

Automated Bio-decontamination Service Saves Large Pharmaceutical Manufacturer \$2M

Application: Sterile manufacturing

Segment: Biopharmaceutical

Challenge: Extensive downtime caused by contamination event

Recommended product: Ecolab's Bioquell RBDS



Situation

A large German pharmaceutical manufacturer had a contamination event caused by microorganisms that were spreading quickly throughout the facility. Efforts to reclaim the space failed as the company could not determine the origin of the contamination.

Production had to be drastically reduced until the entire facility was disinfected. The process was estimated to be a 10-day manual disinfection effort involving multiple cleaning methods. The locations requiring attention included production areas with difficult to reach spots and complex shapes. With no guarantee that every exposed surface could be disinfected and a lengthy shutdown period, alternative methods were explored.

Solution

Ecolab's Bioquell Rapid Bio Decontamination Service (RBDS) was selected to disinfect the area*. Ecolab's Bioquell RBDS is an all-inclusive fully managed service that provides a 6-log sporicidal kill* on exposed surfaces with automated hydrogen peroxide vapor. The process delivers a sterilant into enclosed areas and can be verified instantly with chemical indicators and validated through biological indicators with a quick turnaround time. These factors, along with Ecolab's Bioquell RBDS established expertise, all played a pivotal role in the selection process.

After selecting Ecolab's service, more than 30 Bioquell RBDS generators, that provide the bio-decontamination, were expedited on-site and readied with a one-day response time. The scope of the area receiving disinfection was able to be expanded as well. Initially cleanrooms were only to receive attention, but the automated service included the stairs, elevator areas, and HVAC surfaces.



*When used according to the label instructions for Bioquell Hydrogen Sterilant (EPA Registration Number: 72372-1-86703)




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Results

After three days of downtime, which included the additional zones, the area was deemed ready to resume operations. With seven days of downtime avoided, the impact to the client was over \$2M including accounting for the costs of the Ecolab Bioquell RBDS.

The facility remains within its acceptable operational environmental limits and has taken steps to help reduce the risk of a contamination event in the future, through preventative actions such as using Ecolab's Sterishield Delivery System (SDS) spray bottles and sporicidal, and implementing an annual Bioquell RBDS service plan.

SCOPE OF DISINFECTION		
	Internal cleaning procedure	Ecolab RBDS
Cleanrooms	✓	✓
Stairs	✗	✓
Corridors	✗	✓
Elevators	✗	✓
HVAC surfaces	✗	✓
6-log kill validated* by <i>Geobacillus stearothermophilus</i> biological indicators	✗	✓

TIME & COST COMPARISON OF DISINFECTION		
	Internal cleaning procedure	Ecolab RBDS
	10 days internal effort	3 days managed by Ecolab
	\$3M in lost production	\$900K
 TOTAL VALUE DELIVERED		\$2M+

ECOLAB RBDS

Ecolab's Bioquell Rapid Bio Decontamination Service (RBDS) is a fully inclusive service providing everything required to complete a 6-log sporicidal kill* on exposed surfaces within your facility.

The service is designed to work with your operational requirements, whether in an emergency situation or as part of a pre-planned intervention. You can even use our rapid response service to bio-decontaminate critical equipment such as a laminar flow hoods, isolators, lyophilizers and more.



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How Ecolab adds value



Site surveys

Ecolab offers site-surveys from a trained technical team to review new or existing manufacturing and cleaning process.

VALUE+

- Technical recommendations are matched to your most relevant objectives and key performance indicators (safety, water savings, efficiency, etc.)
- Formal report summarizes potential savings
- Delivers implementation strategy that minimizes production disruptions



Lab studies

Ecolab offers a laboratory team that can analyse soils, identify residues and test samples.

VALUE+

- Creates a quicker and more successful cleaning recommendation
- Ensures the chemistry solution is effective against your unique, targeted soils
- Helps determine optimal dilution and implementation parameters



Disinfection with chemistry vs. water

Ecolab can help implement a validated strategy to clean CIP systems with registered chemical disinfectants as an alternative to water and heat.

VALUE+

- Saves water which can help meet sustainability goals
- Reduce energy and time needs by removing need to heat water to required temperature



Validation assistance

Ecolab can assist with the complex validation process and change controls by providing guidance and documentation.

VALUE+

- Guidance includes:
 - Cleaning process design and development
 - Cleaning process validation
 - Continuous cleaning process verification
- Helps ensure process stays in line with regulatory expectations and acceptance criteria



Dedicated regulatory team

Ecolab leverages industry expertise to deliver insights and guidance on regulatory expectations, trends and available tools to help ensure compliance for product safety and quality.

VALUE+

- Helps ensure compliance with cGMP to ensure cleaning and disinfection meet product safety and quality requirements
- Help implement validations that meet regulatory expectations



Customer training

Ecolab's team is comprised of experts to help you implement, manage, and maintain quality & compliance requirements and protocols.

VALUE+

- Gain valuable best-practices and implementation strategies from trained field and technical experts
- Reduce troubleshooting time from on-site support and process training to resolve problems quickly

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

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