

The Complete Hygiene Approach

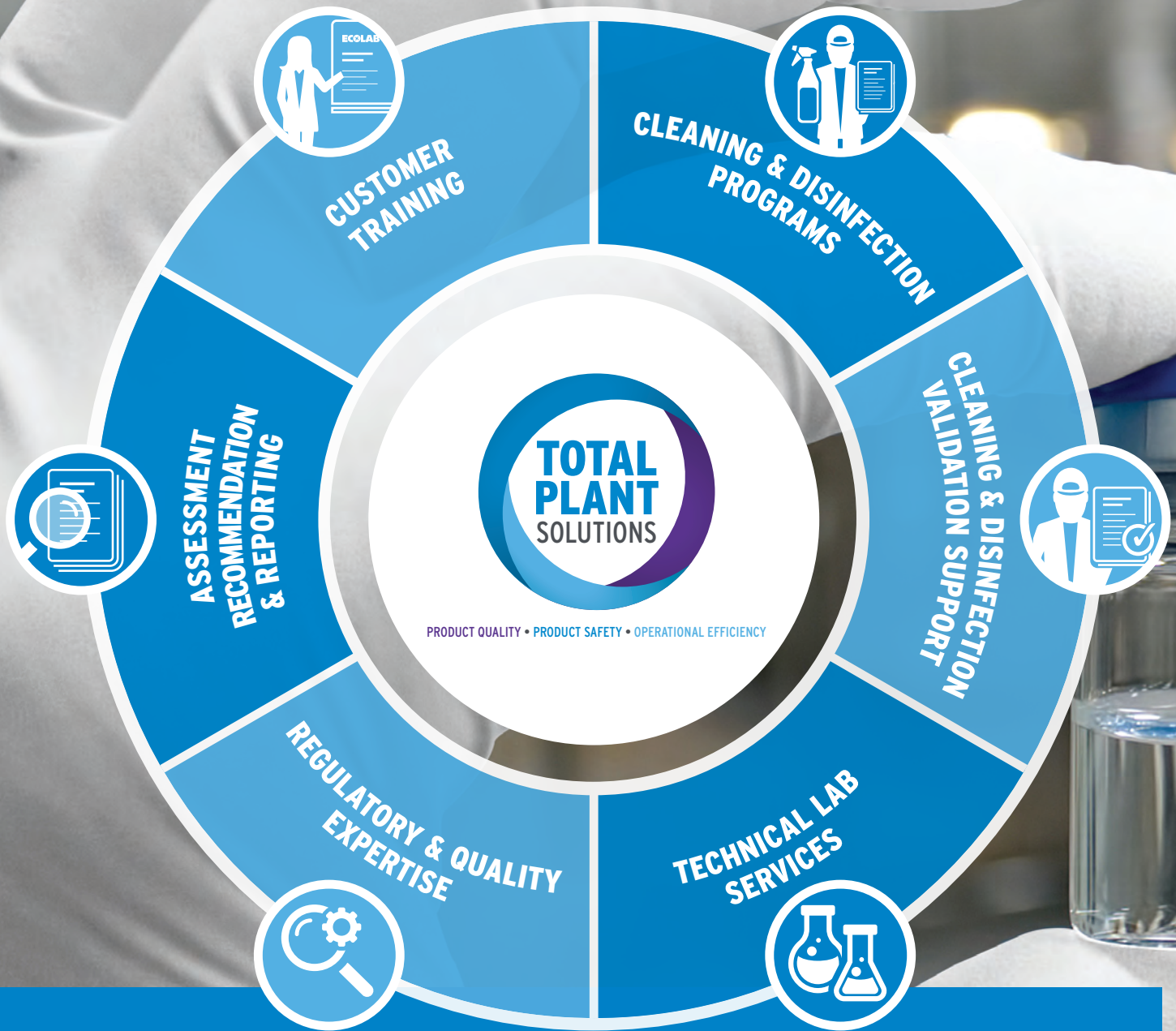
Designed Specifically for Pharmaceutical Manufacturers



ECOLAB®

Everywhere It Matters.™

Addressing the Need with Our Solutions



ECOLAB LIFE SCIENCES

Ecolab's Life Sciences division is dedicated to developing the best possible products and services to support our customers in the industry.

Our tailored end-to-end solutions and technical know-how focus on improving operational efficiency in your cleaning and disinfection processes while keeping product quality and safety top of mind.

Our strategy is to stay focused on two core areas: Global Trends and Regulatory Changes that impact your operations, and develop solutions to keep you on the cutting edge.

Cleaning and Disinfection Programs



Ecolab provides our customers with cleaning and disinfection programs 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:

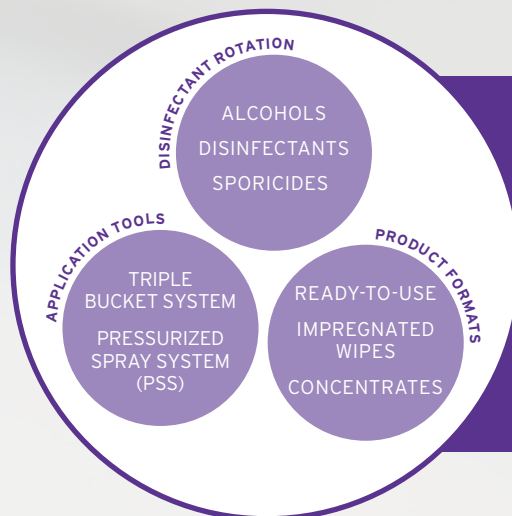
- ▲ Sterile products as part of the **Klercide™ range**
- ▲ Products manufactured in cleanrooms using sterility assurance best practices to ensure sterility. This provides the reassurance that your process validation is secure, using products with substantiated quality

- ▲ 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 provides control of contamination on cleanroom surfaces.



Our Programmatic Approach



CIP (Cleaning In Place) and COP (Cleaning Out of Place)



Cleaning and Disinfection solutions for direct product contact surfaces.

This program provides:

- ▲ 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.

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

ACIDIC CLEANERS

ALKALINE CLEANERS

MANUAL & FOAM CLEANERS

DISINFECTANTS

ADDITIVES

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.



Cleaning and Disinfection Validation Support



We assist our customers in navigating the complex validation processes and change controls.

CLEANING VALIDATION SUPPORT

This support includes:

- ▲ Laboratory testing on the most challenging soils
- ▲ Toxicology Data (LD⁵⁰ or PDE)
- ▲ Allowable residue limit calculation for cleaning and disinfection agents
- ▲ Validated analytical methods for testing residues of cleaning/ disinfection agents (ICH Guidelines)

Specific and non-specific methods available:

- ▲ HPLC (High-Performance Liquid Chromatography)
- ▲ TOC (Total Organic Carbon)
- ▲ Photometric
- ▲ Conductivity
- ▲ Test strips
- ▲ Surface tension

DISINFECTION VALIDATION SUPPORT

We are able to assist with the coordination and project management of external laboratory testing and with the selection of test methods to ensure successful validation of Ecolab products in line with regulatory expectations and acceptance criteria.

- ▲ Importance of determining surfaces/ in-house isolates
- ▲ Justification of testing or appropriate contact times

- ▲ Recommendation of test labs and help with coordinating samples for testing
- ▲ Reviewing draft protocols and results
- ▲ Advice on rationale for regulatory approval
- ▲ Direct experience in performing disinfectant validation testing

Our Programmatic Approach



Technical Lab Support



Ecolab offers support to identify the right cleaning procedure for your specific processes and products.

The three most common procedures for evaluation are:

1. Solubility Tests - used primarily for tablets and solid surface soiling, or to do pretests
2. Dipping Tests - used primarily for ointments or liquids
3. Material Compatibility Tests to measure the compatibility of our products on customer surface materials

Regulatory and Quality Expertise



We know the regulatory expectations, regulations and available tools that are needed to ensure compliance for product safety & quality. At the same time, we can help customers manage the change processes from end-to-end.

Our internal team continuously monitors and adapts to the latest changes in regulatory guidance.

The following is an example of how we can help:

MHRA (Medicines and Healthcare Products Regulatory Agency) guidance on cleanroom dispensing systems indicates that they should minimize the potential for contamination of the supplied contents by having a mechanism to prevent air back as the unit is used.* Our SteriShield Delivery System is the only fully validated trigger spray available which is designed to prevent 'suck-back' and keep our products contamination-free during use.

While the MHRA is a UK organization, other countries' regulatory bodies may soon follow its lead in this regard.

As an industry leader, it is our aim to remain compliant with the most up-to-date advice from regulatory bodies. We can support our customers through the transition by making sure our products are fully compliant and informing our customers of our commitment to regulatory compliance.

*MHRA Guidance for MS Holders. Version 1, App 2, Sec 3.5.20

Assessment, Recommendations and Reporting



We have a service available from our International Register of Credited Auditors (IRCA) to assess the cleaning and disinfection requirements within your controlled environments.

SITE SURVEY

The Site Survey is a professional service available to review cleaning and disinfection processes in place with a view to recommending opportunities for improvement including;

- ▲ Ensuring compliance with current GMP and regulatory expectations
- ▲ Managing the health and safety of workers and reducing the environmental impact of cleaning and disinfection
- ▲ Increasing the efficiency and cost effectiveness of the cleaning and disinfection process

- ▲ Following the site survey, you will be provided with a detailed report that provides comprehensive recommendations and an executive summary, which together will help you prioritise your opportunities for improvement.



Site Survey

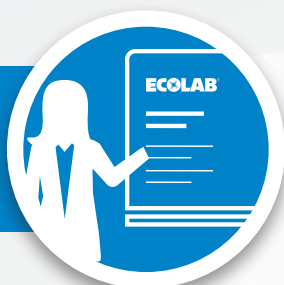
The Comprehensive Site Review Service

Provided by a fully Accredited (IRCA) team experienced in offering technical support and regulatory guidance to pharmaceutical facilities.



Our Programmatic Support

Customer Training



Ecolab develops and delivers in-person training programs by:

- ▲ Identifying training gaps
- ▲ Designing training for adult learners based on proven hands-on techniques
- ▲ Personally delivering on-going support for our customers' personnel

Our comprehensive training covers a variety of topics such as those listed below:

- ▲ Cleaning and disinfection needs for pharmaceutical manufacturing
- ▲ Personal hygiene
- ▲ GMP requirements in relation to Contamination Control
- ▲ Principles of disinfectant validation
- ▲ Personnel safety training
- ▲ Chemical handling safety
- ▲ Application techniques
- ▲ Clean In Place (CIP) and Clean Out of Place (COP) training

The information in this brochure is general in nature and does not constitute representation regarding products and services

PLEASE SPEAK TO YOUR ECOLAB ACCOUNT MANAGER FOR FURTHER INFORMATION

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