

BIOQUELL RAPID BIO DECONTAMINATION
SERVICE APPLICATION

Resume Operations Quickly After Facility Shutdown

Get your GMP Manufacturing Facility Back Online with Bioquell Rapid Bio Decontamination Service (RBDS)

Whether it's after an annual shutdown or just the start of a new batch, getting your GMP manufacturing facility back to an aseptic environment after being out of production is incredibly important. This can be a lengthy and labor intensive process due to the manual cleaning involved. It can also present an opportunity for contamination to enter your facility.

Select Bioquell RBDS for Facility Shutdown Recovery:

- ▲ A time saving alternative to manual cleaning
- ▲ Reduces risk of contamination in critical manufacturing facility
- ▲ Automated process reduces operating labor

Eliminate organisms from every exposed surface in an enclosed area



TECHNOLOGY

Bioquell hydrogen peroxide vapor decontamination technology provides a 6-log sporicidal kill on all exposed surfaces in the area being targeted. The technology is listed as a sterilant in the United States.

Efficacy is verified in each RBDS cycle by industry standard *Geobacillus stearothermophilus* biological indicators and visual chemical indicators.



COMPLIANCE

Bioquell technology is compliant with the BPR in Europe (EU Regulation 528/2012) and Bioquell Hydrogen Peroxide Sterilant is a registered EPA Sterilant (registration number 72372-1-86703), including efficacy data in line with NFT 72-281:2014.

GMP users have ever-increasing data handling and traceability requirements. In order to meet these, the RBDS process is fully documented and a final report can be issued for every decontamination cycle performed to support GMP compliance.



AREAS OF USE

Typical environments where Bioquell RBDS would be the ideal solution to restore an aseptic manufacturing environment after shutdown or between production campaigns include:

- ▲ Vaccine Production
- ▲ Sterile Injectables
- ▲ Pharmacy Compounding
- ▲ Cell Therapy
- ▲ Biologics

CASE STUDY

Biological Decontamination of a Vaccine Production Facility

Industrial Biotechnology Company, Denmark



EXECUTIVE SUMMARY

An industrial biotechnology company producing injectable vaccines in Denmark was looking to introduce more rigorous control measures to ensure a high level of bio-decontamination in its facility.

Commissioning Bioquell's Rapid Bio Decontamination Service (RBDS) team, approximately 4,500m³ was bio-decontaminated using hydrogen peroxide vapor within two days. The RBDS deployment achieved 100% deactivation of all biological indicators used to validate the process, and was fully documented for auditing and regulatory inspections. Due to the success of this initial programme, the Bioquell RBDS team has been commissioned to perform the same decontamination service on an annual basis.

BIOQUELL RBDS IN A VACCINE PRODUCTION FACILITY, DENMARK

The entire **4,500m³** vaccine production facility required a **6-log sporicidal kill**

Bioquell RBDS was selected as **minimal production downtime** was needed without the purchase of capital equipment

Sensors were placed in seven different areas to record **pertinent cycle parameters**

Bioquell's hydrogen peroxide vapor generators were positioned at **36 locations**

Geobacillus stearothermophilus **BIs placed at 150 locations** demonstrated **100% success** rate for decontamination with no detrimental effects on exposed equipment



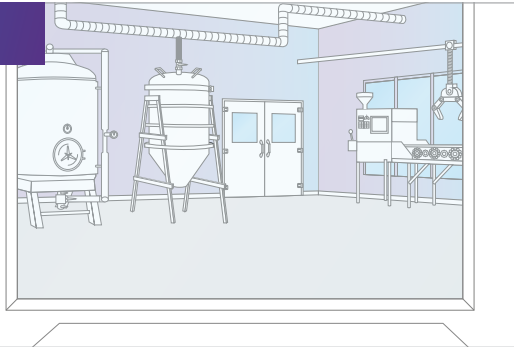
IN TWO DAYS THE ENTIRE VACCINE PRODUCTION SITE WAS FULLY DECONTAMINATED AND OPERATIONAL

Proven **Performance** for **Rapid, Effective** and **Flexible** Organism Elimination

RBDS PROCESS

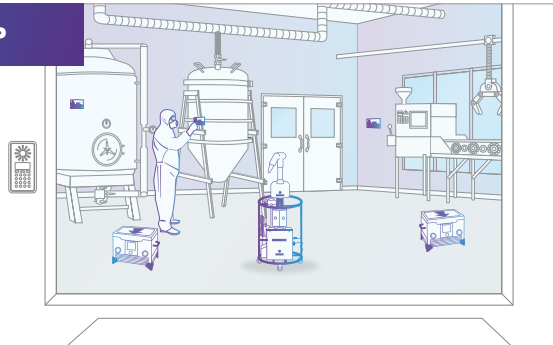
STEP 1 ACTIVATION

In the event of a contamination the Bioquell RBDS team is activated. Equipment and engineers are dispatched to the facility. Site personnel prepare the area following the established response plan.



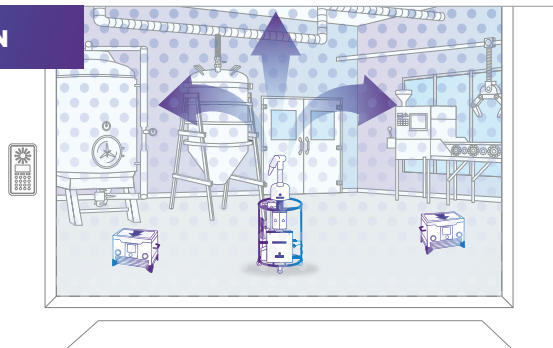
STEP 2 EQUIPMENT SETUP

The Bioquell team bring equipment on to site in line with client SOPs. The equipment, biological and chemical indicators are placed in challenge locations.



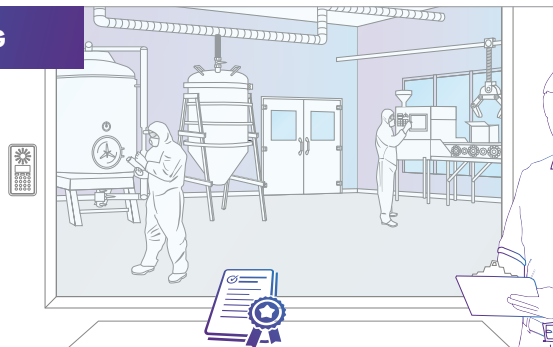
STEP 3 DECONTAMINATION

Vapor is injected to achieve 6-log sporicidal kill. After this, it is safely broken down into oxygen and water.



STEP 4 RECOMMISSIONING

Bioquell equipment is removed and the area is ready for use and detailed reporting follows. The service is fully managed, documented, and verified.



Take **Advantage** of **Bioquell RBDS** for **Facility Shutdowns**

- ▶ Decontaminate your whole critical manufacturing area in one cycle to reduce downtime
- ▶ Bioquell is less labor intensive than manual cleaning, offering potential cost savings and increasing operator efficiency and availability
- ▶ Flexible pricing models for a single service to annual contracts with multiple deployments
- ▶ Fully managed by Bioquell experts allows you to focus on other activities needed to restart production
- ▶ A validated and complete zone decontamination reduces risk of a contamination event during your upcoming critical manufacturing campaign

Bioquell

Rapid Bio Decontamination Service (RBDS)



A scalable bio-decontamination option using 35% hydrogen peroxide vapor



6-log sporicidal kill on all exposed surfaces



Available for scheduled or emergency response situations



Resume operations immediately with no additional wipe downs or residues left behind

ABOUT ECOLAB AND BIOQUELL

Ecolab Life Sciences supports safety, compliance and operational efficiency for global pharmaceutical and personal care manufacturers by delivering a comprehensive programmatic approach to contamination control, cleaning and disinfection.

Our end-to-end contamination control solutions, enhanced by Bioquell technology, allow our customers to have safer products and processes by reducing their risks. Our offerings meet regulatory requirements, support compliance initiatives, and realize operational efficiencies while achieving cost savings for our customers worldwide.

Bioquell RBDS is designed to get your critical manufacturing facility back online as quickly and effectively as possible. Visit www.bioquell.com for additional details

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USE BIOQUELL PRODUCTS SAFELY. ALWAYS READ THE LABEL AND PRODUCT INFORMATION BEFORE USE.

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