



Restore Compliance When it Matters Most



Navigating audit
observations and
ensuring inspection
readiness

When Remediation is Required, Act Quickly and with Certainty

When regulators flag issues, every decision matters. Ecolab's Audit Response Program gives you a structured, defensible path to resolve observations quickly, restore compliance, and help prevent future regulatory findings with a single, audit-ready solution.

Regulators continue to identify recurring issues that compromise product safety and compliance.

You received an audit observation

What now?

Common findings include:

Contamination Control Challenges

- Microbial contamination failures from poor environmental monitoring, facility design, and equipment cleaning
- Cross contamination risks due to inadequate cleaning between products
- Sterile manufacturing deficiencies from a failed Contamination Control Strategy (CCS)
- Insufficient root cause investigation to identify contamination sources and prevent recurrence

Quality Management & Investigation Failures

- Weak deviation investigations (FDA reports a 171% increase in 21 CFR 211.192 citations)
- Ineffective quality management systems and unclear accountability

Data Integrity & Documentation Risks

- Documentation control failures
- Inadequate audit review logs
- Rising 21 CFR Part 11 computer system validation violations

Facility & Equipment Deficiencies

- Outdated facility design (21 CFR Part 211.42 violations)
- Equipment qualification failures and inadequate cleaning validation



Our Action Plan

A swift, thorough response is critical to maintaining compliance and keeping operations on track. Our Global Technical Consultants (GTCs) are trained in Root Cause Analysis (RCA) and microbiological investigations, equipped to tackle complex audit findings on-site.

They lead RCA, guide systemic fixes, and help ensure corrective actions stick - combining consulting strength with proven solutions for measurable compliance results.

Prevent Future Observations with Our Integrated Solutions

Responding to today's audit is only the beginning. Strengthening your compliance framework helps you avoid repeat findings and restore compliance confidence. Ecolab Life Sciences provides solutions to directly address the root causes behind the most common regulatory findings.

STEP 1

Site Visit

Our Global Technical Consultants conduct an on site assessment to observe operations in real time, gather essential data, and understand the full context of the observations.



STEP 2

Root Cause Facilitation & Findings Report

We work with your cross functional team to analyse findings and uncover systemic contributors, not just symptoms. You receive a comprehensive report that details root causes, operational impact, and actionable recommendations prioritised by risk.



STEP 3

Remediation & CAPA

Together, we build and execute a clear remediation plan. Using proven change management principles, we define specific corrective actions and prevention strategies using an integrated portfolio of chemistry, equipment, preventative services, and software solutions. Our experts use our proven Change Management program to implement these recommendations, easing the burden of change and performing effectiveness checks to maintain changes.



Water Treatment Solutions

- ▾ **Pre treatment solutions:** Help downstream processes and supports facility design compliance
- ▾ **Boiler & cooling water programs:** Helps mitigate contamination vectors tied to utility failures and thermal stress
- ▾ **Wastewater treatment:** Manage environmental compliance and plant hygiene holistically



Digital Solutions

- ▾ **CLEEN by Ecolab**
Integrate our software solutions for real-time deviation tracking, data integrity and audit-ready documentation, and improve investigations by surfacing patterns and insights to help reduce repeat findings and strengthen compliance with 21 CFR 211.192



Contamination Control Solutions

- ▾ **Manual & CIP/COP cleaning and disinfection:** Help prevent microbial contamination risks
- ▾ **Automated bio-decontamination:** Reset controlled environments with vaporised hydrogen peroxide to quickly address facility contamination challenges
- ▾ **Validation & change management services:** When new cleaning or decontamination methods are implemented, we help ensure compliance, with full documentation and audit-ready protocols



Pest Elimination Services

- ▾ **Customised, risk-based plans:** Controls external factors and reinforces facility integrity
- ▾ **Ecolab Service Specialists (no subcontractors):** Helps ensure consistent execution, documentation quality, and defensible audit records

Restore Compliance. Prevent Recurrence.



Faster, safer
restart



Regulator ready
documentation



Sustained
compliance



Lower total cost
of disruption

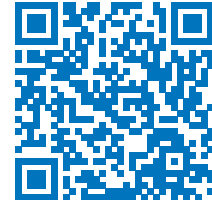
Scan to find out more about:



Ecolab's Change
Management
program



Ecolab's Validex™ program



Ecolab's Best-In-Class
program

For information about our **Audit Response Program**, speak to your
Ecolab Account Manager or visit ecolab.com/caparemediation

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