

# Program

## Managing Cross-Contamination in the 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.

**Pre-requisites :** no pre-requisite

Training accessible to people with disabilities

### Teaching goals

- Understand the regulatory requirements on the subject at the European GMPs level
- Understand the difference between Particulate, Microbial and Pyrogenic Contamination Management as described in Annex 1 and the Management of Cross contamination as described in chapters 3 and 5 of part I of the European GMPs and its Annex
- To be able to build risk analyses for managing cross-contamination adapted to and liked to the manufacturing process used
- Incorporate CAPAs suggestions based on the trainer's experience feedback
- Identify the theoretical and practical aspects of the cleaning validation process
- Understand the general differences between cleaning equipment compared to cleaning and disinfecting premises.

### Training content

- Refer to the different international regulatory texts and Association texts (FDA, ISPE, A3P, WHP, PIC'S...)
- Describe the general content of the European GMPs
- List the different contaminants
- Define the concept of Cross-Contamination
- Define the EDP Approach
- Understand and interpret the documents: EMA, CHMP, CVMP, SWP, 246844, 2018
- Explain the Quality Risk Management approach described in the ICHQ9 and included in Part II of the GMPs
- Describe and discuss an example of an analysis put in place by the trainer on the topic
- Identify general approaches to Validation
- Understand the issues involved in Cleaning Validation
- Describe the general approach to the Cleaning Validation Process
- Understand the regulatory expectations of Chapter 10 of Appendix 15
- Review in detail 3 topics related to Cleaning Validation : QbD approach to the cleaning process : visual inspection, manual cleaning and operator training, certification and Qualification

## How the course is organised

### Speakers :

Christophe GAMBLIN

### Teaching and technical tools

- Training materials.
- Theoretical presentations, examples of concrete cases
- Practical application exercises
- Question and answer sessions
- Self-assessment using a grid

### Tool for monitoring the implementation of the training results assessment

- Attendance sheets.
- Knowledge acquisition assessment test
- Certificate of training.