Biodecontamination Process: Revalidation

A service for hydrogen peroxide-using production isolation systems

A developed, optimized, and validated H_2O_2-driven-biodecontamination process must be re-validated regularly, usually in yearly intervals. Based on the initial validation parameters for the isolation system, it is proved that the process is still yielding a complete kill of biological indicators inoculated with at least one million spores of *Geobacillus stearothermophilus*.

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 BIs prior to onsite use
- Creation of GMP-compliant documents (protocols, test sheets, reports)
- Onsite execution of isolator process revalidation (including placement of biological indicators, process performance and subsequent collecting of the indicators)
- Consultancy on isolator loading schemes

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 revalidation process
- System revalidation to release (e.g., for media fills
- GMP- and audit-compliant documentation

valicare
GMP Compliance Services & Solutions

Contact us if you are planning a biodecontamination process revalidation for your isolation system. We will support you!

Dr. Ellen Sons-Brinkmann
Business Development & Marketing
Phone +49 69 153 293 709
Mobile +49 172 413 0603
Ellen.Sons-Brinkmann@valicare.com

I. Köse
Validation Team Leader
Phone +49 7951 402 1421
Mobile +49 162 603 470 4
Ilker.Koese@valicare.com

Valicare GmbH
Eschborner Landstr. 130-132
60489 Frankfurt, Germany

Phone +49 69 153 293 700
info@valicare.com
www.valicare.com