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CONCLUSION

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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 LPRSt, 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.

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
- Contamination Control and Process Strategies
- 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

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 Residues- 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/adaptation) based limits approach and calculations
  - Residence Contamination Risk Matrix
- Critical Quality Attributes-Surface Acceptance Limit (SAL)
- Use of visual criteria for determining if equipment is clean

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
- Flexible Management, Organization and Documentation practices
  - Master plans, area plans, protocols, reports
- Organizing for Ongoing, Incremental Process control and Improvement
  - Process Development Guidelines
  - Continuous Process Verification, Post 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

Analytical, Laboratory, Validation Issues
- Specific vs. Non-specific Methods
- Suitability, sensitivity and specificity issues (LOD/LOQ)
- Analytical Method development, validation
- Recovery studies, qualification sample method; special topic-rinse qualification
- Special topic-Visual analysis and inspection