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From the Blog

R&D Treatment Cycles for Pre-Clinical Sterilization

31st August 2026

Sterilization requirements should be considered early in the development of medical devices and pharmaceutical products. Materials, product design, packaging configuration and process conditions can influence the suitability of a sterilization method and the subsequent validation strategy.

R&D Treatment Cycles provide a controlled approach to evaluate these parameters during the pre-clinical phase, before progressing to formal sterilization validation.

At Medistri, R&D Treatment Cycles can be performed to support feasibility studies, product and material compatibility assessments, preliminary process definition and the evaluation of specific product or packaging configurations.

What Is an R&D Treatment Cycle?
An R&D Treatment Cycle is a non-validated cycle performed for research, development and pre-clinical purposes. The objective is to expose a product to defined process conditions and evaluate its response before establishing a validated sterilization process.

Depending on the sterilization technology and study objectives, parameters such as temperature, relative humidity, pressure, exposure time and process conditions can be defined and monitored. For EO applications, the cycle can also be adapted according to EO concentration, conditioning, gas exposure and degassing requirements.

R&D Treatment Cycles are exploratory and do not replace sterilization validation. Products treated through a non-validated cycle cannot be considered sterile for commercial release on the basis of that treatment.

Material and Product Compatibility
Material compatibility is an important consideration when selecting and developing a sterilization process. Medical devices may incorporate polymers, adhesives, coatings, electronics, batteries or other components that can be affected by temperature, humidity or sterilization agent exposure.

R&D Treatment Cycles allow products and materials to be exposed to selected conditions before validation. Following treatment, the impact on product characteristics can be assessed through appropriate laboratory or functional testing.

For EO, the relatively low processing temperature and ability of the gas to penetrate packaging and complex geometries make the technology suitable for many heat-sensitive medical devices. Product-specific compatibility, however, remains an important part of process development.

Supporting Pre-Clinical Feasibility Studies
An R&D Treatment Cycle can also be used as part of a broader feasibility study when the sterilization strategy has not yet been finalized. This approach enables the evaluation of a sterilization technology without requiring the complete validation framework associated with a commercial sterilization process.

Preliminary Process Parameters
During pre-clinical development, final sterilization parameters may not yet be established. R&D Treatment Cycles can be used to evaluate preliminary parameters and determine how selected conditions behave within the product and load configuration. Depending on the study, this may include the assessment of:

- Temperature and relative humidity
- Pressure profiles
- EO concentration and exposure time
- Product and packaging configuration
- Load configuration
- Degassing conditions

Environmental sensors and instrumented loads can be used to monitor process conditions at selected locations. The information generated during these cycles can contribute to the definition of the parameters and configurations that will subsequently be evaluated during sterilization validation.

Product Geometry and Worst-Case Configurations
Product geometry can influence the distribution and penetration of sterilization conditions. Devices containing lumens, enclosed areas, multiple components or complex assemblies may present locations that are more difficult to process. Packaging materials, product orientation and load configuration can introduce additional variables.

R&D Treatment Cycles can be used to investigate these characteristics and identify potentially challenging or worst-case configurations before validation.

Different product variants, orientations or packaging configurations can therefore be assessed under controlled conditions to support the selection of representative configurations for subsequent studies.

From Pre-Clinical Development to Routine Sterilization
Sterilization development is part of a broader product development process. Information generated during R&D Treatment Cycles can support the definition of product configurations, packaging systems,

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Treatment can be followed by laboratory analyses to assess specific product characteristics or investigate the effects of processing. Depending on the development program, this may include microbiological, analytical, chemical or packaging-related testing.

The objective is to generate relevant technical information during the pre-clinical phase and support decisions before progressing to formal validation.

R&D Treatment and Validated Sterilization
R&D Treatment and validated sterilization serve different purposes within the product lifecycle. An R&D Treatment Cycle is used for exploration, feasibility and process development. It is non-validated and does not provide the documented evidence required to support a sterile claim for commercial release.

Validated sterilization requires a defined and documented process demonstrating that the required sterilization conditions can be consistently reproduced. For medical devices, EO sterilization processes are developed, validated and routinely controlled according to ISO 11135, while moist heat sterilization processes are addressed by ISO 17665. Once the product configuration and preliminary process conditions have been established, the project can progress from R&D Treatment to formal sterilization validation.

Pre-Clinical Sterilization at Medistri
Medistri provides R&D Treatment Cycles for medical device and pharmaceutical development programs requiring controlled exposure to sterilization process conditions before validation. Studies can be adapted according to the product, packaging configuration, sterilization technology and objectives of the development program.

The resulting data can support feasibility assessment, process development and the preparation of subsequent sterilization validation activities.

To learn more about Medistri's R&D Treatment Cycles, please visit our website here or contact us at contact@medistri.com.

— The Medistri Team

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process parameters and worst-case conditions before validation.

Following successful process development and sterilization validation, the product can progress toward routine sterilization under controlled and reproducible conditions.

Medistri supports this progression through R&D Treatment Cycles, laboratory testing, sterilization validation and routine sterilization services, allowing sterilization requirements to be addressed from the pre-clinical phase through commercial production.

With sterilization and laboratory capabilities available within the same infrastructure, treatment activities can also be coordinated with subsequent testing according to the requirements of the development program.