Schedule

Providing a Framework for Effective Contamination Control Regimes in line with Regulatory Requirements

Speakers: Juliana Nassette, Senior Global Technical Consultant, Ecolab
Denis Streitt, Global Technical Consultant, Ecolab

Time	Topic
9.00	Arrivals, Coffee & Refreshments
9.30	Welcome & Introduction to the Day
9.45	Implementing a New Disinfectant Regime: Commissioning to First Use A detailed account taking you through the stages of implementing a new cleaning and disinfection regime. Whether you are a new start up facility or are switching your disinfectant supply, all elements of the process are presented to ensure effective change management.
10.15	The Importance of Detecting and Effectively Removing Disinfectant Residues in the GMP Environment This presentation highlights the importance of detecting, proactively controlling and removing residues, aswell as the visual and chemical impact of residues if not effectively removed. Ecolab will present their published analytical methodology, to give the audience guidance on how to quantify disinfectant residues in situ and demonstrate the effectiveness of the removal techniques employed at a facility level. The audience should go away with a framework on how to perform this analysis themselves, retrospectively for their existing regimes or as part of performance qualification (PQ) for implementation of new regimes.
10.45	Q&A
11.00	Coffe Break
11.30	Factors to Consider for Effective Material Intake The transfer of materials and equipment poses a significant of microbial contamination within pharmaceutical cleanrooms. Effective design and implementation of transfer disinfection processes are pivotal elements in contamination control strategies. Poorly designed processes poses a significant contamination risk due to the potential introduction challenging microorganisms into critical areas. This presentation delves into the regulatory frameworks, inherent risks and best practices surrounding material and equipment transfer into the cleanroom. Join us as we explore crucial considerations for enhancing the effectiveness of transfer disinfection procedures.
12.00	Disinfectant Efficacy Testing: Methodology and Approach to Annex 1 Validation The use of disinfectants as agents to control microbiological contamination of an environment is well established and is governed by regulatory bodies in both Europe and the United States. Data demonstrating the efficacy claim of a disinfectant, whether it is bactericidal, fungicidal, sporicidal or viricidal, is a clear requirement of BPR for a disinfectant manufacturer to achieve registration. In Europe, European Norm (EN) standards provide reference to required test methods to be used by disinfectant manufacturers to support claims of microbiocidal activity. These standard tests are commonly utilized and modified for end user validation. This presentation provides an overview of the EN standards available for disinfectant efficacy testing whilst providing an oversight to the specific requirements of Annex 1 validation and testing for disinfectant wipe application
12.30	Q&A
12.45	Lunch
13.45	Phase III: Performance Qualification of the Disinfection Regime A review of the final phase of implementation of a cleaning and disinfection regime; the performance qualification phase, also referred to as Phase III or in-situ field studies. The purpose of this phase is to demonstrate the effectiveness of a cleaning and disinfection regime once it is in use within the facility, through the generation of data. The presentation will outline possible structures to a Phase III program, how to handle the data generated and how to capitalise on the study to address other elements of a cleaning and disinfection regime, such as residue management and surface deterioration.
14.15	Q&A
14.30	Contamination Control Strategy Workshop for Cleaning and Disinfection The Contamination Control Strategy (CCS) has become fundamental for the pharmaceutical industry, driven by its broad inclusion in the revision of Annex 1 EU GMP guidelines. It is a critical tool for proactive risk management covering all aspects of the manufacturing process such as design, equipment, facility, process and utilities. The workshop will provide attendees an opportunity to work through prepared examples relating to cleaning and disinfection. Attendees will assess contamination by reviewing the current state, proposing a risk rating, and considering actions to mitigate the risks identified.
15.45-16.00	Close

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