Medistri

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

From the Blog

Routine Sterilization During the Industrialization Phase

February 9th 2026

As medical devices and pharmaceutical products transition into the industrialization phase, manufacturing activities evolve from development-driven execution to stable, repeatable production under controlled conditions.

At this stage, sterilization is no longer an experimental or validation-only activity. It becomes a routine industrial operation that must demonstrate:

- Process consistency
- Regulatory compliance
- Predictable lead times
- Full traceability across the supply chain

Medistri supports this transition through an integrated sterilization, laboratory, logistics, and digital infrastructure operating across Switzerland and Hungary, enabling manufacturers to move from first industrial batches to sustained commercial production.

Industrial Scale and Market Coverage
Medistri's routine sterilization infrastructure supports industrial-scale operations, with more than 90,000 pallets sterilized annually across its Switzerland and Hungary facilities. These activities serve products intended for both European and United States markets, covering a broad spectrum of medical devices, pharmaceutical products, and pharmaceutical packaging systems. The platform is designed to accommodate the full lifecycle of customer needs, from small-scale production supporting newly developed or recently validated products to high-volume routine sterilization for established commercial manufacturing.

This combination of scale, regulatory alignment, and lifecycle flexibility ensures that manufacturers can rely on Medistri for consistent, compliant, and globally deployable sterilization capacity.

Integration of Laboratory Services into Routine Operations
Routine sterilization cannot be separated from analytical verification and monitoring.

Medistri integrates laboratory services directly into the routine sterilization workflow, including:

- Bioburden and sterility testing
- Endotoxin (LAL) analysis
- Residual EO and material compatibility testing
- Sterility Testing

With Medistri, this single-provider model reduces transfer risk, shortens investigation timelines, and ensures data continuity between validation and routine production.

Post-Sterilization Handling and Release Readiness
Post-sterilization steps are executed according to the validated process definition and sterilization technology:

Steam Sterilization
- Preparation for secure transport and logistics integration.

Regulatory Scope of Routine Sterilization Operations
Routine sterilization activities performed during the industrialization and commercial production phases are executed within a fully controlled regulatory framework aligned with applicable international standards and regional requirements. Sterilization processes are validated and routinely operated in accordance with recognized standards such as ISO 11135 for ethylene oxide sterilization and ISO 17665 for moist heat sterilization, with supporting laboratory activities conducted under relevant quality and testing standards.

Operations across Medistri's Switzerland and Hungary sites are performed within certified quality management systems aligned with ISO 13485 and applicable GMP expectations, ensuring traceability, documented process control, and compliant product release. Environmental management, emissions control, and sustainable EO processing are implemented in line with evolving regulatory expectations, including current FDA guidance on sterilization sustainability and emissions reduction.

Routine Sterilization as a Controlled Industrial Process
During industrialization, sterilization is performed under defined routine operating parameters that reflect real production conditions rather than development assumptions.

Most of these parameters are established during sterilization validation, including:

- Load configuration and worst-case definition
- Packaging systems and material compatibility
- Exposure conditions and acceptance criteria
- Aeration or drying requirements
- Release strategy and documentation structure

Routine processing therefore represents the operational continuation of the validated state, ensuring that commercial production remains aligned with the validated sterilization envelope.

Medistri

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

From the Blog

Routine Sterilization During the Industrialization Phase

February 9th 2026

EO Sterilization
- Controlled active degassing and aeration
- Residual reduction aligned with ISO and regulatory limits

These steps ensure that products exit sterilization in a state suitable for validation confirmation, regulatory release, and downstream distribution.

Sustainable Sterilization and Regulatory Alignment
Routine EO sterilization is increasingly evaluated through a sustainability and emissions lens, particularly under evolving FDA environmental expectations.

Medistri supports sustainable cycle strategies, including:
- Mixed-load and single-load EO cycles
- Advanced gas treatment systems
- Annual CO_2 and emissions reporting per pallet, enabling: Environmental impact visibility, Product-level sustainability metrics, ESG and regulatory reporting support

This allows quality and regulatory teams to integrate environmental performance into routine sterilization governance.

Lead Times Supporting Industrial Planning
Defined lead-time tiers support production scheduling and inventory strategy:

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

These options allow manufacturers to balance speed, volume, and cost within validated routine operations.

Routine Sterilization as a Foundation of Industrial Readiness
Routine sterilization during industrialization is more than repeated cycle execution. It is the operational realization of the validated sterilization strategy, supported by:
- Dual-site European infrastructure (Switzerland & Hungary)
- Integrated laboratory verification
- Sustainable EO cycle design and emissions transparency
- Digital traceability via MyMedistri
- Dedicated customer success governance
- Predictable industrial lead times

Together, these elements ensure that sterilization becomes a stable, compliant, and scalable pillar of commercial medical device and pharmaceutical manufacturing.

To learn more about Medistri's Routine Sterilization Service, please visit our website here or contact us at contact@medistri.com.

– The Medistri Team

#Medistri

Medistri delivers this routine execution across:
- Switzerland – supporting high-compliance production, EU/US regulatory alignment, and complex product portfolios
- Hungary – enabling scalable industrial throughput, redundancy, and European supply-chain resilience

Together, these sites provide a dual-location sterilization infrastructure designed for reliability and continuity of supply.

Digital Traceability and Operational Transparency
Routine industrial sterilization requires continuous visibility and coordination.
Medistri provides this through MyMedistri, a digital platform enabling:

- Live order and cycle tracking
- Quality Documentation access and traceability
- Synchronization with logistics partners
- Predictable shipment coordination

This ensures real-time operational control for quality, supply-chain, and regulatory stakeholders.

Customer Success Governance for Routine Production
At Medistri, Each routine sterilization program is supported by a dedicated Customer Success Specialist, ensuring:

- Single point of contact for all routine operations.
- Continuity between validation and routine production
- Rapid deviation management
- Coordinated laboratory, logistics, and documentation workflows
- Structured communication with quality and regulatory teams

This role acts as an operational extension of the manufacturer's quality organization.