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Pharmaceutical Process Support

Current Requirements for Cleaning Validation

Overview:
Validation of cleaning procedures is critical for any cleaning programme as defined in the current GMP Guidelines (Annexe 15, Section 10): "Cleaning Validation should be performed in order to confirm the effectiveness of a cleaning procedure for all product contact equipment"

Since the first statement regard cleaning in the GMP Regulations, the number of guidelines in regard to Cleaning Validation has greatly increased, especially since 2000. This has coincided with the increased focus by regulators within this area.

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.

For those new to this area, this course provides a detailed and structured introduction to cleaning validation, whilst for those who have been working in the field for some time this up to the minute course will provide details of current best practice, cGMP expectations, industry trends and regulatory issues for both the EU and US markets. 50% of the course will be spent in lectures and the remainder will be spent performing practical exercises and in interactive workshops. It will cover subjects such as development of regulatory expectations, effective cleaning procedures and disinfectant regimes, development of effective cleaning techniques, interactive case studies and the validation and control of these procedures.

Who Should Attend:
This course will be beneficial to new comers and experienced personnel from QC, validation, engineering, production and QA.

Course Content:
The course will cover the following:

- Methods of Cleaning: Manual/Automated
- Risk based approach to cleaning validation requirements and cross contamination
- Cleaning Procedures: Cleaning Validation Master Plans/Establishing Methods of Cleaning
- Cleaning Procedures: Protocol Development/Development of Cleaning Acceptance Criteria/Cleaning Reports
- Analytical Cleaning Methods: Analytical Methods/Sampling Techniques
- Maintaining the Cleaning Validation State: Cleaning Stability Studies/Change Control
- Industry Case Studies: From API to Finished Products/Regulatory Requirements including Annex 15 (2015)

Course Objectives:
Upon completing the course delegates will:

- 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

Course Notes and Certificates:
Full course notes and a certificate of attendance will be issued to each delegate who attends the full course. Certification is for knowledge gained, not just attendance.

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Day 1

09:15 - 09:30	Registration
09:30 - 10:00	Course Introduction
10:00 - 10:45	Cleaning Validation Basics and Approach
10:45 - 11:15	Tea/Coffee
11:15 - 12:00	Cleaning Validation Documentation
12:00 - 12:30	Cleaning Acceptance Criteria including new Annex 15 requirements for PDE
12:30 - 13:30	Lunch
13:30 - 14:15	Sampling and Recovery Analysis
14:15 - 15:00	Rapid Equipment Cleaning Verification and Monitoring Using TOC Analysis
15:00 - 15:15	Tea/Coffee
15:15 - 16:30	Practical Workshop
16:30 - 17:00	Cleaning Stability and Change Control

Day 2

09:00 - 09:15	Review of Day 1
09:15 - 10:45	Review of Practical Workshop
10:45 - 11:00	Tea/Coffee
11:00 - 11:45	Risk based approach to cleaning validation and cross contamination
11:45 - 12:30	Case study workshop
12:30 - 13:30	Lunch
13:30 - 14:00	Discussion of workshop case study
14.00 - 15:15	Worked example interactive risk assessment session
15.15 - 15.30	Tea/Coffee
15:30 - 15:45	Maintaining Cleaning Validation and Disinfectant Efficacy Status
15:45 - 16:15	Questionnaire/Answers and Feedback/Closing Comments and Questions

Registered Address: Harmire Enterprise Park, Harmire Road, Barnard Castle, County Durham, DL12 8BN, U.K.
Tel: +44 (0) 1833 690101 Fax: +44 (0) 1833 690102 Email: enquiries@honeyman.co.uk Web: www.honeyman.co.uk
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