

Biodecontamination Process: Development and Validation

A service for hydrogen peroxide-using production isolation systems

By using physical, chemical, and microbiological test methods the parameters for the biodecontamination process are developed and optimized. Biological indicators (spores of *Geobacillus stearothermophilus* on stainless steel carriers) are used to prove the efficacy of the developed process for the assigned loading scheme.

Subsequently the optimized process is validated for the assigned loading scheme.

The used biological indicators (BIs) are inspected prior to onsite use by performing a spore count, a spore identification, and a D-value determination in Valicare's own pharma-grade isolator.

Valicare provides the necessary GMP-compliant documentation, like protocols, test documentation and reports.



Our Services & Support

- Inspection of biological indicators prior to onsite use
- Creation of GMP-compliant documents (protocols, test sheets, reports)
- Consultancy on loading schemes
- Onsite execution of isolator process development using physical, chemical, and microbiological test methods
- Subsequent validation of the developed and optimized process

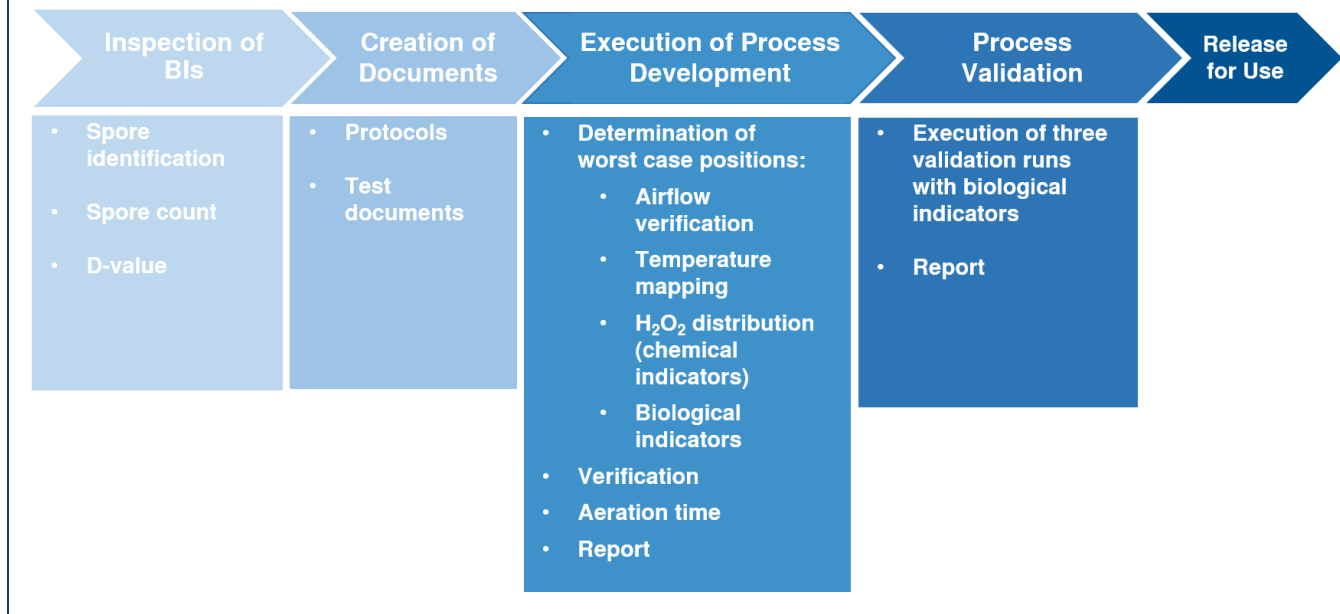
Our Competence

- More than 15 years of experience in biodecontamination process development and validation
- Engineers of various disciplines with technical expertise
- Natural scientists with microbiological and process expertise
- Experience in the evaluation of process parameters

Your Benefits

- Personnel relief and time savings by outsourcing the activities to experienced and experienced validation experts
- Valid resistance of the BI batches, transferable to production isolators, allow an efficient validation process
- System validation to release (e.g., for media fills)
- GMP- and audit-compliant documentation

Biodecontamination Process Development and Validation



Contact us if you are planning a biodecontamination process development and validation for your isolation system. We support you!



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