Workshop Agenda on “Cleaning Validation in Pharmaceutical Industries”

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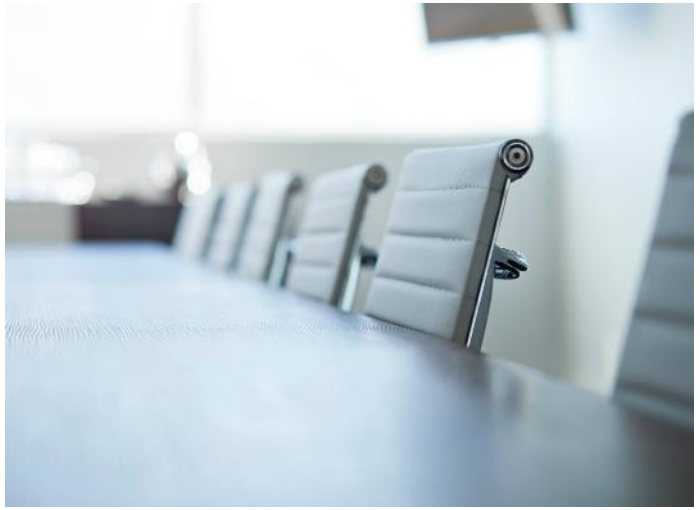
Date: 18 & 25th of June 2022



Purpose

Expand your knowledge on CLEANING VALIDATION and learn how to improve your skills/knowledge particularly required for each QA specialist.

Topics – Day 1

Time	Description
10:00 – 12:00	• Introduction • Definitions • Guidelines
12:00 – 12:30	**Break**
12:30 – 13:30	• Validation branches • Brief history of how GMP came to be.
13:30 – 14:00	**Recap and Q&A**

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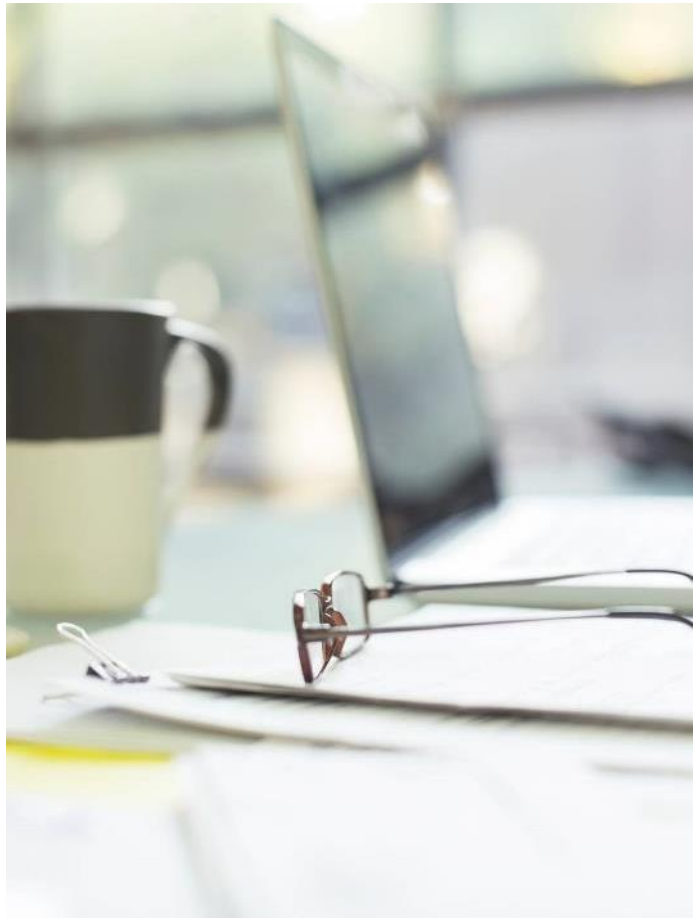
Topics – Day 2

Time	Description
10:00 – 12:00	• Risk based approaches in cleaning validation • Steps and prerequisites • Toxicity threshold • PDE calculations • Matrixing and how to build one
12:00 – 12:30	**Break**
12:30 – 13:30	• MACO Calculations • Other supporting studies (Clean equipment holding time, etc…) • Reporting
13:30 – 14:00	**Recap and Q&A**

Reference documentation:

1. Annex 15 EudraLex
2. Guideline on setting heath-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (EMA/CHMP/CVMP/SWP/169430/2012)
3. Appendices 3 of the ICH Q3C



Thank you

The attendees are asked to be engaged and ask as many questions as they please to enrich the session and to take as much notes as they please to solve the in-session exercises