

## CASE STUDY

# Priority Response Plan (PRP) for Bio-decontamination of a Biopharmaceutical Production Facility

Multinational Biopharmaceutical Company, Singapore



## EXECUTIVE SUMMARY

A multinational biopharmaceutical company in Asia, was looking to introduce a rigorous plan to ensure high-level bio-decontamination of their manufacturing facility in the event of contamination.

The customer chose Bioquell's Rapid Bio Decontamination Service (RBDS) to produce a Priority Response Plan (PRP) that enables swift mobilisation of RBDS personnel and equipment and reduces the risk of unforeseen challenges thus minimising downtime of the manufacturing facility. Bioquell RBDS perform hydrogen peroxide vapour decontamination that achieves a rapid 6-log sporicidal reduction on all exposed areas within an enclosed environment. The process is scalable in order to cover various needs should a contamination event occur.

Every deployment is fully documented with detailed results verified through the use of biological and chemical indicators, ensuring a successful decontamination, as well as covering any regulatory and auditing concerns.

## USING BIOQUELL TO DEVELOP AND IMPLEMENT A ROBUST CRITICAL RECOVERY PLAN

The facility required a complete contamination recovery plan that would achieve a **6-log sporicidal reduction** in the event of a viral contamination incident

Bioquell was commissioned to create a comprehensive proposal - **the Priority Response Plan (PRP)**

The equipment setup was mapped and the target cycle parameters derived for the **H<sub>2</sub>O<sub>2</sub> vapour** decontamination cycle

A **comprehensive site assessment** including all production processes was carried out by the RBDS team in conjunction with the client

Having a **robust PRP** enables the client to contact Bioquell RBDS immediately, to contain the contamination event quickly and limit the spread of it



**THE PRP REDUCES THE RISK OF UNFORESEEN CHALLENGES AND PROVIDES A GUARANTEED RAPID RESPONSE TO CONTAMINATION EVENTS**

## CASE STUDY

# Requirements and Set-up

Multinational Biopharmaceutical Company, Singapore

## BACKGROUND

A leading multinational biopharmaceutical company in Singapore required a complete contamination recovery plan that would achieve a 6-log sporicidal reduction in the event of a contamination incident within its state-of-the-art biomanufacturing facility. Although there was no active contamination incident to deal with, the company understood the importance and impact that a bio-decontamination recovery plan could provide as a precautionary measure should a viral contamination event be discovered.

## CHALLENGE

**Efficacy:** A full PRP was required to enable an effective decontamination process which could be validated by the client to remove any potential bioburden within the manufacturing areas being targeted.

**Documentation:** The PRP documentation is a vital part of the client's business continuity planning, giving them a robust list of procedures should a contamination emergency arise. In the event of a contamination incident, the Bioquell RBDS process is fully documented for auditing and regulatory inspections.

## SOLUTION

The biopharmaceutical company was impressed by Bioquell's expertise in writing PRP plans for clients in Europe and the United States and, after reviewing the other bio-decontamination options in the market, Bioquell was commissioned to create the comprehensive PRP.

For the client, having a PRP in place offers a number of additional benefits over and above using the standard RBDS service in the event of a contamination incident. Procedures have already been mapped, increasing the speed to mobilise and reducing the risk of unforeseen challenges for both the client and the Bioquell RBDS team. The facility has already been surveyed, allowing swift deployment of Bioquell RBDS equipment to pre-defined locations dependent on where the contamination event has occurred. A rapid response in this instance is made possible due to Bioquell's presence in Asia along with a dedicated, local RBDS team and equipment.

In the event of a decontamination incident, the hydrogen peroxide vapour technology offered by Bioquell's RBDS generates a 6-log sporicidal kill on all exposed surfaces and is validated against *Geobacillus stearothermophilus* Biological Indicators (BIs), considered the industry standard validation benchmark for determining hydrogen peroxide vapour decontamination efficacy.



