CASE STUDY

### **Bioquell Rapid Bio Decontamination Service**

Resuming Operations in Wuhan after COVID-19 Shutdown

SUCCESSFUL
POST COVID-19
DISINFECTION
WAS CONDUCTED
IN A MAJOR
PHARMACEUTICAL
MANUFACTURING
FACILITY, CHINA

#### **BACKGROUND INFORMATION**

**Issue:** Following the COVID-19 lockdown, Environmental Monitoring (EM) at a major international provider of biologics Contract Development and Manufacturing Organizations (CDMO) services in China indicated spore contamination in a production room.

Despite exhausting all disinfection methods in their records, including the manual application of a sporicide, there was a repeated failure of the EM test standards. Consequently, the production of a valuable batch of product worth \$5M USD was being delayed.

**Our Solution:** The fungal species identified, (*Cheatomium globosum* and *Chaetomium unguicola*) are notoriously challenging to remove using conventional methods, as the key is to locate and eliminate the reservoir from where the contamination starts.

Bioquell, an Ecolab Solution, was able to provide its Rapid Bio Decontamination Service (RBDS), utilizing 35% hydrogen peroxide vapour technology to cover **every exposed surface** as well as the air within the deployment area. This provides a 6-log sporicidal kill, including in the contamination reservoir.

# RAPID BIO DECONTAMINATION SERVICE (RBDS) FROM BIOQUELL FOR SPORE ELIMINATION

Following the COVID-19 lockdown in China, the facility was ready to begin manufacturing Environmental Monitoring revealed the presence of excessive spores in a cleanroom, delaying the production of a batch worth \$5M USD

Bioquell Rapid
Bio Decontamination Service
(RBDS) was selected to
perform enhanced disinfection
on an as needed contract basis

Existing disinfection methods were tried and repeatedly failed EM test standards

18 **Bioquell RBDS** units were deployed by trained Bioquell staff and the **3,800m**<sup>3</sup> space was **successfully decontaminated** at the facility



AFTER BIOQUELL RBDS, THE COMPANY PASSED ITS ENVIRONMENTAL MONITORING TESTS AND WAS ABLE TO **RESUME** OPERATIONS





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#### **CHALLENGES**

#### **Timescale**

**Requirement:** To rapidly resume production immediately following the COVID-19 outbreak and lockdown.

*Our Solution:* Almost immediately after the lockdown was lifted, Bioquell was able to quickly complete the decontamination of almost 4000m<sup>3</sup> of production space including the HVAC.

#### **Efficacy Needs**

**Requirement:** 6-log bio-decontamination throughout the entire enclosed space to ensure no spores remain.

*Our Solution:* Bioquell hydrogen peroxide delivers a 6-log sporicidal kill on all surfaces in an enclosed area.

#### **Documentation Needs**

**Requirement:** To demonstrate efficacy against the spores causing the continuous EM failures.

*Our Solution:* Full evidence-based efficacy report showcasing Bioquell's capability in effectively eliminating the targeted pathogen.

#### **Additional Challenges**

**Requirement:** Integrity of wall panels must be maintained to avoid blistering. No compatibility testing possible in advance.

*Our Solution:* To provide evidence of previous results on panel integrity after Bioquell Bio Decontamination in other comparable facilities.

**Requirement:** Validation of eradication of identified fungal species (*Cheatomium globosum* and *Chaetomium unguicola*) in the HVAC with use of Biological and Chemical Indicators (BIs & CIs).

*Our Solution:* Use of an alternative decontamination protocol involving pulsing through hydrogen peroxide vapour during a decontamination cycle.



\*\*Bioquell RBDS
allowed us to quickly
resolve our challenge
and begin operations
with confidence.\*\*

QA SENIOR DIRECTOR

Bioquell RBDS may be able to **respond immediately** in your region.

Visit **bioquell.com** for additional details.











18 BIOQUELL RBDS UNITS DEPLOYED

3800m<sup>3</sup>
AREA COVERED

**274** BIS & CIS USED **100% SUCCESS** 

**100%** PASS RATE FOR INDEPENDENT AIR SAMPLES\*

COMPLETED ON SCHEDULE

\*Dust particle counter, dust particle multi-point inspection system, sampling device, environment comprehensive parameter monitor and FFU central controller.

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

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52 Royce CI Andover SP10 3TS, UK www.bioquell.com Richtistr. 7 8304 Wallisellen Switzerland

www.ecolablifesciences.com

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