PHARMACEUTICAL

AGENDA

Regulatory Hot Topics and Best Practices for Effective Cleaning and Disinfection

Wednesday 7th November 2018

TIME	SUBJECT	PRESENTER
09.00 - 9.15	**Welcome from Ecolab Life Sciences**	Beatriz Cervantes *Key Account Manager, Iberia*
09.15 - 10.15	**Regulatory Requirements and Expectations including a Review of the New GMP Annex 1** Annex I EU GMP/FDA/PIC/S and USP<1072> requirements and guidance, including a review of the proposed NEW changes to Annex 1 Requirements and best practice for personnel training, documents and records, preparation and use of disinfectants, rotation, cleaning and EM, transfer disinfection and validation.	James Tucker *Global Scientific Affairs Manager*
10.15 - 11.00	**A Practical Approach to Validation of Disinfectants** This presentation will explore the various test methods available for disinfection validation, European or US or Harmonised (EN, GST, AOAC, USP). It will discuss pros and cons of the different methods end users could choose and modifications which can/should be made so they are suitable for regulatory expectations.	James Tucker *Global Scientific Affairs Manager*
11.00 - 11.30	Break	
11.30 - 12.00	**The Low Residue Concept** A review of the impact of residues on a cleanroom and your surfaces. Specific disinfectant types and their residues will be reviewed.	James Tucker *Global Scientific Affairs Manager*
12.00 - 12.30	**The Biocidal Products Regulation** We will provide an overview of the authorization process for biocides according to the European BPR, as well as timelines and potential implications for both producers and end-users of biocidal products in Europe.	Michael Richter *Director Business Development Life Sciences*
12.30 - 13.30	Lunch	
13.30 - 14.00	**Detergent Requirements for the Pharmaceutical Industry** A focus on cleaning processes and detergents used in pharmaceutical non-sterile manufacturing environments. The regulatory requirements such as FDA CFR and EU GMP as well as other regulations such as PIC/S, APIC etc will be reviewed. General requirements for pharmaceutical detergents as well as specific composition needs will be outlined.	Beatriz Cervantes *Key Account Manager, Iberia*

14.00 - 14.45	**Cleanability Studies with Respect to Current Regulations** Annex 15 of the EU GMP guideline outlines that criteria for determining the worst case product may include, as well as other parameters, the cleanability. Laboratory cleanability studies can provide valuable sources of cleaning process knowledge and understanding. We will discuss different setups of cleanability studies and their specific aspects. This will also include the implementation of lab results in practice.	Thomas Altmann *Global Technical Manager*
14.45 - 15.15	Break	
15.15 - 16.00	**Limit Calculations for Detergent – Past & Future** The purpose of this presentation is to provide guidance to end users on cleaning agents and help them establish a strategy and rationale to set acceptance limits for cleaning agents that are in line with a harmonised approach based on scientific rationales. Different methods of limit setting for cleaning agents within the context of cleaning validation will be discussed, and example calculations will be conducted to compare the results and evaluate the risk using different approaches.	Thomas Altmann *Global Technical Manager*
16.00 - 17.00	**Cleaning Validation & Cleaning Optimisation - is this possible?** Annex 15 of the EU GMP guideline outlines that a continuous verification approach can be used for a manufacturing process. This can also include cleaning processes. A risk assessment based approach can identify if optimisation in cleaning will result in a higher patient safety risk. In this discussion we will review different optimisation possibilities of existing validated cleaning processes and assess if a revalidation would be required or the arguments to use in order to outline that patient safety is unchanged.	Thomas Altmann *Global Technical Manager*
17.00	**Questions and Close**	

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