

# Bio-decontamination Process Development

A service for hydrogen peroxide-using production isolation systems

By using physical, chemical and microbiological test methods the parameters for the bio-decontamination 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 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 isolator loading schemes
- Onsite execution of isolator process development using physical, chemical and microbiological test methods
- Subsequent validation of the developed and optimized process

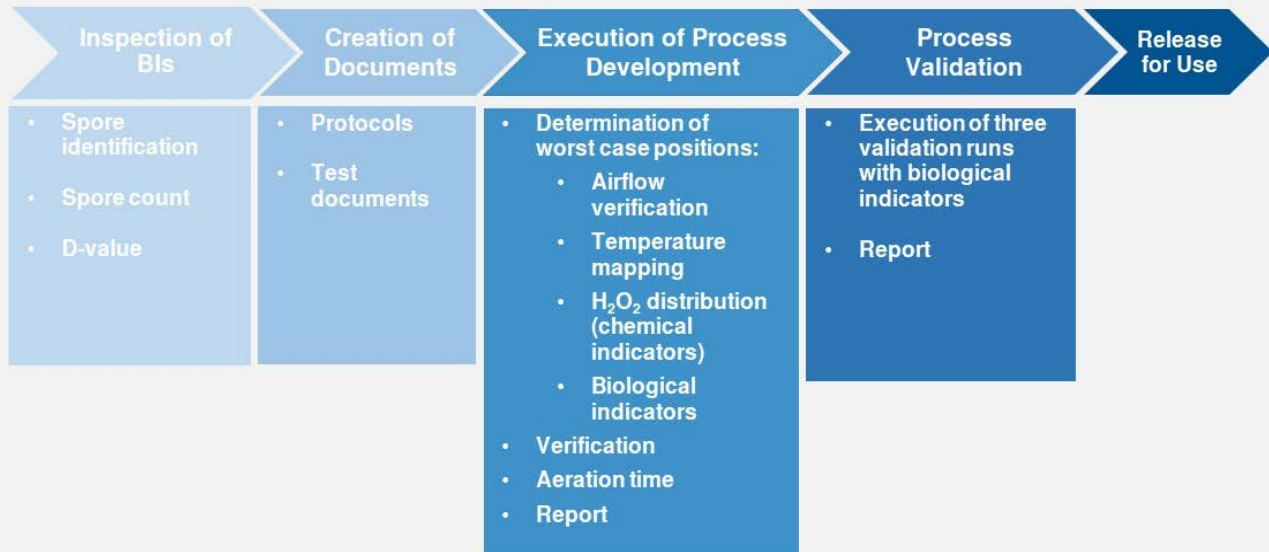
## Our Competence

- More than 15 years of experience in bio-decontamination process development and validation
- Multidisciplinary engineers with technical expertise
- Natural scientists with microbiological and process expertise
- Professional GMP compliant documentation

## Your Benefits

- Experienced validation experts for onsite execution, familiar with hydrogen peroxide-using bio-decontamination processes and handling of biological indicators
- Competence in evaluation of process parameters
- Validated system, ready for release (e.g. media fills)
- Audit-suitable documentation

## Bio-decontamination Process Development and Validation



**Contact us if you are planning a bio-decontamination process development and validation for your isolation system. We will support you!**



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