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Feb 10 – 11, 2020 - Malvern, PA
Jun 15 & 16, 2020 - Boston, MA
Oct 15 & 16, 2020 - Los Angeles, CA

This course provides practical guidance on cleaning validation regulatory compliance, in conjunction with process validation principles to facilitate reasonable and informed decision making and activity planning. Regulatory requirements and the latest industry practices will be included in the discussion to identify questionable practices that may be misdirected as well as the better practices that support and align with current process validation principles. The program will describe a risk-based approach for establishing an effective cleaning validation program, including the development of policies, master plans and the appropriate content for each study to be performed incorporating critical quality attributes and critical process parameters and process control. In addition, validation maintenance and life cycle aspects will be reviewed. Cleaning validation examples will be included from different sterile and non-sterile product types, and different types of dosage forms including oral, topical, and injections. Concepts will apply to any FDA regulated manufacturing including drugs, supplements, personal care, medical devices. Additional benefits of this class include interacting and learning from peers. Participants will have the opportunity to discuss their challenges and problems.
INSTRUCTOR CREDENTIALS

Steven A. Weitzel is Vice President-Technical Operations of CANI, Inc. Critical Process Cleaning. He is a recognized subject matter expert on process development and on validation of cleaning and contamination control for FDA regulated manufacturing, including sterile and non-sterile drug dosage forms, biologics, APIs, devices and combination products, cosmetic and consumer products, and emerging natural medicines and supplements. He has conducted technical training or consulted for the world’s leading pharmaceutical, biotech, cosmetic and medical device companies. He primarily works in North America and Europe, but his work has extended to the Middle East, India and Southeast Asia within companies of all size and structure.

Mr. Weitzel earned a B.S. in chemical engineering from the University of Missouri, and a Master’s in Business Administration from Washington University in St. Louis. He is a pharmaceutical process engineer with over 25 years technical experience in FDA regulated industry, holding technical and management positions at Novaflex, Bristol-Myers Squibb, Calgon-Vestal/Merck, Mallinckrodt, and Dow Chemical with direct experience in engineering, manufacturing and validation of medical devices and in-vitro diagnostics, APIs, oral drugs and nutritional, terminally sterilized and aseptic parenterals. While at Calgon-Vestal/Merck (now Steris) he started their business life science business unit and introduced CIP 100 and other cleaning agents for validated cleaning as well as LpHst, Spor Klenz and products and support for aseptic manufacturing. Mr. Weitzel has been involved in hundreds of facilities, projects and applications related to critical systems, contamination control, cleaning or process validation.

REGULATORY ASPECTS

- Cleaning validation Guidelines, & Expectations
  - US FDA
  - EMEA
  - PICs, organizations
- Regulatory trends-Process Validation
- Regulator concerns about cleaning validation
- Cleaning validation Establishment Inspection Reports (EIRs), FDA 483 observations and Warning Letters.

REVIEW OF INDUSTRY PRACTICE

- Approach to Process understanding and control
- Approach to Residue Risk and Limits
- Approach to Inspection and Sampling
- Cleaning Validation Management-Typical elements of a policy/program

BETTER PRACTICES TO IMPLEMENT A ROBUST CLEANING VALIDATION PROGRAM

EVALUATE EQUIPMENT AND RESIDUE- RISK ASSESSMENT

- The information gathering process
- Equipment/product matrix/Substrate/residue matrix
- Equipment use type and use patterns
- Qualitative residue risk assessment

CLEANING PROCESS FUNDAMENTALS

DEFINE AND CONTROL CRITICAL PROCESS PARAMETERS (CPPS)

- Review of current cleaning processes/procedures
- Agents-Select and Justify the right Cleaning Agents for your Substrate/residue
- Methods- Immersion, film flow, impingement, pipe flow, defining adequate parameters to provide consistent results
- Procedural Aspects
  - CIP vs. COP; Manual vs. Automatic- advantages and disadvantages
  - Sequence, Duration, Interval, pattern, direction
  - Other Time Concepts- dirty hold time (DHT) and clean hold time (CHT)

ESTABLISH SCIENTIFICALLY SOUND CONTAMINATION LIMITS

- Convert Qualitative risk to Quantitative risk: Health based contamination levels
  - Maximum Allowable Carryover (MAC) vs. Acceptable Daily Exposure (ADE)
  - Drug Activity-Minimum Therapeutic Dose, Largest Daily Dose
  - Toxic, Allergenic and other bioactive materials
  - Purity/Adulteration based limits approach and calculations
- Residue Contamination Risk Matrix
- Critical Quality Attributes-Surface Acceptance Limit (SAL)
- Use of visual criteria for determining if equipment is clean

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CPIE room rate of $167/night if booked 3 weeks in advance of the course date)
The Desmond Hotel & Conference Center, Malvern, PA (CPIE room rate of $141/night if booked 3 weeks in advance)
Club Quarters Hotels, Boston, MA (CPIE room rate of $255/night if booked 4 weeks in advance)
DoubleTree by Hilton London - Victoria (CPIE room rate of £199.00/night if booked 4 weeks in advance)

FIRST DAY

Compliance Overview
Why Clean? Manage Risk of Batch to Batch Contamination
- Contamination Types and sources
  - Single-use, dedicated, campaigns
- Cleaning Validation Compliance Scope

SECOND DAY

Better Practices to Implement a Robust Cleaning Validation Program (cont.)

Develop and Qualify Inspection and Control Methods
- Inspection, Sampling , Monitoring Methods
  - Sampling rationale and impact
  - Choice of sampling type (visual, swab, rinse) Special topic-Visual analysis
  - Process Indicators and control scheme- type, frequency, timing

SELECT AND JUSTIFY ACCEPTANCE CRITERIA AND QUALIFICATION TEST PLANS

- How to convert batch limits and surface limits to sample acceptance criteria
- Special Topic- How to avoid unrealistic “worst case” traps
- Calculated criteria vs. documented process capability
- The correct way to implement a Grouping/matrix concept: How to use product/equipment matrix and risk matrix to select protocol challenge conditions, worst case products & equipment and determine acceptance criteria
- Process Performance Qualification-Understanding the validation space

INSTALL A LIFE CYCLE MANAGEMENT PROGRAM FOR CLEANING VALIDATION MAINTENANCE

- Process Life Cycle Overview
  - Continuous, Incremental Process control and Improvement
- Process Development Guidelines
- Process Validation Monitoring after equipment cleaning (Visual Inspection and Type and Frequency of Sampling/Testing)
- Planned reviews and assessment
- Revalidation and Change Control (Known vs, Hidden Change)

DISCUSSION TOPICS AND FORUM

- Microbiological aspects of a cleaning validation program for manufacturing equipment
  - Cleaning impact on viable contamination (Clean Hold Issues)
  - Cleaning, Sanitization and sterilization after use versus before use
- Issues for Specific Sub-Industries and Related Manufacturing Facilities
  - Active Pharmaceutical Ingredient (API) Manufacturers
  - Biotechnology Facilities
  - Dietary Supplement Manufacturers
- Cosmetic Manufacturers
- Best Practices Going Forward-The future of cleaning processes and cleaning validation
  - Containment Concept, EMEA, and ISPE
  - Use of Disposable Equipment
  - New innovative equipment design facilitating easier cleaning
  - New cleaning technology (e.g. sprayball design)
  - New surface analyzers