

Contamination Control Strategy Assessment

Support for compliant cleaning,
disinfection & bio-decontamination

ECOLAB[®]

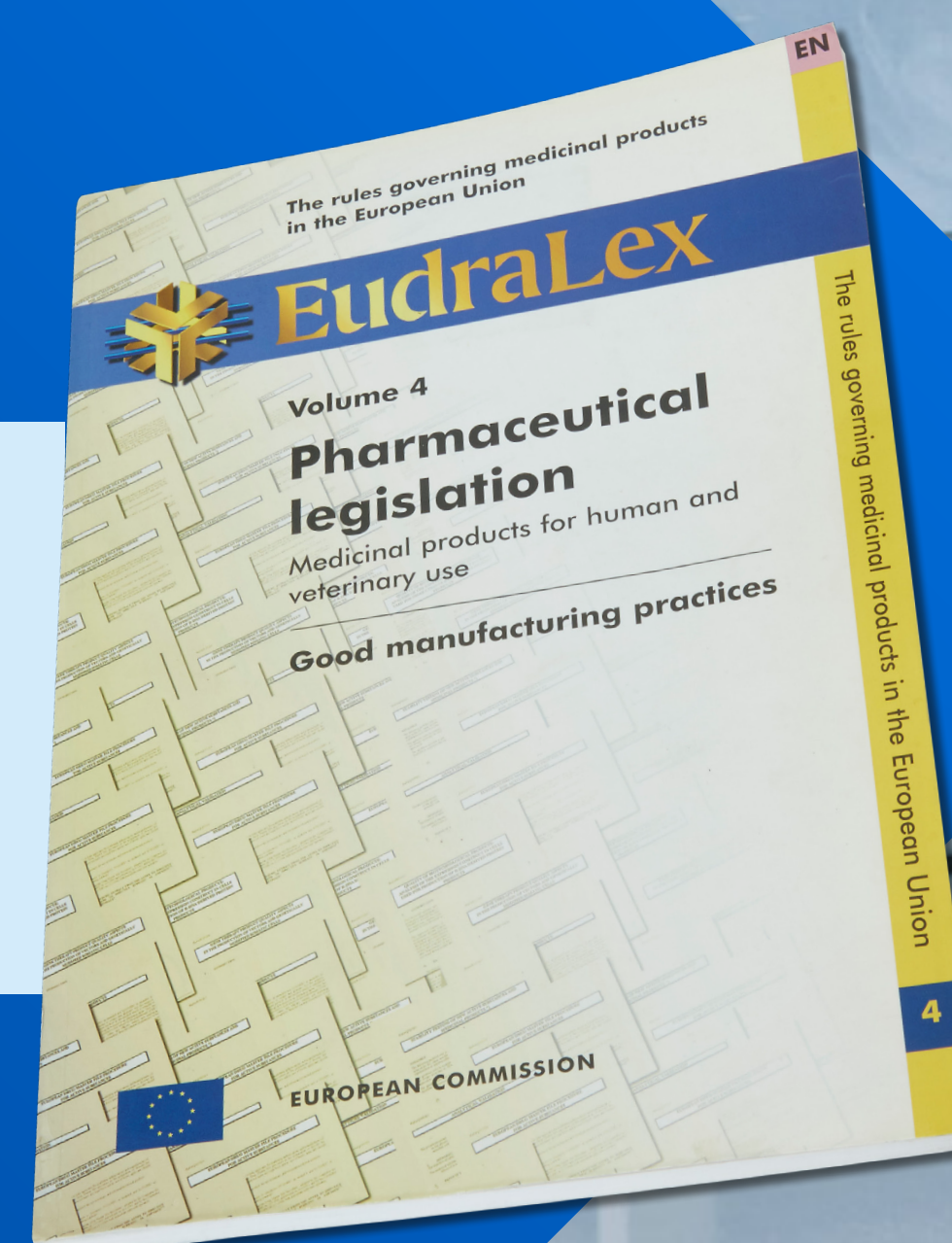
GLOBAL EXPERTS IN
CONTAMINATION CONTROL

CCS What is Required?

The goal of a Contamination Control Strategy (CCS) is to drive a deeper understanding of facilities and processes through identification, assessment and management of contamination risks.

Cleaning, disinfection and bio-decontamination are critical contamination control measures. Ecolab Life Sciences can support the adoption of these solutions into your facility to deliver an effective, compliant and efficient Contamination Control Strategy.

The 2022 update to European GMP for pharmaceutical manufacturers (EudraLex Volume 4 Annex 1) states that it is a mandatory requirement to have a Contamination Control Strategy in place.



CCS For Continuous Improvement

Cleaning and disinfection is listed as one of the topics which must be included within a Contamination Control Strategy (CCS), which highlights the significance of these activities in maintaining control of contamination within a facility.

This guide details our CCS services. Our Global Technical Consultants assess your current strategy to identify compliance gaps against relevant regulations (eg. Annex 1) and suggest improvements to reduce your contamination risks within classified areas.

Additionally, our team can offer a complete change management program to introduce the changes onto your site, from supplier approval, through validation, to implementation.



“The CCS should be a ‘living’ set of documents that drives continuous improvement throughout a facility’s entire manufacturing process. It should be continually reviewed and updated as required.”

Matt Cokely Global Technical Consultant Regional Leader

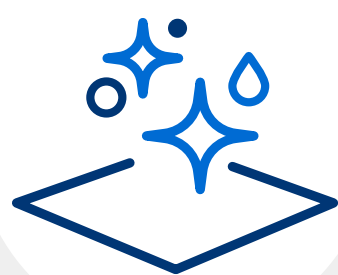


An Overview of Our CCS Assessment

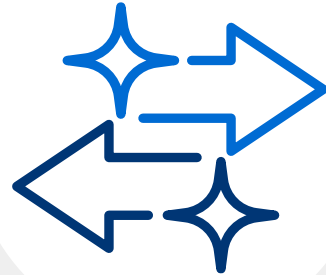
Ecolab’s Contamination Control Strategy assessment includes a full review of Environmental Monitoring data and cleanroom cleaning and disinfection processes.

We conduct an assessment of the current state for controlling contamination risks and compliance to regulations.

We review current contamination control measures in the scope of:



Large / small surface
cleaning and disinfection



Material
transfer



Hand
hygiene



Cleanroom automated
bio-decontamination



Disinfectant residue
management



Disinfectant efficacy
validation



Our Expertise

Your assessment is carried out by one of our Global Technical Consultants, who have decades of industry experience working in the pharmaceutical environment, saving internal time and resources. The team proactively monitor regulatory changes in industry through engagement with relevant bodies such as EP, USP, PDA, CEN, FDA and EPA.



“We are IRCA* accredited and skilled in the identification, assessment and control of contamination risks.”
Helen Gates Strategic Technical Consultant Lead

Assessment Deliverables

- 2-3 days off-site documentation review
- 1-2 days on-site assessment
- Provision of detailed report capturing:
 - Current state
 - Risk rating with rationale for rating
 - Proposed mitigations
 - Executive summary for leadership



The value of this assessment is to document a gap analysis against current regulations, with the classification of risks to support the prioritisation of corrective and preventative actions (CAPA).



* International Register of Certificated Auditors



Recognising the Risks

Ecolab's GTC team will conduct an in-depth review of activities associated with cleaning, disinfection and bio-decontamination. The team will help to identify and document the risks to your cleanroom contamination control and assess the impact of the risks.

- ▼ Review SOPs, EM trends, validation status
- ▼ Review on-site practices to review preparation of agents, application techniques, and equipment use

Our consultants use their breadth of industry expertise to categorise risks; our process is flexible and can align with the site risk scoring system. Our assessments can support the prioritisation and endorsement of actions within the change control process.



CCS Risk Assessment

The risk assessment enables us to recommend opportunities for improvement across the following areas:

- ▼ Ensuring compliance with current GMP and regulatory expectations
- ▼ Increasing the cost effectiveness of the cleaning and disinfection process
- ▼ Managing the health and safety of staff
- ▼ Increasing the efficiency of the cleaning and disinfection process
- ▼ Reducing the environmental impact of cleaning and disinfection



Identifying the Gaps

The mitigation of risks with existing controls will be captured, as will any gaps in your contamination control processes.

Ecolab will then work with you to implement solutions, aligning to the change control process. Our expertise can be utilised throughout the change management stages to reduce the burden on internal resources. We can support the end to end process.

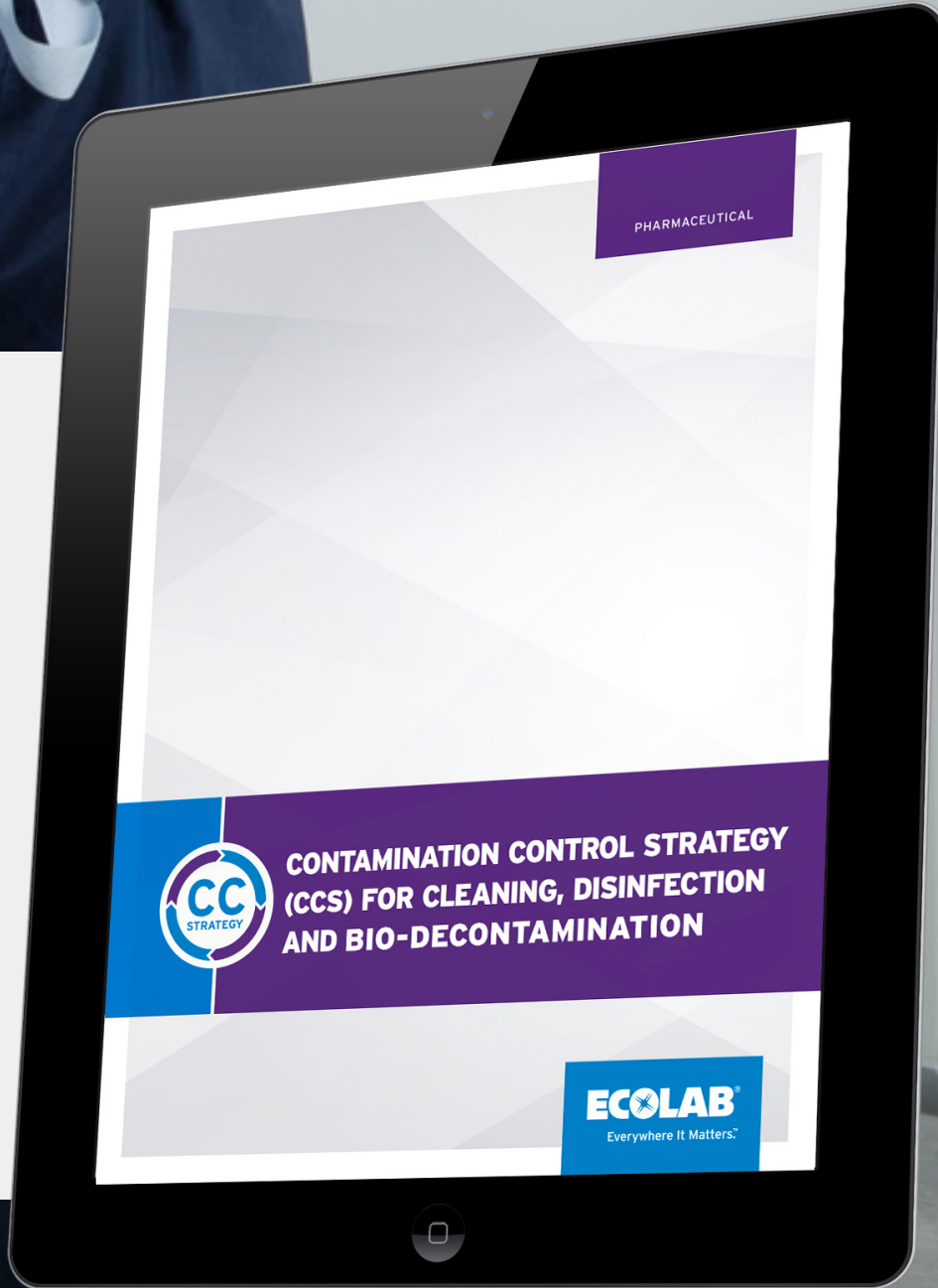


“Where gaps are identified, we can work with you to reduce the risks, providing documentation and validation support.”

Karan Khairnar Global Technical Consultant

Our Assessment Framework

We have used our knowledge and experience of assessing risk to create a CCS assessment document to capture your current status of contamination control for cleaning, disinfection and bio-decontamination.



How can Ecolab support implementing your Contamination Control Strategy

Discover Ecolab's Change Management Program

Compliance with the updated Annex 1 may drive the need to change the cleaning and disinfection practices within your facility.

Our team of Global Technical Consultants can support you through the process with a customised end-to-end change management plan that suits your specific needs. Support is available for all steps in the process that are relevant for you, from initial risk assessment (Ecolab's CCS Assessment), all the way through to training and implementation.



To arrange an in-depth assessment of your facility, submit your request [here](https://www.ecolab.com/ccs) or visit [ecolab.com/ccs](https://www.ecolab.com/ccs)

