Medistri

Providing Sterilization & Laboratory Services for the world's most innovative healthcare companies.

From the Blog

Medistri's Routine Sterilization Services

November 16th 2026

Sterilization is a critical stage in the manufacturing of medical devices and pharmaceutical products. Once a sterilization process has been validated, manufacturers must ensure that its performance remains consistent as production volumes increase and products enter commercial distribution. The transition from validation to routine sterilization introduces new operational requirements. Processes must remain within established parameters while accommodating production schedules, changing batch volumes, logistics constraints, and quality documentation requirements.

Routine sterilization connects validated processes with industrial manufacturing, ensuring that products are processed consistently under controlled conditions throughout their commercial lifecycle.

Medistri supports routine EO and Steam sterilization through its infrastructure in Switzerland and Hungary, combining sterilization operations with laboratory testing, logistics coordination, and digital traceability.

From Validated Processes to Routine Operations

Sterilization validation establishes the conditions under which a process can consistently achieve the required Sterility Assurance Level (SAL). During routine production, these conditions must be maintained across successive sterilization batches. The transition requires manufacturers to establish clear operating procedures and ensure that production activities remain aligned with the validated process. Several parameters must be controlled:

Load Configuration: Maintaining approved product arrangements, packaging configurations, and loading conditions.
Process Parameters: Monitoring temperature, humidity, exposure duration, and other technology-specific requirements.
Batch Traceability: Linking each production batch to its sterilization cycle and associated documentation.
Release Requirements: Verifying that applicable process and quality acceptance criteria have been satisfied.

These controls support repeatable sterilization performance while allowing manufacturers to integrate sterilization into their routine production planning.

Managing Production Volumes Through Digital Sterilization Planning

As manufacturing volumes increase, sterilization must be integrated into production scheduling and supply chain planning. Batch frequency, load configurations, processing requirements, and shipment coordination all influence the organization of routine sterilization activities. Managing these operations requires visibility over sterilization orders, processing status, and documentation, particularly when manufacturers operate across multiple production sites or manage different product portfolios.

Medistri supports this coordination through MyMedistri, a digital platform designed to simplify routine sterilization management and improve operational visibility. The platform enables manufacturers to:



EO and Steam Sterilization

EO and Steam sterilization are widely used in healthcare manufacturing, with each technology presenting different operational considerations.

EO Sterilization

EO sterilization is commonly selected for heat-sensitive medical devices, polymer-based products, and complex packaging configurations. Routine processing requires controlled gas exposure, temperature, humidity, and aeration conditions. Processes are validated and routinely controlled according to ISO 11135, with residual EO and ethylene chlorohydrin evaluated against applicable requirements under ISO 10993-7.

Steam Sterilization

Steam sterilization uses moist heat to achieve microbial inactivation and is suitable for compatible medical devices, surgical instruments, and pharmaceutical applications. Routine operations require consistent temperature distribution, steam penetration, exposure duration, and drying conditions. Process validation and routine control are addressed under ISO 17665.

Both technologies require continuous monitoring and documented verification to maintain the validated state during commercial production.

Laboratory Testing and Batch Release

Routine sterilization involves more than the execution of validated cycles. Laboratory monitoring and batch documentation provide supporting evidence that processing requirements continue to be met. Depending on the product and sterilization method, laboratory activities may include bioburden monitoring, biological indicator evaluation, sterility testing, bacterial endotoxin analysis, and EO residual testing. Not every analysis is required for each production batch. Testing requirements are established according to the validated process, product specifications, and applicable regulatory expectations.

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- Create and repeat sterilization orders using validated customer cards, reducing repetitive administrative tasks.
- Select the sterilization location between Switzerland and Hungary, according to validated products and approved customer configurations.
- Monitor order progress in real time, from product transit and sterilization to shipment readiness.
- Access sterilization certificates and documentation through a centralized dashboard linked to orders and lot numbers.
- Coordinate activities across teams, with task assignments and shared access for stakeholders working across different locations.

These capabilities help manufacturers coordinate sterilization activities with production schedules while maintaining access to essential processing information. Combined with Medistri's dual-site sterilization infrastructure, MyMedistri supports operational continuity, documentation traceability, and coordination between manufacturing, quality, and supply chain teams throughout routine production.

Dedicated Customer Success Support Across Switzerland and Hungary
Routine sterilization requires continuous coordination between manufacturers, sterilization facilities, laboratories, and logistics teams. As production volumes increase, maintaining clear communication and operational continuity becomes essential.

Medistri supports customers through dedicated Customer Success Specialists across its Switzerland and Hungary operations, providing a consistent point of contact throughout routine sterilization activities. Their responsibilities include:

- **Operational Coordination:** Supporting sterilization scheduling, order management, and production planning.
- **Laboratory and Quality Follow-Up:** Coordinating requests related to testing, documentation, and quality requirements.
- **Logistics Management:** Facilitating communication regarding product arrivals, collection, and shipment arrangements.
- **Issue Resolution:** Coordinating with internal departments to address operational questions, deviations, and processing requirements.

By combining dedicated customer support with its dual-site infrastructure and MyMedistri platform, Medistri helps manufacturers maintain clear communication, operational visibility, and continuity of service throughout commercial production.

Maintaining Process Reliability
Routine sterilization requires continuous coordination between process engineering, quality assurance, laboratory testing, and production planning. Changes in product design, packaging materials, load configurations, or processing equipment must be assessed to determine whether they affect the validated sterilization process. Periodic process reviews, equipment maintenance, calibration, and documented change control help maintain compliance with ISO 11135, ISO 17665, and applicable quality management requirements.



Batch release is a separate quality verification step in which sterilization records, monitoring results, and deviations are reviewed against predefined acceptance criteria. The release process ensures that each sterilization batch has been processed according to the approved requirements before proceeding to its next stage.

Medistri integrates sterilization operations with laboratory capabilities and quality documentation, supporting manufacturers in maintaining traceability between processing, analytical results, and sterilization release.

Environmental Performance in Routine Sterilization
Environmental considerations are increasingly integrated into industrial sterilization planning, particularly for EO processes. Routine EO sterilization involves gas consumption, emissions management, and energy requirements that must be controlled alongside sterilization performance. Technical measures may include gas treatment systems, cycle optimization, and the evaluation of different load configurations.

Medistri incorporates EO emissions treatment technologies and environmental monitoring into its operations. Its environmental management systems are certified according to ISO 14001 across its Swiss and Hungarian facilities.

Environmental information, including CO_2 reporting per pallet, supports manufacturers seeking greater visibility over the environmental impact associated with their sterilization activities.

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Operational planning also plays an important role in maintaining product availability. Medistri provides different routine sterilization lead-time options according to customer requirements and service arrangements:

SuperExpress: 2–5 days
Express: 5–7 days
Standard: 7–14 days

Dedicated Customer Success Specialists coordinate routine activities between customers and Medistri's operational departments, supporting communication related to scheduling, documentation, and processing requirements.

Supporting Long-Term Manufacturing Continuity
Routine sterilization is an ongoing manufacturing activity that must maintain the performance established during process validation while adapting to industrial production requirements.
Reliable operations depend on controlled sterilization parameters, laboratory monitoring, documented batch release procedures, and effective coordination across the supply chain.
By integrating EO and steam sterilization with laboratory services, digital traceability, and logistics coordination, Medistri supports manufacturers throughout the transition from initial commercial batches to sustained routine production.

This approach contributes to consistent sterilization performance, regulatory compliance, and continuity of supply for medical devices and pharmaceutical products.

To learn more about Medistri's Routine Sterilization Services, visit our website or contact our team at contact@medistri.com.

– The Medistri Team

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