Bio-decontamination Process Revalidation

A service for hydrogen peroxide-using production isolation systems

A developed, optimized and validated hydrogen peroxide-using bio-decontamination process has to be revalidated 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 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 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

Our Services & Support

- Inspection of biological indicators 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)

Your Benefits

- Professionally executed onsite revalidation of hydrogen peroxide-using bio-decontamination processes with qualified biological indicators
- Competently evaluated process parameters
- Consultancy on isolator loading schemes

valicare
GMP Compliance Services & Solutions

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

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