CELL & GENE THERAPY
CONTAMINATION CONTROL

Cell & Gene Therapy
Complete Contamination Control Strategy for Any Stage

From R&D to clinical trial to production, learn how keeping contamination risk under control can keep your operations on track.

ECOLAB®

About **Ecolab**

A trusted partner at nearly three million customer locations, Ecolab is the global leader in water, hygiene and infection prevention solutions and services. With annual sales of $12 billion and more than 50,000 associates, Ecolab delivers comprehensive solutions, data-driven insights and personalized service to advance food safety, maintain clean and safe environments, optimize water and energy use, and improve operational efficiencies and sustainability for customers in the food, healthcare, hospitality, Life Sciences and industrial markets 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.

It All Begins with **Regulatory & Compliance** in Cell and Gene Therapy

With new regulatory standards being introduced as the field advances, the Cell and Gene Therapy industry provides a unique challenge to navigate. For that reason, compliance very often relies on a case by case risk assessment.

From early process development to commercial manufacturing, GMP and regulatory guidance become increasingly stringent.

However, in this complex regulatory landscape, some key highlights and trends should be considered a priority:

Protocols that demonstrate process control and prevent product contamination are required to ensure patient safety during clinical trials.[1]

Closed systems with high levels of protection are more frequently recommended for Grade A areas to achieve a closed system with consistent Sterility Assurance.[2]

A Closed & Validated Process Gives You an **Immediate Advantage**

One of the most common ways to close bioprocesses is to use isolators that will maintain your operations in a controlled environment. Isolators help prevent microbial contamination, support operator safety and provide many other advantages.

Additionally, adhering to GMP principles and closing your process early in your development phase can ease the transition to clinical trials and commercial manufacturing.

Ecolab has extensive expertise in GMP compliance related to cleaning and disinfection applicable to Cell & Gene Therapy manufacturing. We will guide you through appropriate contamination risk assessments to achieve compliance thereby avoiding delays and expensive process redesigns.

Contamination control strategies should ensure appropriate contamination risk management and proactive procedures to prevent ATMP contamination.[3]

Cleaning and disinfection of regulated areas shall be performed according to a written and validated procedure using broad spectrum disinfectants.[3]

Isolators in GMP areas shall be contained in Grade C/D cleanrooms.[3]

FUNDAMENTAL RESEARCH

Research & Development

CLINICAL TRIALS

Preclinical Trial | Phase One | Phase Two | Phase Three

MANUFACTURING TRANSFER & SCALING UP

First Commercial Batch | Routine Production

INCREASE IN GMP REQUIREMENTS

RESEARCH & DEVELOPMENT PHASE

- A controlled environment can decrease process variability
- Saves time and money by preventing process redesign at later phases
- Ease readiness for clinical trial

CLINICAL TRIAL PHASES

- Increased contamination control improves patient safety, reducing delays to your study
- Helps to get prepared for significant increase of GMP requirements for Phase 2 & 3
- Facilitates drug dossier approval before first commercial batch

MANUFACTURING PHASE

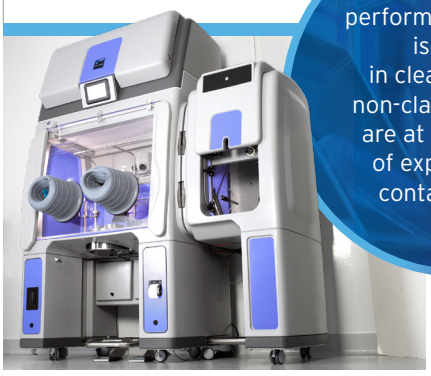
- Helps ensure products' quality assurance
- Offers a scalable solution with regulatory compliance at the forefront

Ecolab is Your **Comprehensive Solution Provider** To Help **Prevent Contamination** During Your Operations

ISOLATORS WITH INTEGRATED BIO-DECONTAMINATION TECHNOLOGY

Bioquell Qube

The Bioquell Qube is the perfect fit to secure your most critical operations in both GLP and GMP environments.



Operations performed outside of isolators in cleanrooms or non-classified areas are at greater risk of exposure to a contamination.

CLEANING AND DISINFECTION SOLUTIONS

Automated Bio-Decontamination Options

Discover Bioquell Hydrogen Peroxide Vapor generators* for repeatable, automated and validated bio-decontamination of rooms, equipment and large zones.

Manual Cleaning and Disinfection

In addition, Ecolab provides sterile and non-sterile biocides suitable for manual cleaning and disinfection in both classified and non-classified areas. A complete range of hand hygiene products and dispensers are also available.

From GLP to GMP, **Mitigate Your Contamination Risk**

The development of novel Cell & Gene therapies such as CAR T-Cells, mRNA or stem cell therapy requires extended Research and Development activity before starting clinical trials. For that reason, the Bioquell Qube has been designed to fit both GMP and GLP environments.

At this stage it is important to find a closed containment system that offers the least invasive option while retaining an aseptic space for you to work within. This would mean no building work, no HVAC connections needed, and no additional electrical work to use the device.

Discover the perfect fit for your working environments with the Bioquell Qube

LABORATORY & OTHER GLP ENVIRONMENTS

PRODUCTION ROOM & OTHER GMP ENVIRONMENTS

Be prepared for the next development phase with closed systems in your laboratory and GLP environments

Help protect your product from contamination in production rooms and other GMP environments

The Ideal Closed Environment Solution **The Bioquell Qube**

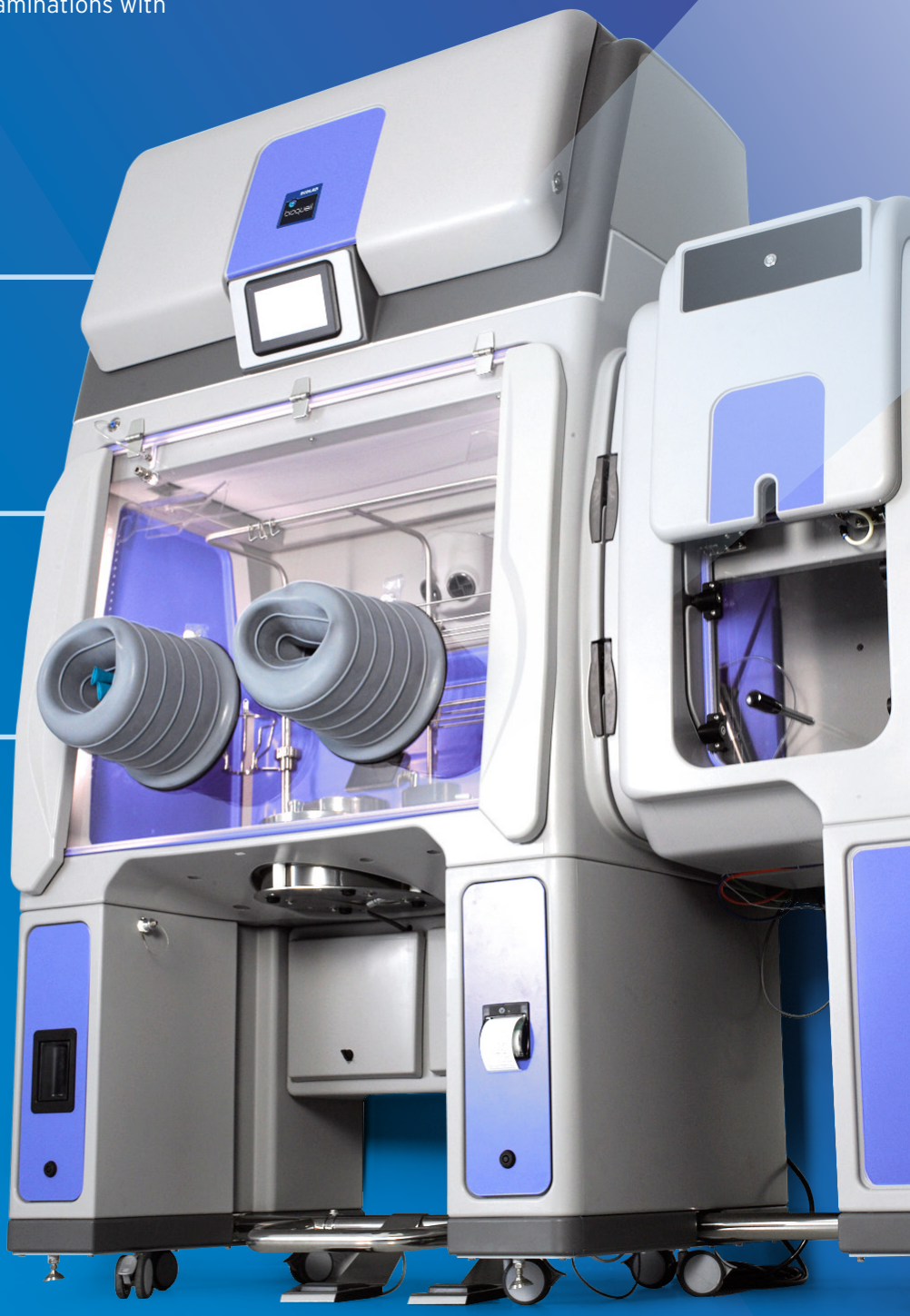
Ecolab's Bioquell Qube is an isolator with numerous configurations that uses an EPA registered sterilant (Bioquell Hydrogen Peroxide Sterilant*) to create aseptic operating areas that can be maintained for long periods of time.

It is a key tool to reduce the risk of operator and product exposure to viral and other biological contaminations with regulatory compliance and GMP in mind.

Creates validated Grade A / ISO 5 environment

Environmental control and monitoring

21 CFR Part 11 compliance



The Bioquell Qube is the perfect fit for your Cell and Gene Therapy manufacturing operations

Bioquell Qube Benefits are Aligned with Cell & Gene Therapy Manufacturing **Main Challenges**

The Bioquell Qube is tried and trusted in the most demanding of environments, including high grade pharmaceutical facilities, and can quickly create a Grade A / ISO 5 environment in any area.

Integrated Bioquell bio-decontamination technology

Operate in positive or negative pressure

Supports GMP compliance

No need for HVAC connection

SPEED

- Quick implementation and short lead time
- Fast decontamination cycle

CONSISTENCY

- Create a Grade A / ISO 5 area with validated and automated cycles for repeatable results

COST

- Cost effective option for scalable and effective work environments
- Operate a Grade A / ISO 5 environment while hosting in Grade C/D location

FLEXIBILITY & SCALABILITY

- Meet future capacity to grow as you do

COMPLIANCE

- Bio-decontamination with EPA registered sterilant (Bioquell Hydrogen Peroxide Sterilant)
- Meets requirements to help provide product consistency for regulatory bodies around the world
- 21 CFR Part 11 compliant audit trail
- Uses EU Biocidal Product Regulation (BPR) compliant sporicidal disinfectant

The Bioquell Qube provides a controlled and secured environment for the most critical operations in Cell & Gene Therapy like:

- Cell lines purification
- Genetic Engineering
- Cellular culture and Viral propagation
- Aseptic Filling
- Sterility Testing
- Media handling and preparation

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 generators for automated room and equipment decontamination.

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

ROOM AND ZONE BIO-DECONTAMINATION

Bioquell ProteQ

A mobile room to room system for small and large open spaces. Link multiple systems for even larger areas.

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.

PASS-THROUGHS, MALS AND SMALL ROOMS

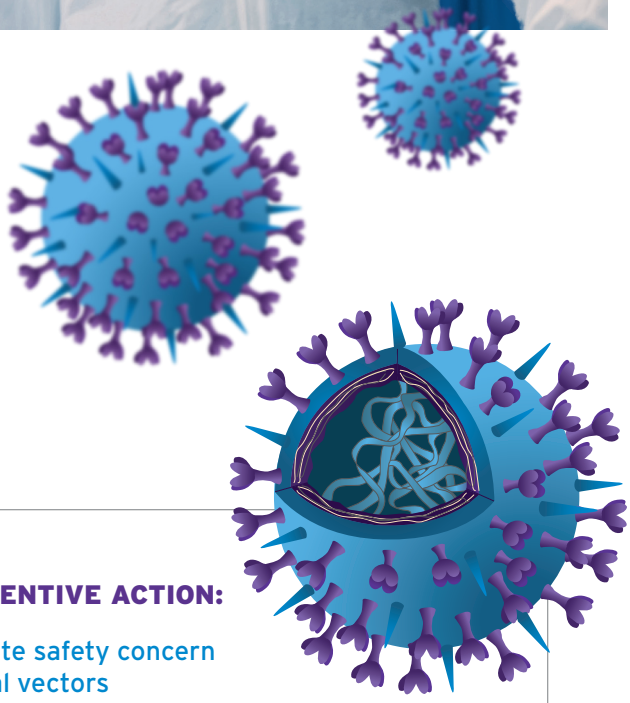
Bioquell SeQure

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

Help **Ensure Continuity** of Your Operations with a **Bio-Decontamination Service**

Contamination in your Cell & Gene Therapy manufacturing facility may 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 with detailed reporting.



CORRECTIVE ACTION AND EMERGENCY RESPONSE:

Keep your laboratories or GMP area under control

Whether environmental level thresholds have been reached or a contamination event has occurred, Bioquell RBDS offers a 6-log sporicidal reduction on exposed surfaces, including difficult to clean areas.

PREVENTIVE ACTION:

Mitigate safety concern of viral vectors

In-process viral contamination, cross-contamination and operator safety are at risk due to exposure to viruses and biological agents used in Cell & Gene therapy development. Bioquell Hydrogen Peroxide Sterilant kills microbial life in the inanimate environment (EPA Registration No. 72372-1-86703).*

*A sterilant kills microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, and viruses per the code of Federal Regulations Title 40 Chapter I Subchapter E Part 158 Subpart W § 158.2203

Effective **Manual Cleaning** and **Disinfection** for Your Cell & Gene Therapy Facility

In addition to the Bioquell Hydrogen Peroxide Vapor generator, the Ecolab Klercide range of cleaners and disinfectants provides effective products for manual cleaning and disinfection in critical areas.

SMALL AND LARGE SURFACES IN CRITICAL AREAS

A wide range of both pre-impregnated wipes and ready-to-use liquids

- Alcohols
- Broad spectrum biocides & sporicides
- Cleaning and maintenance solutions
- With supporting equipment for efficient application

BIOQUELL QUBE CLEANING

Klercide Low Residue Peroxide and Klercide Neutral Detergent sprays and wipes are specifically recommended to clean the Bioquell Qube.

SMALL SURFACES IN CONTROLLED ENVIRONMENTS

Alcohol wipes are a perfect fit for quickly cleaning work areas in laboratories and low-grade cleanrooms.

HAND HYGIENE PRODUCT RANGE

Clean and sanitize hands in both GMP and GLP areas.

Our **Complete Contamination Control Package** For Cell & Gene Therapy

Annex 1 regulations require isolators to be contained in a classified cleanroom, with significant validation resources required to achieve compliance.

In the pharmaceutical industry, cleaning and disinfection validation can take 6-12 months to implement and cost up to $100k per facility. Ecolab has experience with global regulatory criteria that can significantly reduce the time and cost of validation.

Save **Time**
Save **Money**
Gain **Control**

References:

1. Section V.a.2.E., "Process Validation And/Or Evaluation (3.2.S.2.5)," EMA Guidelines And/Or Evaluation (3.2.S.2.5)," EMA Guidelines
2. Annex 1
3. Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products

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