

Achieve Personnel, Product & Patient Safety

With Ecolab's
contamination control
solutions for
compounding
pharmacies



ECOLAB®

GLOBAL EXPERTS IN
CONTAMINATION CONTROL

About Ecolab

A trusted partner for millions of customers, Ecolab is a global sustainability leader offering water, hygiene and infection prevention solutions and services that protect people and the resources vital to life.

Building on a century of innovation, we deliver comprehensive science-based solutions, data-driven insights and world-class service to advance food safety, help maintain clean and safe environments, optimize water and energy use, and improve operational efficiencies for customers in more than 170 countries around the world.

Our assurance

Ecolab is committed to providing exceptional service, total plant solutions and unsurpassed industry expertise to help you achieve your business goals.

Our breadth of resources and integrated business model ensure consistency across your operations.



From TPN compounding to cytotoxics, Ecolab delivers solutions to help bring your product to patients faster, more safely and efficiently



COMPOUNDING ISOLATORS



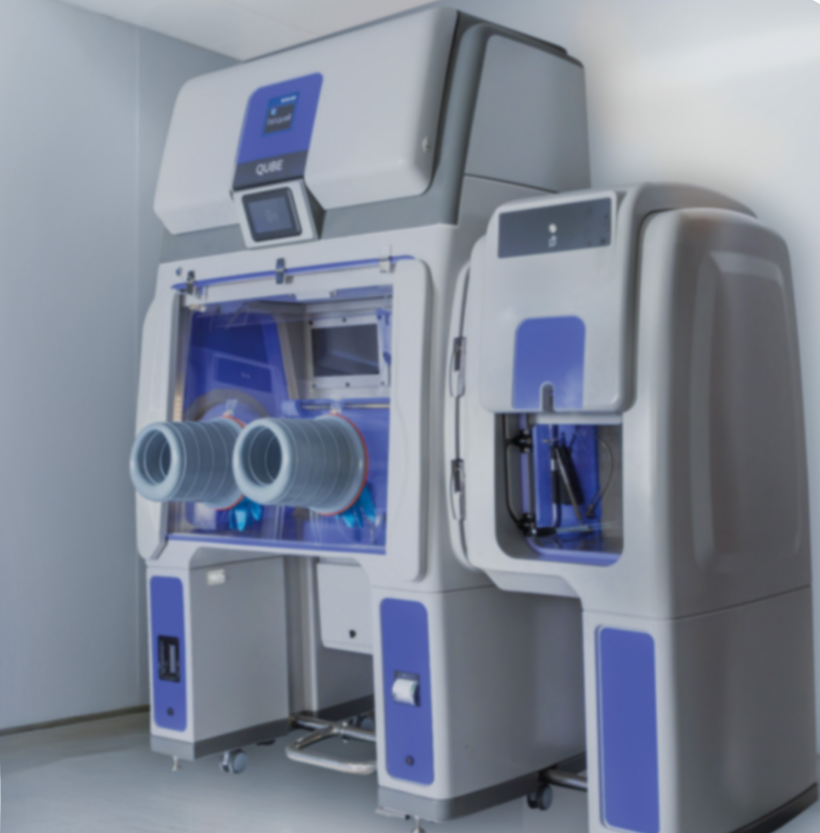
AUTOMATED BIO-DECONTAMINATION



REGULATORY EXPERTISE



CLEANING AND DISINFECTION



Superior contamination control protects your personnel, your product and your patients

Maintaining an environment free of contamination is not only desirable, it is also crucial to ensure the drugs and treatments intended for patients are as safe and effective as possible.

Partnering with Ecolab will help you deliver this environment, enabling your team to focus on what they do best, efficiently and in line with regulatory guidance.

Benefits of using an isolator for drug compounding

Critical work demands the optimal workstation

With the expansion of the drug compounding market, using a closed system for aseptic processing such as an isolator is an increasing trend which mitigates risk and is expected by EU GMP Annex 1¹ regulations.

While biosafety cabinets limit protection to operators, isolators can be designed to protect the operator from cytotoxic drug exposure, and the product from contamination.

Isolator systems can also achieve lower facility running costs than biosafety cabinets as they can be located in a lower grade cleanroom, saving cost on gowning,

energy (HVAC system), environmental monitoring, cleaning and disinfection, and maintenance.

In addition, there is a regulatory trend towards performing compounding in isolators. Investments in isolators made today align with the future industry expectations.



Biosafety cabinets

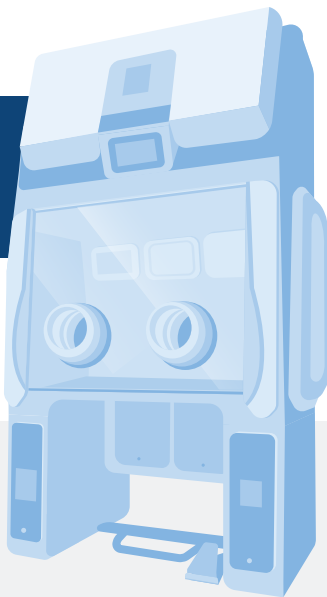
Open systems provide limited operator and product protection²

Reside in Grade B cleanrooms per GMP guidance

Isolators

Provide total operator and product protection²

Reside in Grade C (open isolators) or C/D (closed isolators) cleanrooms per GMP guidance



Comparison between approaches

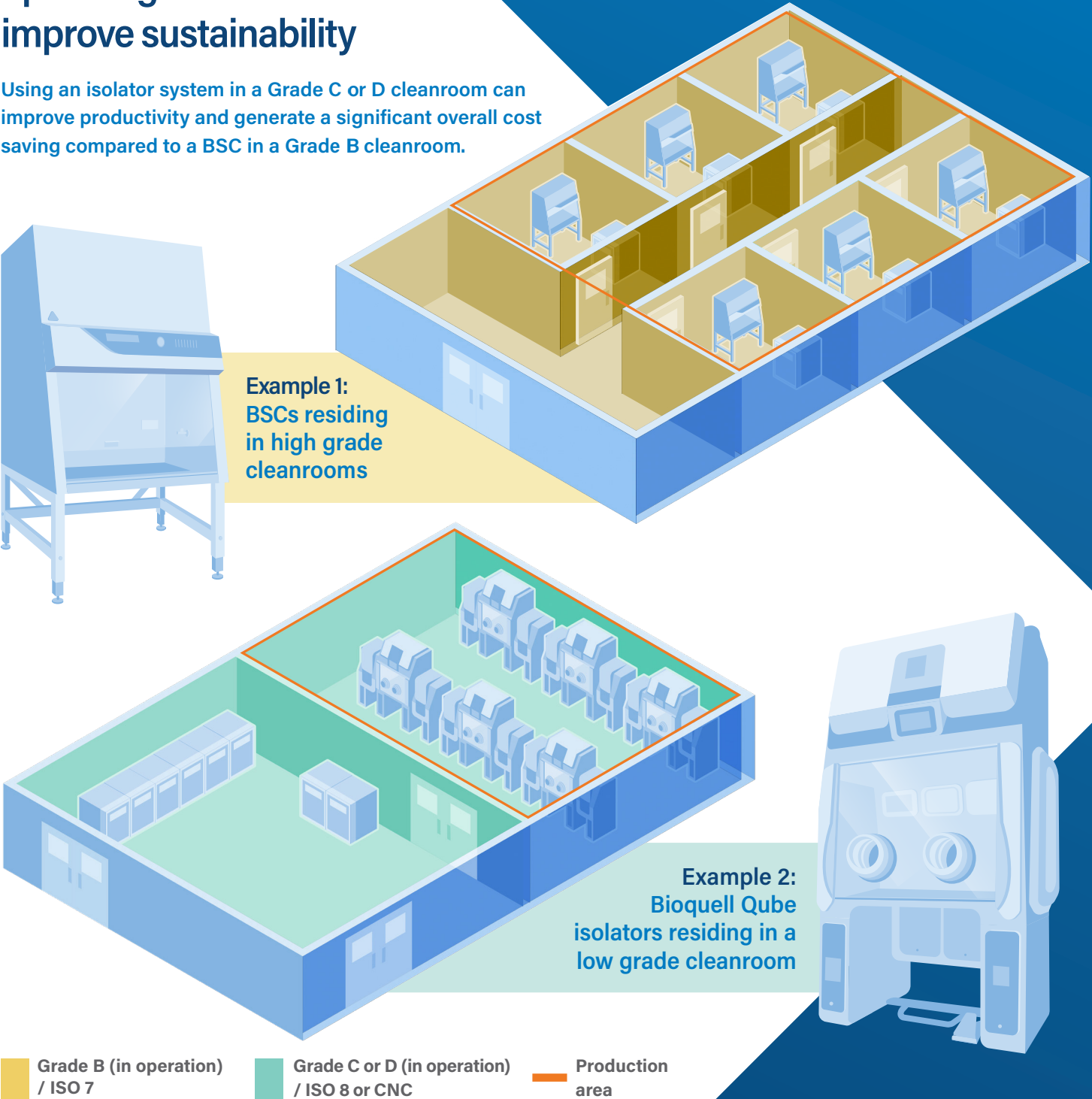
BSC/LAF in Grade B cleanroom	Criteria	Isolator system in Grade D cleanroom
10% ²	Batch failure rate	3% ²
High	Gowning requirements	Low
No	In line with regulatory guidance (EU GMP Annex 1)	Yes
Manual with IPA (3-log reduction)	Material transfer process	Automated with hydrogen peroxide vapor (6-log sporicidal reduction)
30% higher ³	Cleanroom running costs	30% lower ³

1. EU GMP ANNEX 1 MANUFACTURE OF STERILE MEDICINAL PRODUCTS (2022)
2. LOPES ADRIANA G ET AL. "COST ANALYSIS OF CELL THERAPY MANUFACTURE: AUTOLOGOUS CELL THERAPIES, PART 1." BIOPROCESS INTERNATIONAL, TUESDAY 27TH MARCH 2018
3. COMPARAISON DES COUTS. TEST DE STÉRILITÉ: SALLE PROPRE OU ISOLATEUR IN SALLE PROPRES N° 81 - OCT 2012

ISO 8 cleanrooms can cost 78% less than ISO 7 per square foot⁴

Reduce cleanroom operating costs and improve sustainability

Using an isolator system in a Grade C or D cleanroom can improve productivity and generate a significant overall cost saving compared to a BSC in a Grade B cleanroom.



4. COSTING A CLEANROOM PER SQUARE FOOT, CLEANROOM TECHNOLOGY, 28 FEBRUARY 2018. https://www.cleanroomtechnology.com/news/article_page/costing_a_cleanroom_per_square_foot/139470

The ideal closed environment solution the Bioquell® Qube

For drug compounding and preparation, operating in a Grade A / ISO 5 environment is vital. Ecolab's Bioquell Qube provides just that.

With its numerous configurations, the Bioquell Qube's closed system provides protection for operators and product, and can be hosted in a lower grade cleanroom. The Bioquell 35% hydrogen peroxide vapor bio-decontamination technology achieves a 6-log validated sporicidal kill on exposed surfaces including materials*.

The Bioquell Qube is a key tool to reduce the risk of operator and product exposure to bacterial (vegetative and spores), fungi, and other biological contaminants including viral vectors, and is designed with regulatory compliance and GMP in mind.



Maintains validated Grade A / ISO 5 environment

Optional environmental monitoring systems



Supports 21 CFR Part 11 compliance

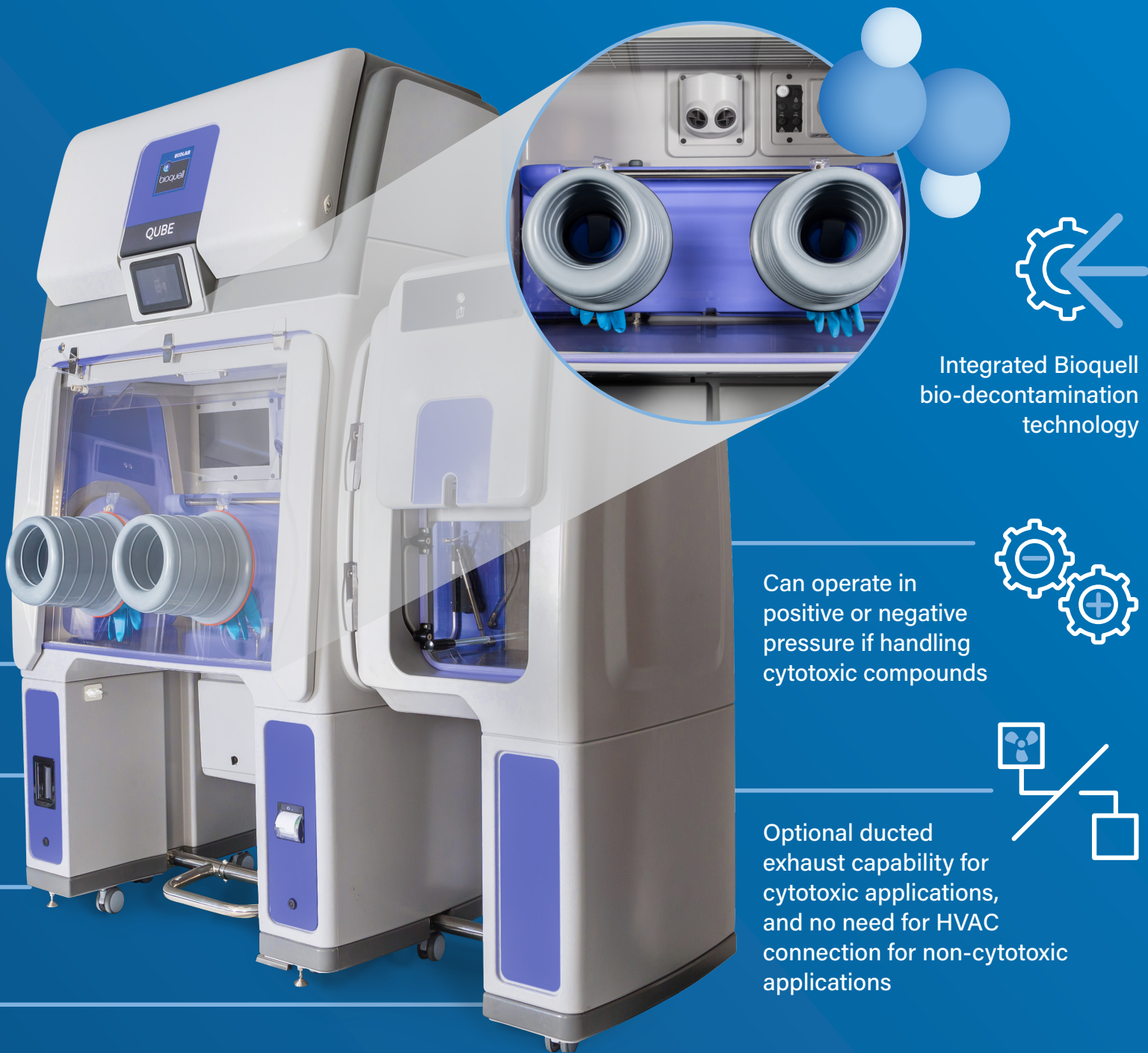
Supports GMP compliance



*When used according to the label instructions, Ecolab Bioquell systems utilize Bioquell Hydrogen Peroxide Sterilant-AQ (EPA Registration Number: 1677-277)

The hydrogen peroxide vapor bio-decontamination process inside the Bioquell Qube

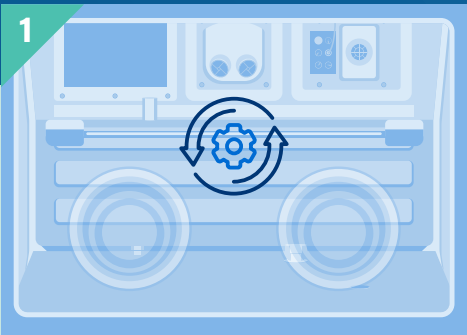
The four step visualization, seen in right, shows how an enclosed area, like the Bioquell Qube, is bio-decontaminated. A hydrogen peroxide vapor bio-decontamination generator connected to enclosures, equipment, or pass-throughs will operate in the same manner.



Quick & easy setup

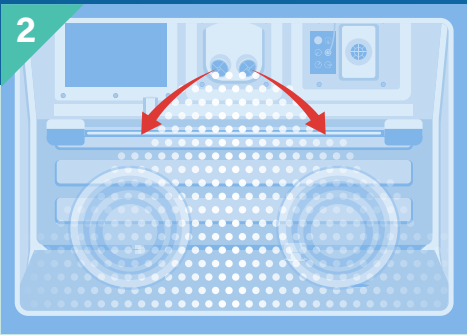
As a standalone, modular system, the Bioquell Qube can be installed and operating with minimal delay and investment.

- Compatible with BD-Cato and other compounding workflow solutions
- Up and running in as fast as 3 months
- Plug and play, no construction etc.
- Consistent build allows for quick validation
- Expert team capable of enacting change or helping build SOPs to add in a system quickly



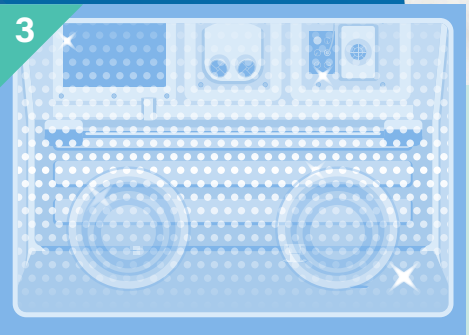
Preparation

The Bioquell Qube warms up, getting ready to disperse the vapor. The Bioquell Qube can operate in a wide range of environmental conditions, so it is not required to reach or wait for a specific temperature or humidity level before starting the process.



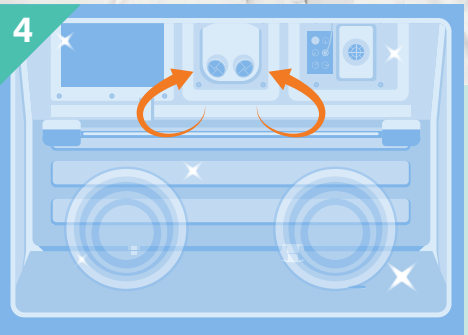
Vaporization

The Bioquell Qube emits the vapor into the enclosed area and fills the space, directing the vapor to exposed surfaces, including materials with complex shapes and crevices.



Dwell

With vaporization complete, the enclosed area is at a standstill, allowing the peroxide to dwell on exposed surfaces and kill pathogens.



Aeration

High-powered aeration units in the Bioquell Qube safely remove all of the hydrogen peroxide vapor from the enclosed area. When aerated with Bioquell units, the vapor is converted into water vapor and oxygen.

The ideal solution for all compounding pharmacies



Protect product and organization reputations

For commercial organizations who are producing at scale, the quality, safety, and efficient throughput of product are critical, as is compliance with regulations.

- ▼ Cleanroom cost savings
- ▼ Compliance with EU GMP Annex 1
- ▼ Protection of product and, therefore, reputation
- ▼ Multiple chamber Bioquell Qube configurations allow continuous workflow, improving efficiency
- ▼ Protection of operators (if handling cytotoxic compounds)



Optimize compounding processes in hospital pharmacies

The preparation of drugs, especially cytotoxics for chemotherapy, demands a rapid turnaround for quick delivery to the patient. The Bioquell Qube can help this process through:

- ▼ Protection of operator from exposure to cytotoxic compounds
- ▼ Locatable in a variety of areas within a hospital
- ▼ Ability to house specialized compounding equipment, e.g. weighing scales
- ▼ Built in pressure/leak test and optional glove leak tester

Numerous configurations and options to meet every need

With its modular design, the Bioquell Qube can be built to meet your needs by offering a 2, 4 or 6 glove option that can include a material pass through transfer device or RTP on either or both sides of the system selected.



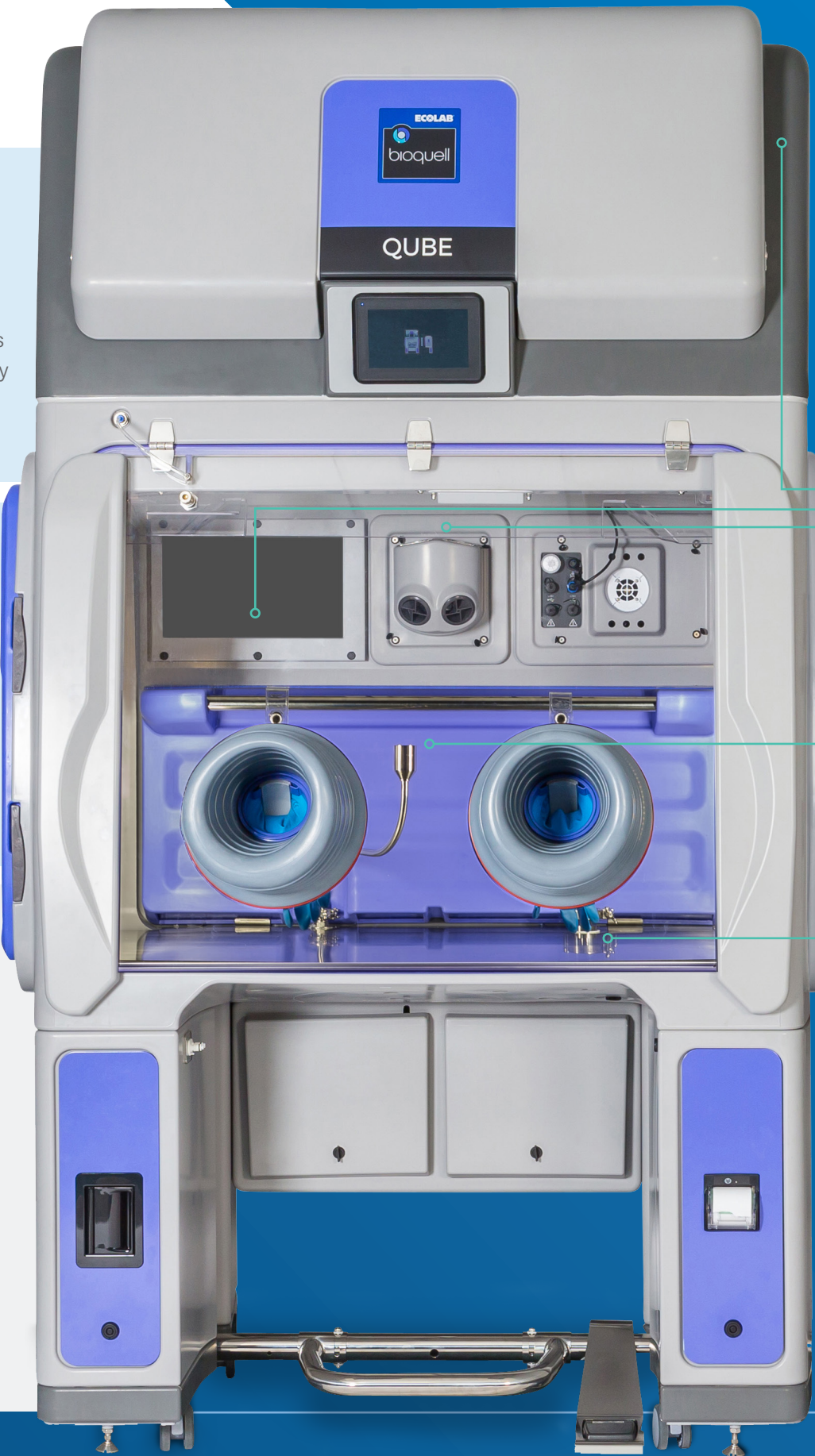
Never slowdown your workflow as 4 and 6 glove options allow you to work in one or two chambers, while bio-decontaminating incoming supplies in the other.

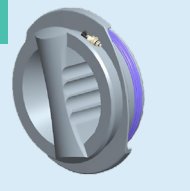


*RETRACTABLE INNER DOOR REQUIRED BETWEEN HYDROGEN PEROXIDE VAPOR CHAMBER AND ANY ADJACENT CHAMBERS

Accessories & features

While integrated bio-decontamination comes as standard, optional features provide efficiencies and assurances to any process.

For a complete list of accessories and features, speak to an Ecolab Bioquell Qube expert today.



- 1 Ducted exhaust system
- 2 Display monitor
- 3 Camera
- 4 Central iso-kinetic cone
- 5 Tri-clover port for cable / tubing entry
- 6 Audit trail software
- 7  Glove tester
- 8  Rapid Transfer Port (RTP)
- 9  Environmental Monitoring: Active Air Head or AAH (viable) & Continuous Particle Monitoring (non viable)

Automated bio-decontamination solutions for all your needs

As well as Bioquell Qube isolators, the Bioquell offering includes a full range of hydrogen peroxide vapor bio-decontamination solutions for automated room and equipment bio-decontamination.

These devices help eliminate microorganism* throughout your process, from rooms to pass-throughs to existing isolators and more.

Room and zone bio-decontamination Bioquell® ProteQ

An advanced, mobile bio-decontamination system with automated cycles and greater ease of use, for rooms and zones in GMP regulated environments.



Equipment & multipurpose bio-decontamination Bioquell® L-4

A versatile system that can bio-decontaminate existing isolators, biosafety cabinets, material airlocks (MALs), pass-throughs and, with optional equipment, small rooms.



Material airlocks (MALs) and small production cleanrooms Bioquell® SeQure

A wall-mounted bio-decontamination offering is ideal for larger material transfer chambers, providing validated, trusted and repeatable results.



Corrective action and emergency response

Bioquell® RBDS

Contamination in your facility can result in costly delays to your operations.

With Bioquell Rapid Bio Decontamination Service (RBDS), an expert rapid response team can be deployed to meet scheduled, or emergency needs of facilities across the globe. Highly trained and experienced technicians provide professional and validated bio-decontamination services with detailed reporting.



Effective manual cleaning & disinfection

Ecolab offers a range of cleaning and disinfection products that can be confidently used on the surfaces of the Bioquell Qube and other surfaces in the cleanroom.

With a long history of cleanroom contamination control, the Klercide range features a variety of formats which vigorously denature and destroy the active chemicals in cytotoxics helping to ensure safe removal.

The recommended best practice to remove and destroy cytotoxic residues, which has been tested effectively, is to first use Klercide Sporidical Active Chlorine followed by Klercide 70|30 IPA.*

A full range of other Klercide products are available for highly effective cleaning and disinfection in general areas.



*Ecolab technical report TR1502R

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How can Ecolab support switching to an isolator system?



Discover Ecolab's Change Management Program

Discover how Ecolab's expert team of Global Technical Consultants can help you make the switch from BSCs to Bioquell Qube isolator systems, and support with validating an adapted cleaning and disinfection regime that aligns with the requirements of lower grade cleanrooms.

Support is available for all steps of the change process, from initial assessment of all your contamination risks and needs through to validation. Ecolab will conduct the installation and IQ/OQ of the Bioquell Qube isolator system, as well as bio-decontamination cycle development and PQ, prior to operator training and handover. Leverage Ecolab's expertise to ease the acceptance, approval and implementation of change, enabling you to focus on your core competencies.



For expert implementation of automated bio-decontamination measures in your facility contact your **Ecolab Account Manager** or visit www.bioquell.com

For regional office details, please visit bioquell.com

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

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