Current Requirements for Cleaning Validation
CURRENT REQUIREMENTS FOR CLEANING VALIDATION

Overview

This course covers topics such as the development of regulatory expectations, effective cleaning procedures and the validation and control of these procedures. It will cover all areas of Cleaning Validation from the inception of a cleaning strategy and policy through the development and performing of the exercise to the maintenance of the validated cleaning regimes.

Uniquely developed and delivered, to make it relevant to both novice to experts.

50% of the course will be spent in lectures and the remainder will be spent performing practical exercises and in interactive workshops.

Course Objectives & Learning Outcomes

- Understand the key GMP requirements for cleaning validation and verification
- Understand the methods of cleaning including manual, automated or COP
- Be able to develop effective cleaning procedures
- Understand the significance of product development data in cleaning validation
- Develop approaches to cleaning validation based on scientific rationale
- Develop cleaning validation protocols, define worst case locations, set limits and define acceptance criteria
- Apply best practice techniques for direct surface sampling and recovery
- Understand the suitability and technology associated with specific and non specific analytical techniques
- Apply risk assessment techniques to cleaning validation
- Understand the importance of maintaining the cleaning validation state: cleaning stability studies and change control

Who Should Attend?

This course will be beneficial to new comers and experienced personnel from:

- QC
- Validation
- Engineering
- Production
- QA
CURRENT REQUIREMENTS FOR CLEANING VALIDATION

Course Programme

Day One
Cleaning Validation Basics and Approach
Cleaning Validation Documentation
Cleaning Acceptance Criteria
Annex 15 Requirements for PDE
Sampling and Recovery Analysis
Rapid Equipment Cleaning Verification
Monitoring Using TOC Analysis
Practical Workshops
Cleaning Stability and Change Control

Day Two
Risk Based Approach to Cleaning Validation and Cross Contamination
Case Study Workshop
Discussion of Workshop Case Study
Interactive Risk Assessment Session
Maintaining Cleaning Validation and Disinfectant Efficacy Status
Questions and Answers

"Dynamic and interactive, relevant to our operations, made a technical subject accessible”

Product Manager, Benchmark Vaccines

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Microbiology for Non-Microbiologists
Sterile Product Manufacture
Cleaning Validation
Pharmaceutical Sterilisation
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