Medistri

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

From the Blog

Post-Validation Training

April 27th 2026

Strengthening Process Control, Compliance, and Audit Readiness
Sterilization validation does not end with cycle approval. As regulatory expectations continue to evolve, maintaining validated conditions, controlling changes, and ensuring consistent routine release require structured expertise within internal teams.

To support this need, Medistri has developed a Post-Sterilization Validation Training program designed for medical device manufacturers seeking to reinforce in-house capabilities across validation, routine control, and regulatory compliance.

Delivered directly by sterilization specialists operating within an industrial contract sterilization environment, this training connects regulatory frameworks with real-world practices.

From Validation to Routine Control
Following initial validation, sterilization processes enter a controlled operational phase where consistency, traceability, and compliance must be continuously demonstrated. This includes:

- Maintaining validated parameters within defined limits
- Managing changes, deviations, and impact assessments
- Ensuring alignment between process performance and regulatory expectations
- Preparing for audits through structured documentation and technical understanding

The training addresses these aspects through a combination of technical review, operational context, and applied examples.

Training Formats and Delivery
The training is designed to remain focused and practical, ensuring direct interaction with subject matter experts.

Duration: 6 hours (morning and afternoon, including lunch)
Format: On-site (Medistri Switzerland or Hungary) or live virtual session
Group Size: Maximum 5 participants
Language: English
Certification: Issued upon completion

On-site sessions include a process visit, allowing participants to observe sterilization processes and supporting infrastructure within an operational environment.

Target Audience
The program is intended for professionals involved in sterilization lifecycle management, including:

- Quality Assurance and Regulatory Affairs teams
- Validation and Compliance Managers
- Internal sterilisation subject matter experts (SMEs)
- Production and Process Engineers

Operational Perspective
In addition to regulatory alignment, the training integrates operational considerations observed across routine processing activities. For quality-focused teams, this includes:

- Improved audit readiness through deeper process understanding.

Training Scope
The program provides a structured approach to post-validation activities, covering both EO and steam sterilization processes. Key topics include:

Validation & Re-validation
A step-by-step review of process qualification, including lifecycle considerations and requirements for maintaining validated states over time.

Routine Release
Understanding parametric and microbiological release approaches, with focus on acceptance criteria, process monitoring, and documentation.

Regulatory Standards
Application of key frameworks such as ISO 11135 (EtO sterilization) and ISO 17665 (Steam Sterilization), with emphasis on interpretation and implementation.

Real-World Application
Case studies and troubleshooting scenarios reflecting operational challenges observed across industrial sterilization environments.

Process Integration
Understanding how sterilization interacts with upstream and downstream activities, including packaging, logistics, and environmental considerations.

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- Alignment on critical parameters, limits, and acceptance criteria
- Structured handling of change control and deviations post-validation
- Direct exposure to industrial sterilization processes

Supporting the Sterilization Lifecycle
Post-validation activities are critical to maintaining compliance and ensuring consistent product sterility. By strengthening internal expertise, organizations are better equipped to manage routine operations, respond to regulatory requirements, and maintain control over sterilisation processes across their lifecycle.

Medistri's Post-Sterilization Validation Training is designed as a direct extension of this lifecycle approach, bridging validation, routine control, and operational execution.

Learn more about Medistri's Post-Sterilization Validation Training, please contact your Customer Success Specialist or contact our team at development@medistri.com.

— The Medistri Team

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A Practical Approach to Training
Unlike third-party training providers without direct sterilization operations, the Medistri program is developed and delivered within an active contract sterilization environment. This ensures that all content reflects current industrial practices, validated processes, and regulatory expectations observed across a broad customer base.

The training is open to both Medistri clients and non-clients, supporting access to applied knowledge without commercial bias.