably by easily adapting their operations to changes in demand, opportunity or requirements, anywhere, at any time.

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