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E-LEARNING

VAL

8

Equipment Cleaning Validation

This module provides an introduction to the requirements of equipment cleaning validation.

Objectives:

- Define cleaning validation terminology and explain regulatory requirements
- Determine the scope of cleaning validation
- Define cleaning validation pre-requisites
- Determine your acceptance criteria (“How Clean is Clean?”)
- Develop a cleaning validation protocol
- Analyse cleaning validation results and prepare reports

Course Outline

INTRODUCTION
- o Welcome
- o Outcomes
- o Meet the V team
- o Introduction
- o Worst-case scenario
- o The new line
- o Definitions
- o Review I
- o Summary
- o Review II

SCOPE
- o Introduction
- o Two approaches
- o SOP validation
- o SOP requirements
- o Classifying equipment
- o What to validate I
- o What to validate II
- o Common equipment
- o Bracketing
- o Cleaning requirements
- o CIP qualification
- o Using previous data
- o Testing surface residues
- o Microbial limits and residues
- o Summary
- o Review

PRE-REQUISITES
- o Analytical techniques
- o LOD and LOQ
- o Swab recovery studies I
- o Swab recovery studies II
- o Visual inspection
- o Role of flush sampling
- o Summary
- o Review

ACCEPTANCE CRITERIA
- o Introduction
- o How clean is clean?
- o Worst-case products I
- o Worst-case products II
- o Toxicity study
- o Considerations I
- o Considerations II
- o Maximum Daily Dose
- o Surface residue limits
- o Calculating SAL
- o Summary
- o Review

WRITING PROTOCOLS
- o Introduction
- o Worst-case conditions
- o Sampling locations
- o Applying the protocol
- o Are we prepared?
- o Documenting results
- o Summary
- o Review

REPORT WRITING
- o Introduction
- o On-going requirements
- o Review

CONCLUSION
- o Summary

GLOSSARY/RESOURCES
- o Glossary
- o Resources

Contact us for more information

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