



A Comprehensive Approach to Cleaning, Disinfection & Bio-decontamination

—
Designed specifically
for pharmaceutical
manufacturers

Ecolab Drives Every Site To Be Your Best Site

The right products.
Integrated equipment.
Insights to guide action.
Expertise to drive success.



Ecolab Digital Solutions

Digital workflows, real-time monitoring, and advanced analytics insights to help you optimize cleaning protocols and use Ecolab products most effectively.

Ecolab Expertise

Steering the entire Total Program engine toward maximum value — matching chemistry and equipment to your needs and acting on digital insights to optimize efficiency.

Ecolab Chemistry

Comprehensive portfolio of targeted solutions to tackle your toughest soils and increase cleaning efficiency.

Ecolab Equipment

Get the most out of Ecolab products with innovative equipment built to drive consistency, efficiency and safety.

Bringing out the best in your business to achieve greater total value

Ecolab Life Sciences offers unparalleled contamination control, efficiency and compliance.

With industry-leading expertise and data-driven insights, we unlock your full potential, leading to optimized manufacturing performance and reduced risk.



EFFICIENCY

Reduce cleaning time to accelerate productivity



PRODUCT QUALITY

Ensure reliable, consistent cleaning



SUSTAINABILITY

Reduce water & energy usage and minimize waste



COMPLIANCE

Automate documentation & reporting for audit-readiness

Our Programmatic Approach

Cleaning & disinfection programs

Ecolab provides you with site-specific cleaning and disinfection programs to help manage risk and improve process efficiency for external surfaces of manufacturing equipment and cleanrooms, in addition to direct product contact surfaces.

Cleanrooms

Cleaning and disinfection solutions for external surfaces of manufacturing equipment and rooms.

This program includes:

- ▼ Sterile products as part of the Klercide™ range
- ▼ Products manufactured in cleanrooms using sterility assurance best practices to ensure sterility. This provides the reassurance that your process validation is secure, using products with substantiated quality
- ▼ Plant maintains full validated batch traceability and can be audited on request

- ▼ Innovative packaging solutions, such as our patented SteriShield™ Delivery System (SDS) on the trigger spray bottles, which works as a closed system designed to preserve the sterility of the contents throughout use
- ▼ Certificates of Analysis available for all chemical SKUs

Klercide™ Range

Manufactured in our state-of-the-art facility, our extensive range of sterile alcohols and biocides provide tools for controlling contamination on cleanroom surfaces.

- ▼ Application tools
- ▼ Triple bucket system
- ▼ Mop wipe frames
- ▼ Product formats
- ▼ Ready-to-Use
- ▼ Pre-saturated Wipes
- ▼ Concentrates
- ▼ Disinfectant rotation
- ▼ Alcohols
- ▼ Disinfectants
- ▼ Sporicides

CIP (Clean In Place) & COP (Clean Out of Place)

Cleaning and disinfection solutions for external surfaces of manufacturing equipment and rooms.

This program provides:

- ▼ Cleaning and disinfection solutions for direct product contact surfaces
- ▼ A specific product range for the pharmaceutical industry – COSA® Range
- ▼ Formulations providing high rinsability
- ▼ No silicate, perfume, silicone or coloring
- ▼ Products manufactured to GMP quality with fully documented work instructions and procedures
- ▼ Fully validated batch traceability and can be audited on request
- ▼ Certificates of Analysis available for all chemical SKUs
- ▼ A comprehensive Ecolab Cleaning Validation support web page, which has been designed to help our customers with their cleaning validation processes or revalidation in the pharmaceutical industry
- ▼ CIP Optimization: An evaluation and recommendation on methods to optimize time, temperature, mechanical action, chemistry and chemistry residuals in CIP systems
- ▼ We offer installations for automatic cleaning and disinfection. After an assessment of your process, we are able to recommend the equipment installation to meet your requirements. These installations could cover a variety of equipment, such as: storage stations, pump systems, conductivity dosing systems, CIP Kits, etc.

COSA® Range

Manufactured in a pharmaceutical GMP production facility, our comprehensive range of cleaners and additives provides process optimization in your CIP and COP systems.

Our range includes:

- ▼ Alkaline Cleaners
- ▼ Acid Cleaners
- ▼ Additives/Boosters
- ▼ Manual Cleaning
- ▼ Sanitizers & Disinfectants

We go beyond identifying the right chemistry - we develop site-specific hygiene programs to maximize process efficiency and help manage risk.



Inspired Cleanroom Innovations

THE CHALLENGE

Current ready-to-use applications



Key



Health & safety



Cost of use



Product quality



Regulatory compliance

Poor

Marginal

Good

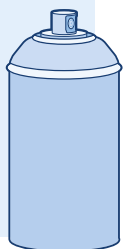
Trigger systems

Do not form a closed system and are unable to prevent air from being drawn back into the bottle, posing a risk of contaminating the contents of the bottle during use. This is applicable to both bag-in-bottle and standard trigger spray systems. This puts your product quality and compliance at risk due to potential loss of sterility of the contents and increases in-use cost.



Aerosols

Can pose a safety risk due to the generation of higher levels of small airborne particulates and may result in an increase in overall cost given their higher disposal costs. Aerosols also lack an adjustable spray pattern that may limit the coverage of surface areas.



THE SOLUTION: The Validated SteriShield™ Delivery System



SteriShield Delivery System (SDS)

Engineered to seamlessly integrate our bag-in-bottle design with a patented trigger system, delivering a validated, closed system that prevents contamination throughout the product's in-use shelf life.

Closed system

No air suck back ensures sterility

Validated system

In use shelf life of three months

Variable spray pattern

Ensures optimum surface coverage

Reduced airborne particulates

Safer compared to aerosols



What makes the trigger so effective?

A patented precision engineered trigger head to ensure that air is not drawn back into the bottle.

- ▾ A variable rotating nozzle to deliver the desired spray pattern as required
- ▾ A unique venting system, fitted with 'duck billed valve', to ensure ONLY one way venting during irradiation

What makes the bottle so effective?

A bottle with dual layers:

- ▾ A rigid outer bottle to provide structural stability
- ▾ An inner flexible bag protects its contents and creates a post-dispensing vacuum in which remaining liquid is stored and allows complete dispensing of the product

A Minimal Residue Solution You Can Rely On

Residues from products used in the cleanroom pose a challenging problem in contamination control, potentially inhibiting effective disinfection or creating quality risks.

By minimizing the initial residue left behind by a product and the build up of residues over time, a less disruptive, scientifically sound approach to managing residues can be implemented as part of a holistic contamination control approach.



Ecolab can help implement a validated strategy combined with the right products and best practices to reduce residues and ensure audit readiness.

Managing cleanroom residues through the Ecolab approach and use of minimal residue products deliver:



Safety

- Reduce the likelihood of slips and trips from residue build up on floors
- Lower residue levels mean less residual chemistry left behind
- Reduce the risk of foreign particulate contamination from the disinfection process



Compliance

- Visually demonstrate the facility's cleaning and disinfection processes are under control
- Help decrease the risk of inspectors citing a lack of cleanliness and prevent a further deep dive into associated processes



Operational efficiency

- Create more time for other functions with fewer SOPs
- Shorten downtime and additional costs associated with disinfection and residue removal



Klercide™ Cleanroom Quat

The minimal residue benefit

A ready-to-use sanitizer, Klercide Cleanroom Quat provides a minimal initial starting residue as well as a significant reduction in the accumulation of residues. This makes it ideal for high grade cleanrooms and critical manufacturing areas.

Effective at lower concentration, Klercide Cleanroom Quat leaves **LESS RESIDUE** after the **FIRST APPLICATION** compared to all other products tested.*

Results in **LESS ACCUMULATIVE RESIDUE.** Less residue leads to **LOWER FREQUENCY** of rinsing.

Has **LOWER SURFACE TENSION** than other formulations, reducing the amount required to achieve **BETTER SURFACE CONTACT** and contributing to residue management.*

Hydrogen Peroxide Vapor Technology



Automated bio-decontamination systems and services

Validated, repeatable and compliant hydrogen peroxide vapor offerings.

- Powered by proprietary Bioquell™ Hydrogen Peroxide Sterilant† for a 6-log sporicidal reduction
- Ideal for open areas such as cleanrooms, production suites, pass-throughs and more
- Bio decontaminate various equipment including BSCs, isolators, MALs, lyophilizers, incubators and more
- Offering includes isolators with integrated bio-decontamination
- Unit and service options available to provide thorough bio-decontamination for any size need, frequency or urgency

Recover Enclosed Spaces Quickly

After a shutdown for routine bio-decontamination or an excursion event, getting your GMP manufacturing facility back to an aseptic environment is incredibly important.

This can be a lengthy and labor intensive process due to the manual cleaning involved and the possibility for contamination to enter your facility and put production at risk.



With Bioquell RBDS, production areas can commence quickly and safely after the service.

Bioquell™ Rapid Bio Decontamination Service (RBDS) provides:



A fast, fully managed approach to help eliminate microorganisms before restoring operation in your critical manufacturing areas.



Hydrogen peroxide vapor bio- decontamination technology delivers a sterilant† for use on environmental surfaces.



Each cycle validated in situ with 6-log *Geobacillus stearothermophilus* Biological Indicators (BIs).



The RBDS process is scalable, expertly operated, and rapid. Every deployment comes with a comprehensive final report.

How Bioquell™ technology can be used

- All-inclusive bio-decontamination service coordinated and performed by Ecolab experts
- Rapid response to emergencies of all sizes
- Scalable to accommodate small or large spaces
- Verified and validated results with chemical & biological indicators

Isolator with Integrated Bio-decontamination



Bioquell Qube™



SUPPORTS GMP COMPLIANCE



USES AN EPA REGISTERED STERILANT*



MODULAR



6-LOG SPORICIDAL KILL†

The ideal isolator with integrated bio-decontamination

- Light, flexible, modular aseptic isolator in convenient configurations
- ISO Class 5 with rapid air recovery and validated hydrogen peroxide vapor bio-decontamination process achieving a 6-log reduction of bacterial spores*
- Optional 21 CFR Part 11 audit trail compliance package available
- Validated bio-decontamination cycles using Bioquell™ Hydrogen Peroxide Sterilant†

The Bioquell Qube isolator has built-in hydrogen peroxide vapor bio-decontamination technology making it an ideal solution for aseptic processing. With multiple configurations available and a range of options and accessories, the Bioquell Qube isolator is suitable for applications such as:

- Cell and Gene Therapy
- Sterility testing
- Cytotoxics preparation
- Small batch production (clinical trials, R&D, etc.)



*THIS SYSTEM USES BIOQUELL HPV-AQ 35% HYDROGEN PEROXIDE WHICH HOLDS A EUROPEAN UNION AUTHORIZATION UNDER THE BICIDAL PRODUCTS REGULATION (BPR, REGULATION (EU) 528/2012) †WHEN USED ACCORDING TO THE LABEL INSTRUCTIONS, ECOLAB BIOQUELL SYSTEMS UTILIZE BIOQUELL HYDROGEN PEROXIDE STERILANT-AQ (EPA REGISTRATION NUMBER: 1677-277) **RETRACTABLE INNER DOOR REQUIRED BETWEEN HYDROGEN PEROXIDE VAPOR CHAMBER AND ANY ADJACENT CHAMBERS

Partner with the Experts

An Ecolab partnership gives you access to our experienced Global Technical Consultants (GTCs). Our technical team is passionate about patient and product safety and guiding our customers to help ensure compliance. We provide manufacturers a partnership and confidence through achievable cleaning and disinfection programs.

Our international team of GTCs are highly experienced in:



Contamination Control Strategy assessments



Execution of bio-decontamination services



Laboratory disinfectant efficacy testing



Cleaning evaluation studies



Progress Through Technology

Our constant search for improvements to cleaning and disinfection in cleanrooms has generated new innovations.

But we don't stop there - every day our teams conduct research that helps keep our customers ahead of regulatory requirements and manufacturing safe products.

With **19** technology and research centers employing **1,600** research and development associates worldwide, Ecolab is committed to innovation.



The Assurance of Validated Cleanroom Manufacture & Secure Supply



Ecolab provides global manufacturing and supply, ensuring product availability to meet your validation obligations and maintaining continuity in your manufacturing process.

Quality systems & basic GMP principles

We use quality raw materials from approved sources and employ systems designed in a similar way to those of our customers.

Audited

Our manufacturing sites have had successful ISO and internal EH&S program audits as well as being successfully audited and approved by our leading pharmaceutical customers.

Manufactured in cleanrooms for cleanrooms



Ecolab offers dual capability manufacturing and cleanroom product offering in our state-of-the-art facilities located in Greensboro, NC and Baglan, UK.



GREENSBORO
North Carolina, USA
CERTIFICATIONS
ISO 9001:2015



BAGLAN
Wales, UK
CERTIFICATIONS
ISO 9001:2015 ISO 14001:2015



Raw materials and packaging from approved sources



Inline blending in a closed system



On-site WFI production



ISO 5 / ISO 7 Cleanrooms



Double and triple bag capabilities

**For more information speak to your Ecolab Account Manager
or visit www.ecolab.com/lifesciences**

USE BIOCIDES SAFELY. ALWAYS READ THE LABEL AND PRODUCT INFORMATION BEFORE USE.

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

WORLDWIDE HEADQUARTERS

1 Ecolab Place
St. Paul, MN 55102
USA

www.ecolab.com/lifesciences

