

A leading laboratory testing company partners with Ecolab to save over \$1M per year by switching to Ecolab's Bioquell Qube

Application:
Sterility Testing

Segment:
Biopharmaceuticals

Challenge: Extensive downtime during and after bio-decontamination

Recommended product:
Bioquell Qube

SITUATION

A world leader in laboratory testing was seeking an alternative to their current isolator, used for sterility testing, due to the following challenges:

- Bio-decontamination Cycle Times:** On a monthly basis their isolator needed to be fully decontaminated using vaporized hydrogen peroxide. This bio-decontamination cycle, plus external exhaust, required a full day. Not being able to utilize the isolator created operational challenges, ultimately reducing production throughput.
- Employee Health and Safety concerns:** The company sought to create a better working environment for its team members. Current isolators were cumbersome, uncomfortable, difficult to clean and required extended periods of standing while in a half suit.
- Operational Challenges & Cost:** The isolators were required to reside in an ISO 5 (Grade A equivalent) cleanroom which created time delays for access and increases operational costs significantly. Additionally, it was

important to reduce cost associated with cleaning, environmental monitoring and data analysis.

- Ongoing Maintenance Cost:** Maintaining the equipment also became a hassle as the company's staff performed all of the planned annual and unexpected maintenance on the isolators (excluding HEPA certifications). This had time consuming and costly consequences. Any alternative selected would need to provide maintenance and service work.

TOTAL VALUE DELIVERED

\$1,136,620

Savings Per Year

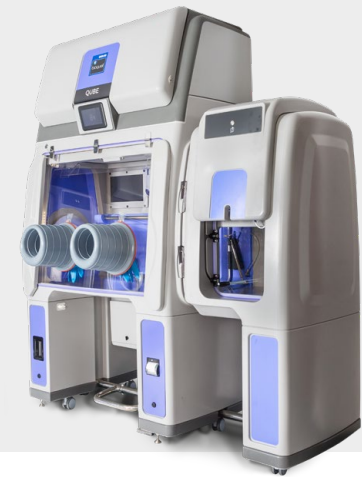
See page 3 for more details

BIOQUELL QUBE

The Bioquell Qube is a modular isolator constructed of hardwearing polypropylene and integrated with Bioquell bio-decontamination technology. The system comes in 2, 4 or 6 glove configurations and offers up to 2 material transfer chambers or rapid transfer ports (RTPs).



A leading laboratory testing company partners with Ecolab to save over \$1M per year by switching to Ecolab's Bioquell Qube



SOLUTION

After a period of independent research, key decision makers met with Ecolab to review its Bioquell Qube, an isolator with integrated hydrogen peroxide vapor bio-decontamination technology.

The company subsequently purchased a Bioquell Qube system in an M-32 variation. This variation (pictured at the top of page 3) allows for 3 chambers of 2 gloves, and a material transfer hatch on each side of the system. This meant that up to two batches at once could be completed for sterility testing (2 chambers per system for testing, with one chamber used for bio-decontaminating any incoming supplies needed).

The Bioquell Qube's modular design concept allowed the company to select a unit that was customized for their operation. The Bioquell Qube was selected for the following reasons:

- Available in multiple configurations to suit their needs with up to 6 gloves and 2 transfer chambers
- Integrated hydrogen peroxide vapor technology utilizing Bioquell Hydrogen Peroxide Sterilant* to **create an ISO 5 / Grade A** working environment
- Operates in negative or positive pressure
- Validated for rapid cycles with a 6-log kill on exposed surfaces (as short as 30 minutes)
- Optimized for sterility testing, including optional integrated sterility testing pump
- Software fitted to enable compliance with 21 CFR part 11 and Eudralex Vol. 4 Annex 11 regulations
- Does not require construction or electrical work for installation

RESULTS

The Bioquell Qube was built, installed and validated within 16 weeks from date of order. The installation, validation and training was managed by Ecolab's team of Installation Engineers and Validation Specialists.

They have been able to realize the following value:

- **Shorter Bio-decontamination Cycle Times:** Leveraging the Bioquell Qube's fully self-contained and validated hydrogen peroxide vapor Bio-decontamination process, the total cycle time was reduced significantly from their previous isolator bio-decontamination process. The bio-decontamination step was reduced to only 3 hours, resulting in an additional 2-3 batches per week to be processed. The production value of this time was estimated at over \$775,000 per year.
- **Improved Employee Health and Safety:** The Bioquell Qube has the user's comfort incorporated as part of the design allowing operators to stand or sit while working within the isolator's chambers. No longer are half suits required due to the Bioquell Qube being a closed containment system. For the company, this meant that operators no longer needed to stand or wear a half suit for extended period. Additionally, the Bioquell Qube sleeves are made from a lightweight, comfortable EPDM material ideal for extended use.
- **Reduction in Operational Challenges and Cost:** With the Bioquell Qube able to be hosted in a lower grade cleanroom by creating an ISO 5 / Grade A environment within its chamber(s), operational costs were able to be reduced and access to the isolator was much

faster. As a result, they were able to save time and money. See how with these additional operational cost savings:

- Fewer supplies are used as they no longer require environmental monitoring after cycles, creating a supply saving of \$12,000 per year.
- The Bioquell Qube has allowed for the company to use the Electronic Laboratory Notebook (ELN) for bio-decontamination cycles, saving time for data review. A daily reduction of 75 minutes per day analyzing data results in savings of \$139,500 per year.
- Lower operating costs for the lab space due to the Bioquell Qube's footprint compared to soft-walled isolators (and associated bio-decontamination units) creates a saving of \$119,040 per year.
- When manual cleaning of the Bioquell Qube was required, it took a fraction of the time of the previous isolator, saving 2 hours per month or \$7,400 per year.
- **Ongoing Maintenance Cost:** The client would also no longer need to perform maintenance on their equipment as the Bioquell Qube comes with a comprehensive service contract, saving \$46,000 per year. Additionally, costs associated with HVAC integration were eliminated as the Bioquell Qube has a fully integrated HEPA process and does not require connecting to the building's HVAC system.



IMPACT BEYOND COST SAVINGS

There are items that a dollar amount simply was not able to capture, but the impact was substantial:

- Shorter turnaround time (TAT) for high-risk samples has been a highly impactful benefit which allows them to better satisfy client requirements.
- A decrease in training time has made the staff more flexible, a benefit that can allow the company to meet client demand and improve client satisfaction as a result. The training period was significantly reduced by 50%.
- The time saved from using the ELN has been utilized on other revenue generating activities such as data review for client samples.

SUMMARY

With integrated and validated bio-decontamination using Bioquell Hydrogen Peroxide Sterilant (EPA Registration Number: 72372-1-86703), each bio-decontamination cycle would only make the isolator inaccessible for a fraction of the time compared to their previous isolators connected to an alternative bio-decontamination system that was not from Ecolab. A validation process after installation ensured a 6-log sporicidal kill on exposed surfaces within the chambers, creating an ideal, repeatable and monitored environment for sterility testing.

ANNUAL BENEFITS



WASTE

\$12,000
saved on supply costs



PRODUCTIVITY

75 mins saved per day
reviewing data equal to
\$139,500

2 hours saved per month
on cleaning time equal to

\$7,400

50%
decrease in training time



PROFITABILITY

2-3 extra sample batches
per week equal to
\$775,000

\$46,000
saved on maintenance
and services costs



ENERGY

\$119,040
saved on lower
operating costs



TOTAL VALUE DELIVERED

\$1M+

in total value delivered per year

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 analyze 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



Automated Bio-decontamination to meet your needs

Ecolab has automated bio-decontamination solutions to create a validated 6-log sporicidal kill using Bioquell Hydrogen Peroxide Sterilant.*

VALUE+

- Save time and reduce waste by decreasing the risk of shutdown, production stoppage or product failure due to an environmental contaminant
- Help avoid time intensive investigations, and potential patient and reputational harm



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

**ECOLAB'S BIOQUELL
NORTH AMERICA**
702 Electronic Dr., Suite 200
Horsham, PA 19044
www.bioquell.com

**WORLDWIDE
HEADQUARTERS**
1 Ecolab Place
St. Paul, MN 55102
www.ecolab.com/lifesciences