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

From the Blog

Validation Review Services

June 22nd 2026

Sterilization validations define how healthcare products are sterilized and how sterilization processes are controlled throughout routine production. They establish the qualification strategy, the operating conditions, and the activities required to demonstrate compliance with applicable standards.

As healthcare products move from development to industrialization, sterilization validations continue to evolve alongside the product, the manufacturing environment, and regulatory expectations.

At Medistri, Sterilization Validation Review Services help manufacturers review their existing validation strategy, understand how it has evolved over time, and prepare for future industrialization activities. This includes the review of validation documentation and, when appropriate, practical requalification activities.

What Is a Sterilization Validation Review?
A Sterilization Validation Review is a structured assessment of the documents, qualification activities, and technical decisions supporting a sterilization process.

The objective is to review the sterilization strategy as a whole and understand how it has been developed, qualified, and maintained throughout the product lifecycle. This includes evaluating the supporting documentation, the qualification activities, and the rationale behind key decisions such as product family definitions, load configurations, or qualification approaches.

By providing a comprehensive overview of the sterilization process and its historical development, the review helps manufacturers better understand their current strategy and prepare for future developments.

When Are Sterilization Validation Reviews Performed?
Sterilization Validation Reviews accompany healthcare products throughout their lifecycle. As products move from development to industrialization, manufacturers may introduce packaging modifications, optimize production, transfer manufacturing activities, or prepare for new regulatory markets. Each of these developments contributes to the evolution of the sterilization strategy and its supporting documentation.

A Sterilization Validation Review may therefore be performed as part of:

- Product industrialization
- Technology transfers
- Manufacturing transfers
- Packaging modifications
- Process changes
- Regulatory preparation
- Lifecycle management activities

The review provides a structured overview of the sterilization process and the technical decisions that support it, helping manufacturers better understand how their validation strategy has evolved and how it supports future developments.

Reduced MPQ & PPQ Requalification
In addition to the documentation review, Medistri also performs practical requalification activities based on a reduced MPQ & PPQ.

This requalification may, for example, consist of a smaller requalification approach involving a half-cycle using Biological Indicators (BIs) and sensors to verify that the sterilization process continues to perform as expected under practical conditions. The objective is not to repeat a complete validation, but to confirm that the sterilization process remains effective and reproducible throughout its lifecycle.

This practical verification is generally considered the minimum level of requalification recommended by Medistri. Additional activities may then be performed depending on the manufacturer's objectives.

Combining Documentation Reviews and Practical Requalification
At Medistri, Sterilization Validation Review Services are typically performed through alternating activities throughout the lifecycle of the sterilization process.

A Documentation Review may be performed during one review cycle, followed by a practical Reduced MPQ & PPQ Requalification during the next cycle. This alternating approach provides complementary information over time while avoiding the need to repeat the same activities every year.

The Documentation Review focuses on the historical validation strategy and its supporting records, while the practical requalification verifies that the sterilization process continues to perform as expected under routine conditions.

Documentation Review
The first step consists of reviewing the existing validation documentation and evaluating whether the sterilization strategy remains aligned with the product, the manufacturing environment, and the applicable standards. The review may include documents such as:

- Validation Master Plans (VMP)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Validation protocols
- Validation reports
- Qualification activities
- Product family definitions
- Load configurations
- Risk assessments
- Change controls
- Requalification reports
- Historical validation data

Together, these documents provide a historical overview of the sterilization process and the decisions that have shaped its evolution over time. The objective is to obtain a comprehensive understanding of the existing validation strategy and verify that the supporting documentation remains relevant and consistent over time.

Reviewing the Validation Strategy
Sterilization validations are built around a series of technical decisions that define how products are sterilized during routine production. These decisions concern the product itself, the sterilization process, the qualification activities, and the long-term control of the process.

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For example, the reduced requalification may also provide an opportunity to:
- Qualify a minimum load configuration
- Evaluate a backup sterilization chamber
- Assess specific customer requirements
- Introduce additional testing activities

By alternating documentation reviews and practical requalification activities over successive review cycles, manufacturers obtain a broader understanding of their sterilization process and its performance over time.

Standards and Regulatory Framework
Sterilization validations are performed according to internationally recognized standards. For EO sterilization, ISO 11135 establishes the requirements for the development, validation, and routine control of EO sterilization processes. For Steam Sterilization, ISO 17665 defines the requirements for moist heat sterilization processes and their ongoing control. Additional standards may also be relevant depending on the product and the project, including:
- ISO 11737 for bioburden and sterility testing
- ISO 11607 for packaging validation
- ISO 10993-7 for EO residuals

Reviewing sterilization validations within the framework of these standards helps manufacturers better understand the structure of their validation strategy and its different components.

Considering Packaging and Laboratory Activities
Sterilization validations are closely linked to packaging systems and laboratory activities. Packaging influences how products are sterilized, protected, stored, and transported. The packaging configuration may affect sterilant penetration, product protection, and the maintenance of sterility throughout the product lifecycle. Laboratory testing also contributes to the understanding of sterilization processes and product characteristics. Depending on the project, supporting activities may include:
- Bioburden testing
- Sterility testing
- Bacterial endotoxin testing
- Packaging integrity testing

Because these activities are interconnected, reviewing a sterilization validation often requires considering the broader environment surrounding the product.

At Medistri, sterilization, laboratory testing, packaging validation, and manufacturing activities are performed within the same healthcare ecosystem. This allows projects to be approached with a broader understanding of the interactions between these different activities throughout development and industrialization.

Sterilization validations are designed to support healthcare products throughout their lifecycle. As products evolve and industrialization progresses, reviewing existing validations allows manufacturers to revisit their strategy, understand how it has evolved, and prepare for future developments.

By alternating documentation reviews and practical requalification activities, Medistri supports manufacturers in obtaining a clearer understanding of their sterilization processes and the different activities surrounding them, helping ensure continuity throughout the lifecycle of healthcare products.

To learn more about Medistri's Validation Services, please visit our website here or contact us at contact@medistri.swiss.

– The Medistri Team

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For EO sterilization, the review may include:
- Product family definitions
- Worst-case product selection
- Load configurations
- Cycle development approaches
- Qualification activities
- Routine process controls
- Requalification strategies

For Steam Sterilization, the review may consider:
- Load definitions
- Qualification approaches
- Cycle parameters
- Routine monitoring activities
- Requalification strategies

Reviewing these elements helps manufacturers better understand the structure of their validation strategy and how the different activities contribute to routine sterilization operations.

How Medistri Supports Industrialization
At Medistri, Sterilization Validation Review Services are part of a broader ecosystem supporting healthcare manufacturers throughout development and industrialization. Our teams work daily with:
- EO Sterilization
- Steam Sterilization
- Laboratory Testing
- Packaging Validation
- Manufacturing
- Logistics

This multidisciplinary environment allows sterilization validations to be reviewed while considering the broader context of the product lifecycle and the interactions between different activities.

Whether supporting an industrialization project, a manufacturing transfer, or the review of an existing validation, Medistri helps manufacturers better understand their sterilization strategy and its role within the overall healthcare product lifecycle.