

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.

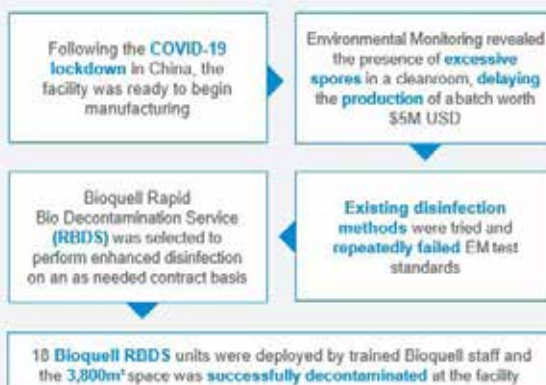
Our Solution: The fungal species identified, (*Cheatomium globosum* and *Chaetomium unguicola*) are notoriously challenging to remove using conventional methods, as the key is to locate and eliminate the reservoir from where the contamination starts.

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.

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

QA SENIOR DIRECTOR

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



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

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 4000m³ 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.



*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.

