

ENSURE  
**PEACE  
OF MIND**

## Ensure **Business Continuity** with Bioquell Rapid Bio Decontamination Service (RBDS)

**The risk of contamination is a major concern in pharmaceutical and particularly biologics manufacturing. The impact of a contamination event can be huge both in terms of costs, lost revenue and drug shortages for patients. While every effort should be made to manage facility bioburden and prevent contamination it is also important to have a robust continuity plan in place in the event the worst does happen.**

Having the right procedures in place to respond to a contamination event limits the impact by minimising downtime and allowing production to resume as soon as possible.

Bioquell's Rapid Bio Decontamination Service (RBDS) provides a fast, fully managed approach to eliminate bioburden in an area. Bioquell's hydrogen peroxide vapour ( $\nu\text{H}_2\text{O}_2$ ) decontamination technology has a scientifically proven broad spectrum of efficacy and each cycle is validated in situ with 6-log *Geobacillus stearothermophilus* Biological Indicators (BIs). The RBDS process is scalable from a single room to an entire facility by the deployment of additional equipment and personnel which enables fast decontamination of areas, allowing a rapid return to clean conditions.

Building Bioquell RBDS into business continuity plans is a proactive approach to limit the impact of a contamination event and minimise the extent of any downtime. RBDS can be incorporated into these procedures in several ways to increase security.

# Selecting the **Right Business Continuity Plan** for your Facility

A **6-log sporicidal kill** on every exposed surface in an enclosed area



## PRIORITY RESPONSE COVER

The simplest way to build RBDS into a business continuity plan is through the writing of a proactive priority response plan (PRP). A Bioquell RBDS expert conducts a detailed site survey to understand specific facility requirements such as layout, HVAC design, gowning and material transfer procedures. Then a detailed plan for area decontamination is written including logistics, equipment positioning, and personnel requirements can be produced and agreed. In the event of a contamination event this PRP can be activated.

### Benefits of having a PRP in place

- ▲ Bioquell will be an approved contractor, significantly reducing the response time of the Bioquell team
- ▲ Reduce deployment time as both site and Bioquell personnel understand each other's procedures
- ▲ Reduce costs compared to standard decontamination deployment



## CRITICAL RESPONSE COVER

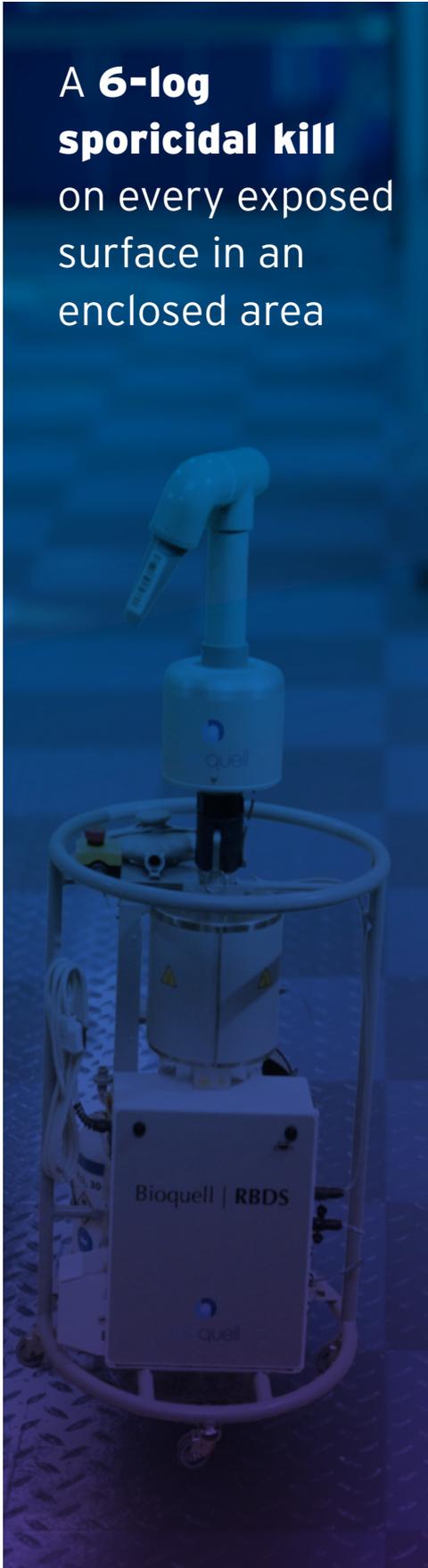
In cases where a higher level of assurance is required the RBDS offering can be enhanced further. In addition to the writing of a PRP, a response time for Bioquell engineers to begin decontamination can be guaranteed.

This is achieved through the provision of dedicated specialised decontamination equipment to support a single site. This equipment is held at the nearest Bioquell facility or on the target site and checked monthly to ensure full operational status, ready for activation.

A **response time** of either **24, 36 or 48 hours** for a single area of a known volume ensures rapid elimination of contamination and return to production.

### Benefits of having a Critical Response Plan (CRP)

- ▲ Swift response time for Bioquell RBDS deployment
- ▲ Reduce deployment time as both site and Bioquell personnel understand each other's procedures
- ▲ Minimisation of lost production time

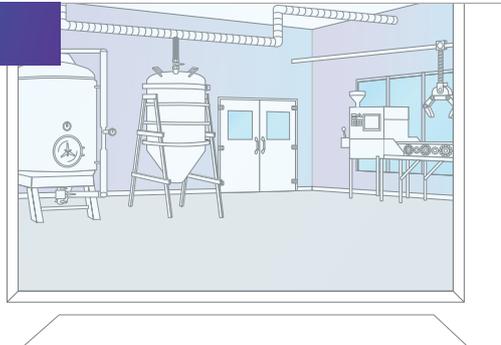


# Proven **Performance** for **Rapid, Effective** and **Flexible** Pathogen Elimination

## RBDS PROCESS

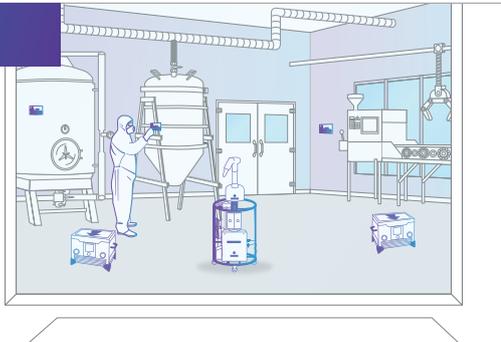
### STEP 1 ACTIVATION

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



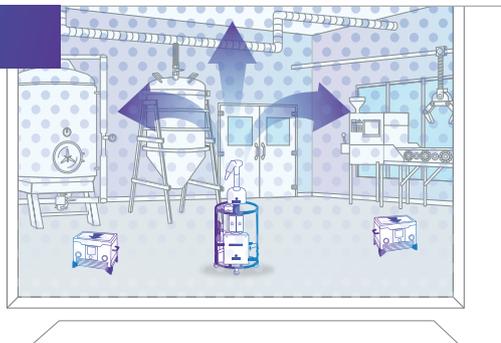
### STEP 2 EQUIPMENT SETUP

The Bioquell team bring equipment on to site in line with client SOPs. The equipment, biological and chemical indicators are placed in the positions defined by the response plan.



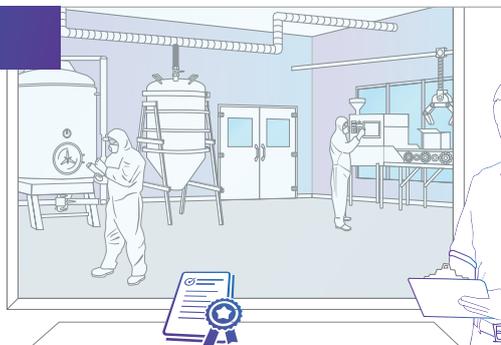
### STEP 3 DECONTAMINATION

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



### STEP 4 RECOMMISSIONING

Equipment removal, handover of the area and delivery of a full report - the service is fully documented, fully managed and verified using BIs.



## Impact of a Shutdown

A shutdown can lead to loss of revenue from longer lead times, competitor sales, impact on reputation and potential fines

SCRAPPED PRODUCT  
UP TO **\$1MILLION\***

TIME CONSUMING  
QA INVESTIGATION  
UP TO **\$20,000\***

CLEANING COSTS  
UP TO **\$100,000\***

**\$MILLIONS\***  
IN DISCARDED PRODUCT  
AND RESIN

BIOQUELL CAN **REDUCE**  
**TURNAROUND TIME, DOWNTIME**  
& **MAXIMISE UPTIME**

\*<https://www.cytivalifesciences.com/en/us/news-center/cost-and-impact-of-a-bioburden-incident-10001>

Bioquell RBDS is designed to get your critical manufacturing facility back online as quickly and effectively as possible. Visit [www.bioquell.com](http://www.bioquell.com) for additional details

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

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