

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 program, 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 **6-log elimination** of 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** of decontamination with no detrimental effects on exposed equipment



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

CASE STUDY

Requirements and Set-up

Industrial Biotechnology Company, Denmark

BACKGROUND

A leading industrial biotechnology company in Denmark that produces vaccines used in the biodefense market, was looking for a large-scale bio-decontamination program.

The business required a service that could refine the sanitization regimes already in place in their facility. With GMP procedures incumbent within production operations, there was no contamination incidence to deal with. The company was simply looking at implementing additional bio-decontamination technology as a precautionary measure to avoid the future prospect of uncontrollable bioburden.

CHALLENGE

Efficacy: The decontamination service needed to offer the benefits of a 6-log sporicidal kill with minimal production downtime. For the company, the purchase of capital equipment was not an option.

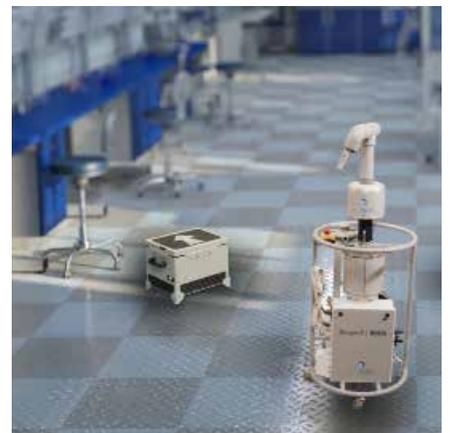
Documentation: It was crucial that the process was fully documented for auditing and regulatory inspections.

SOLUTION

After reviewing the bio-decontamination options on the market, the Bioquell RBDS service was commissioned to undertake the work. It was employed to establish a high bioburden reduction within the facility on a scheduled/ routine basis.

The hydrogen peroxide vapor technology offered by Bioquell RBDS creates a 6-log sporicidal kill on every exposed surface and is validated against *Geobacillus stearothermophilus* Biological Indicators (BIs), which are considered to be the industry standard validation tool for determining hydrogen peroxide vapor decontamination efficacy.

Full documentation was provided via a final report outlining all areas decontaminated including locations of biological indicators with incubation results displaying validated efficacy.



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Requirements and Set-up

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DEPLOYMENT

Firstly, a complete site survey to discuss customer expectations, plus ascertain best management of on-site operations, was undertaken by an experienced Bioquell project manager before the arrival of the Bioquell RBDS engineers and equipment.

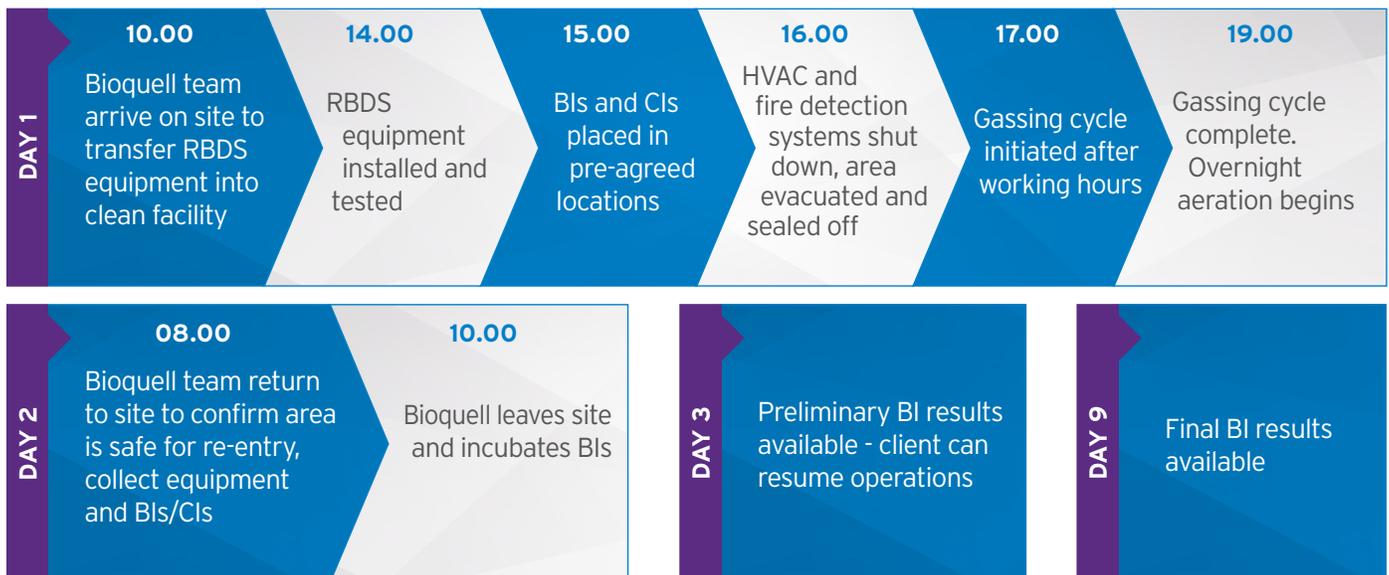
The enclosure was a vaccine production facility of approximately 4,500m³ with varying European Union Good Manufacturing Practice (EU GMP) grades including grade A (inside the filling equipment), B, C and D. Bioquell's hydrogen peroxide vapor generators were positioned at 36 locations to optimize dispersion of the decontaminant. Sensors were also placed in seven different areas to record pertinent cycle parameters.

Bioquell's 6-log *Geobacillus stearothermophilus* BIs were used to demonstrate the efficacy of the process. The BIs were placed at 150 locations throughout the entire production suite. During the bio-decontamination phase, a single external point of control ensured safe management of the process. Using low level hydrogen peroxide vapor sensors, regular monitoring of the zone perimeter for vapor leakage was carried out.

Following cycle completion, Bioquell aeration units were activated to break down the hydrogen peroxide vapor within the zone. The aeration units catalytically convert hydrogen peroxide vapor into oxygen and water vapor and were used in conjunction with the facility's HVAC system.



TIMELINE



CASE STUDY

Outcomes

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RESULTS

As injectable vaccines were manufactured within this facility, re-establishment of all EU GMP grades was paramount. Efficacy of the operation was judged with reference to incubation results of the BIs.

Upon completion of the decontamination process, the BIs were collected in conjunction with the removal of Bioquell RBDS equipment. After a standard seven-day incubation period, no growth was observed in 100% of the 150 BIs retrieved from the site, demonstrating that a 6-log sporicidal kill had been achieved in all areas within the scope.

Additionally, no equipment exposed to the hydrogen peroxide vapor bio-decontamination was affected, demonstrating the excellent materials compatibility of utilizing Bioquell technology.

The aim of biologically deactivating areas situated throughout the production facility within the required two-day time frame was achieved, rendering the entire area completely bio-decontaminated. Due to the success of this initial program, the company engages the Bioquell RBDS team to annually bio-decontaminate the entire site.

“Due to the success of this initial programme, the company engages the Bioquell RBDS team to annually bio-decontaminate the entire site every year”



ENTIRE **4,500m³**
SITE DECONTAMINATED



SUCCESS ON **100%** OF
INDICATORS USED TO VERIFY
BIO-DECONTAMINATION



COMPLETED ON SCHEDULE
IN A TIGHT **TWO-DAY**
TIME FRAME

Bioquell RBDS is designed to offer **immediate response** in many regions around the world.
Visit bioquell.com for additional details.

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

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