

Program

Control of Cross-Contamination in Healthcare Industry

Length :14 hours (2 days)

Training: In-house or inter-site / Face-to-face or remotely

Target audience : Head Pharmacist, Quality control managers and technicians in the pharmaceutical, biotechnology, human and animal healthcare industries.

Prerequisites : no pre-requisite

Training accessible to people with disabilities

Learning objectives

- To know the regulatory requirements on the subject at European GMPs level
- Understand the difference between the control of particulate, microbial and pyrogenic contamination described in Annex 1 and the Control of Cross- Contamination described in Chapters 3 and 5 of Part I of the European GMPs and its Annex
- Be able to construct risk analysis for the control of cross-contamination in relation to the manufacturing process being carried out
- Incorporate suggestions for CAPAs based on the trainer's feedback
- Identify the theoretical and practical aspects of the cleaning validation process
- Understand the general differences between cleaning of equipments versus cleaning and disinfection of premises

Training content

- Reference the various international regulatory texts and Association texts (PDA, ISPE, A3P, WHO, PIC'S...)
- Describe the general content of European GMPs
- List the different contaminants
- Defining the concept of Cross-Contamination
- Define the PDE approach
- Understand and interpret documents : EMA, CHMP, CVMP, SWP, 246844, 2018
- Explain the Quality Risk Management approach described in ICHQ9 and included in Part II of the GMPs
- Describe and discuss an example of an analysis set up by the trainer on the subject
- Identify general Validation approaches
- Understand the challenges of Cleaning Validation
- Describe the general approach to the Cleaning Validation process
- Understand the regulatory expectations of Chapter 10 Annex 15
- Examine in detail 3 topics related to Cleaning Validation: QbD approach for the Cleaning process; visual inspection; Manual cleaning and operator training, certification and qualification

How the course is organized

Speakers :

Christophe GAMBLIN

Teaching and technical tools

- Training materials
- Theoretical presentations, examples of concrete cases
- Practical application exercises
- Question and answer sessions

Tool for monitoring the implementation of the training results assessment

- Attendance sheets
- Assessment tests of the acquisition of knowledge
- Training certificate