



PHARMACEUTICAL



ECOLAB[®]

A COMPREHENSIVE APPROACH TO CLEANING & DISINFECTION

Designed Specifically for Pharmaceutical Manufacturers



Addressing Your Specific Needs with Our **Total Plant Solutions**

The **Ecolab** Benefit

At Ecolab, we provide our customers with the support of a global organization renowned for the most effective programs combined with the highest levels of service.

- ▲ Founded in the US in 1923
- ▲ Operational in over 170 countries
- ▲ Over 48,000 employees
- ▲ Over 3,000,000 customers worldwide
- ▲ Largest sales and service force in the industry

Experienced, highly trained and backed by the full resources of the global leader in sanitation, our dedicated Life Sciences team will deliver the proven solutions customers need to:

- ▲ Produce safe, compliant products that exceed your customers' standards
- ▲ Continuously and measurably improve operational efficiency
- ▲ Help achieve sustainability goals, including reducing water and energy consumption

WE ARE A TRUSTED PARTNER TO OVER 20 OF THE WORLD'S TOP PHARMACEUTICAL MANUFACTURING COMPANIES.

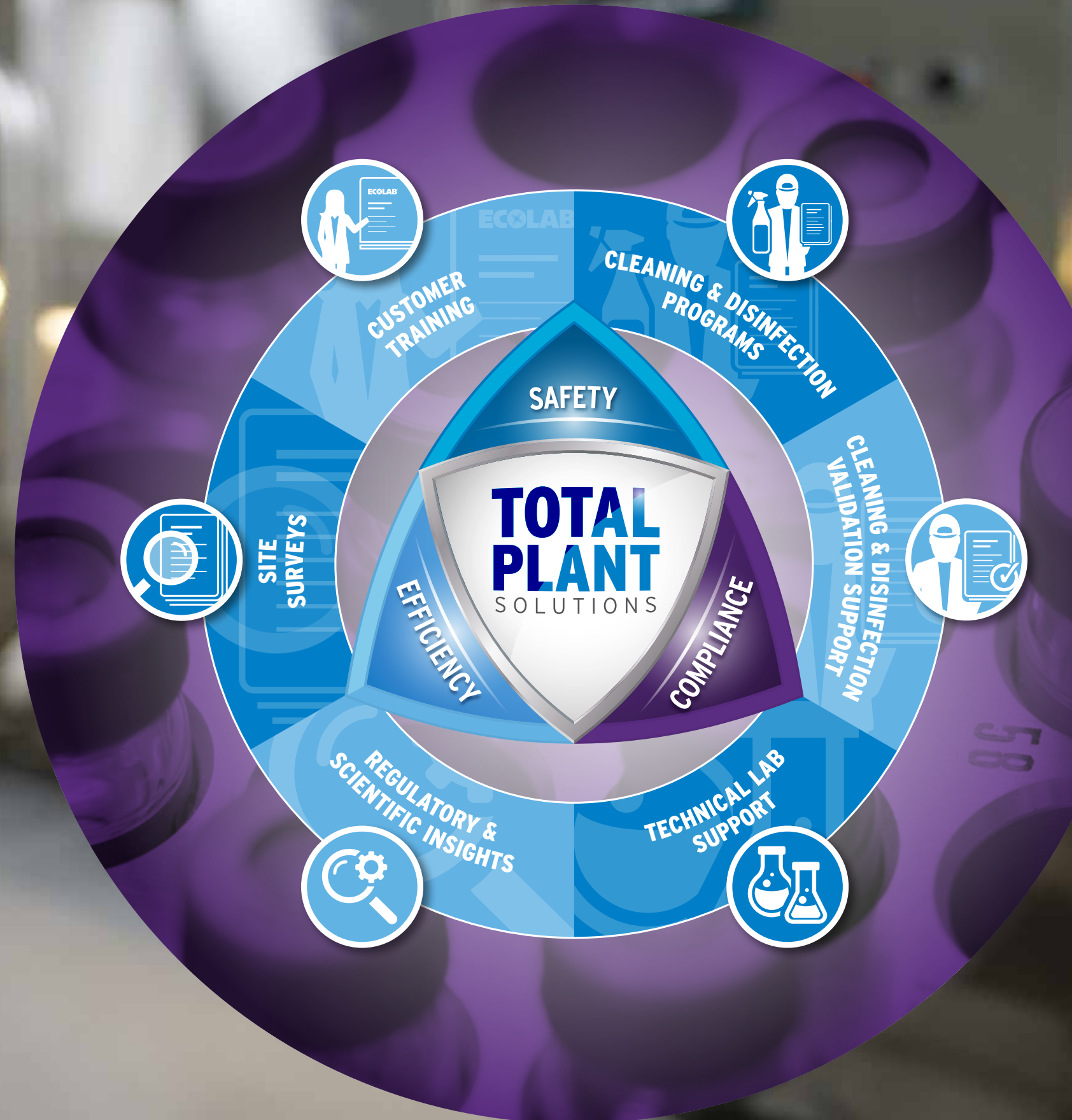
EXPERTISE IN LIFE SCIENCES

Our business has a strong track record in Europe where we are leaders in the cleaning and disinfection market for the Pharmaceutical industry, including partnerships with the leading global Pharmaceutical, Biopharma and Contract Drug Manufacturing organizations.

We provide our customers with complete cleaning and disinfection programs for external surfaces of manufacturing equipment and cleanrooms, and for direct product contact surfaces.

These programs meet the latest regulatory standards and our dedicated products are manufactured in fully auditable and traceable production facilities.

With years of industry experience, our Validation and Technical Support teams will assist you in developing and implementing the best programs for your facilities.



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 provides control of contamination on cleanroom surfaces.

APPLICATION TOOLS
TRIPLE BUCKET SYSTEM
MOP WIPE FRAMES

PRODUCT FORMATS
READY-TO-USE
PRESATURATED WIPES
CONCENTRATES

DISINFECTANT ROTATION
ALCOHOLS
DISINFECTANTS
SPORICIDES

CIP (CLEAN IN PLACE) & COP (CLEAN 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.

ALKALINE CLEANERS

ACID CLEANERS

ADDITIVES/BOOSTERS

MANUAL CLEANING

SANITIZERS & DISINFECTANTS



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.

Global Technical Consultants

TECHNICAL EXPERTISE TO SUPPORT AND ACHIEVE cGMP COMPLIANCE, DRIVE EFFICIENCIES AND ENABLE A HARMONIZED APPROACH ACROSS MANUFACTURING SITES

An Ecolab partnership gives you access to experienced technical experts that partner with you to deliver sustained compliance and operational excellence.

Your account manager works closely with you and our skilled technical team to tackle your unique challenges, providing you with the best-in-class service and solutions to deliver on your key goals – patient safety, product safety and quality, productivity and regulatory compliance.

Our Global Technical Consultants offer:



**CLEANING & DISINFECTION
VALIDATION SUPPORT**



SITE SURVEYS
by IRCA-accredited
SMEs



**REGULATORY
& SCIENTIFIC
INSIGHTS**



From laboratory sample testing to site surveys, you can count on Ecolab to help you maximize product quality, while driving safety, regulatory compliance and operational efficiency.

Our Programmatic Support



Cleaning & Disinfection Validation Support

We assist you in navigating the complex validation processes and change controls, through optimization based on environmental and economic targets, and assistance with validation efficacy project management.

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

VALIDATION EFFICACY PROJECT MANAGEMENT

By partnering with customers to coordinate laboratory studies, we accelerate the validation process. We also provide on-site training and guidance to assure a smooth transition from laboratory studies to practical, real-world application. This includes:

- ▲ Protocol development and coordination with accredited contract testing laboratories

- ▲ A review of draft reports for data accuracy and alignment with protocol intent
- ▲ Consultation on documentation required to meet regulatory expectations

Our Programmatic Support



Site Surveys

We have a service available from our International Register of Credited Auditors (IRCA) to assess the compliance and effectiveness of your cleaning and disinfection programs.

SITE SURVEYS

Conducted on-site, the surveys include an in-depth analysis of cleaning and disinfection processes to determine:

- ▲ Compliance with cGMP and alignment with inspection expectations
- ▲ Opportunities for improvement, cost savings and complexity reduction

- ▲ Operator safety and environmental impact
- ▲ The risks of non-compliance with emerging standards

Following the site survey, a detailed report provides site and consolidated findings together with preliminary recommendations to help you prioritize your opportunities for improvement.



THE COMPREHENSIVE SITE REVIEW SERVICE

Provided by accredited (IRCA) subject matter experts experienced in offering technical support and regulatory guidance to pharmaceutical facilities.



Regulatory & Scientific Insights

Our expert team has knowledge of the regulations and regulatory environment to ensure compliance with cGMP, assure product safety and quality, and help implement validations that meet regulatory expectations.

We:

- ▲ Continuously survey the regulatory landscape for changes in cGMP requirements and standards for cleaning and disinfection

- ▲ Conduct deep analysis of global inspection trends in cleaning and disinfection (EU, US, PIC/S)
- ▲ Lead the development of optimal methods for efficacy determinations, engaging with the scientific and regulatory community to drive acceptance
- ▲ Support customer validation implementation that meets regulatory expectations



Technical Lab Support

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

Testing may include:

1. Soil removal studies on your most challenging soils
2. Studies to assess product compatibility with customer surface materials
3. Performance analysis to compare procedures and techniques
4. Residue analysis for customer surfaces to help determine changes required



Our **Programmatic** Support



Customer Training



Our technical teams conduct on-site training programs to ensure that best practices are understood and implemented correctly to meet the quality and safety standards at customer facilities.

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

- ▲ Optimal cleaning and disinfection application techniques
- ▲ Safety training
- ▲ Regulatory requirements and standards
- ▲ CIP optimization
- ▲ Validation guidance

We also organize and participate in various industry seminars to educate the industry as well as define and improve regulatory standards to achieve optimal process solutions and outcomes.

Dedicated Resources at the Corporate and Local Level

Our customers are at the center of all we do. From customized cleaning and disinfection programs to validation support and beyond, our global account management team partners with you to create customized solutions that meet your needs and exceed your plant goals.

We achieve this by working closely with you at both the local plant and corporate level to design and provide a consistent approach for your facilities that unifies our Ecolab resources and expertise to deliver what you need to be successful.



ACCOUNT MANAGER

- ▲ Connects routinely with your local teams
- ▲ Ensures alignment on plant drivers and KPIs
- ▲ Reviews cleaning and disinfection programs for the facility
- ▲ Identifies opportunities and provides recommendations
- ▲ Executes continuous improvement projects
- ▲ Provides you with our full suite of service standards called Six Star Services
- ▲ Trains plant employees



CORPORATE ACCOUNT MANAGER

- ▲ Connects with customers at corporate level
- ▲ Manages performance KPIs and escalations
- ▲ Drives best practices and portfolio standardization
- ▲ Accelerates progress towards continuous improvement opportunities
- ▲ Drives value delivery

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. We look forward to the opportunity to partner with you on your transformation journey.

PLEASE SPEAK TO YOUR ECOLAB ACCOUNT MANAGER FOR FURTHER INFORMATION

WORLDWIDE HEADQUARTERS

1 Ecolab Place
St. Paul, MN 55102
USA

www.ecolab.com/lifesciences
www.ecolab.com/pharmaceutical

