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DOC
TRAINING MODULES CATALOGUE
2016

1. EQUIPMENT AND SYSTEMS – HVAC AND CONTROLLED ENVIRONMENTS

Module Length: from 1½ day to 2 days

Number of trainers: One

Tailoring option available: No

Final Evaluation Quiz: yes

Training Agenda:

- Regulatory aspect from International Agencies
- Technical Background from cGEP (Good Engineering Procedures)
- Validation Life Cycle
    - Design Qualification
    - Installation Qualification
    - Operational Qualification
    - Calibration
    - Performance Qualification
- Operational and Maintenance Aspects

2. EQUIPMENT AND SYSTEMS – PHARMACEUTICAL WATER AND STEAM SYSTEMS

Module Length: from 1½ day to 2 days

Number of trainers: One

Tailoring option available: Yes

Final Evaluation Quiz: Yes

Training Agenda:

- Regulatory aspect from International Agencies
- Technical Background from cGEP (Good Engineering Procedures)
- Pure Steam
- Validation Life Cycle
    - Design Qualification
    - Installation Qualification
    - Operational Qualification
    - Calibration
    - Performance Qualification
- Microbial considerations
- Industry perspective and Regulatory challenges
- Inspection
- Operational and Maintenance Aspects

3. EQUIPMENT AND SYSTEMS – MOIST AND DRY HEAT STERILIZATION

Module Length: from 1½ day to 2 days

Number of trainers: One

Tailoring option available: Yes

Final Evaluation Quiz: Yes

Training Agenda:

- Regulatory aspect from International Agencies
- Technical Background from cGEP (Good Engineering Procedures)
- Moist sterilization
- Dry Heat sterilization
- Validation Life Cycle
    - Design Qualification
    - Installation Qualification
    - Operational Qualification
    - Calibration
    - Performance Qualification
- Operational and Maintenance Aspects

4. EQUIPMENT AND SYSTEMS – SOLUTION PREPARATION AND FILTRATION

Module Length: from 1½ day to 2 days

Number of trainers: One

Tailoring option available: No

Final Evaluation Quiz: yes

Training Agenda:

- Regulatory aspect from International Agencies
- Technical Background from cGEP (Good Engineering Procedures)
- Validation Life Cycle
    - Design Qualification
    - Installation Qualification
    - Operational Qualification
    - Calibration
    - Performance Qualification
- Operational and Maintenance Aspects

5. EQUIPMENT AND SYSTEMS – VALIDATION OF EXISTING SYSTEMS

Module Length: from 1½ day to 2 days
Number of trainers: One
Tailoring option available: No
Final Evaluation Quiz: yes

Training Agenda:

- Regulatory aspect from International Agencies
- Technical Background from cGEP (Good Engineering Procedures)
- Validation Life Cycle
    - Design Qualification
    - Installation Qualification
    - Operational Qualification
    - Calibration
    - Performance Qualification

6. GMP GENERAL TOPICS – COMPUTERIZED SYSTEM VALIDATION

Module Length: from 1½ day to 2 days
Number of trainers: One
Tailoring option available: yes
Final Evaluation Quiz: yes

Training Agenda:

- Regulatory aspect from International Agencies
- Technical Background
- Validation Life Cycle
    - Design Qualification
    - Installation Qualification
    - Operational Qualification
    - Calibration
    - Performance Qualification

7. GMP GENERAL TOPICS –VALIDATION PRINCIPLES METHODOLOGY AND DOCUMENTATION

Module Length: from 1½ day to 2 days
Number of trainers: One
Tailoring option available: No
Final Evaluation Quiz: yes

Training Agenda:

- Regulatory aspect from International Agencies
- Technical Background
- Validation Life Cycle
    - Design Qualification
    - Installation Qualification
    - Operational Qualification
    - Calibration
    - Performance Qualification

8. GMP GENERAL TOPICS – VALIDATION LIFE CYCLE (FROM DQ TO PQ) APPROACHED AS PER GMP ANNEX 15

Module Length: from 1½ day to 2 days
Number of trainers: One
Tailoring option available: Yes
Final Evaluation Quiz: Yes

Training Agenda:

- Regulatory aspect from International Agencies
- Technical Background
- Validation Life Cycle
    - Design Qualification
    - Installation Qualification
    - Operational Qualification
    - Calibration
    - Performance Qualification

9. GMP GENERAL TOPICS - QUALITY RISK MANAGEMENT

Module Length: half a day to 1 day
Number of trainers: One
Tailoring option available: Yes
Final Evaluation Quiz: Yes

Training Agenda:

- Regulatory background (in detail ICH Q9 "Quality Risk Management", EU GMP Part III Q9)
- QRM methodology following FMEA
- QRM case study 1: Water Systems
- QRM Case study 2: Commissioning & Qualification activity

10. GMP GENERAL TOPICS – ORGANIZATION OF TECHNICAL MANUALS FOR GMP SYSTEMS

Module Length: from half a day to 1 day
Number of trainers: One
Tailoring option available: yes
Final Evaluation Quiz: yes

Training Agenda:

- Regulatory aspect from International Agencies
- General Organization
- Specific Document for different systems
    - Water Systems
    - HVAC
    - Preparation systems
    - Autoclave
    - Etc..

11.PROCESS & PRODUCT VALIDATION - ASEPTIC PROCESSING

Module Length: from 1 day to 2 days

Number of trainers: One /Two

Tailoring option available: Yes

Final Evaluation Quiz: Yes

Training Agenda:

- Material and Primary Containers
- Autoclaves
- Dry-heat Oven and Depyrogenation Tunnels
- VHP Pass Box
- Sterile Manufacturing Operations
- Cleaning Validation in Aseptic Processing
- Sterile Filtration Validation
- Media Fill Test
- In Process Material and Sterile Finished Form Qualification
- Container Closure Integrity Test Validation
- Material Qualification and Toxicological Assessment

12.PROCESS & PRODUCT VALIDATION – STERILIZING FILTER VALIDATION

Module Length: one full day

Number of trainers: One / Two

Tailoring option available: Yes

Final Evaluation Quiz: Yes

Training Agenda:

- International Regulatory Context
  - Requirements (PDA, EMEA and FDA)
- Filter and Filtration process definition
- Vendors and User Responsibility
- Process Validation Studies
- Process Review
- Validation Test Overview
  - Bacterial Retention Studies
  - Compatibility
  - Adsorption
  - Extractables & Leachables
  - Product Wet Integrity Test (PWIT)
- Toxicological Risk Assessment
- Bracketing and Grouping
- Process Revalidation
- Future Regulatory Trends
- Practical Workshop (Optional)

13.PROCESS & PRODUCT VALIDATION – EXTRACTABLES AND LEACHABLES

Module Length: one full day

Number of trainers: One / Two

Tailoring option available: Yes

Final Evaluation Quiz: Yes

Training Agenda:

- Extractables and Leachables
  - General Concepts
  - Importance of a good Extractables & Leachables qualification
- International Regulatory Context
  - Requirements (EMEA, FDA and ICH)
- Extractables and Leachables Strategy Approach
  - Conditions selection
  - Analytical Techniques and Methodologies
  - Leachable Study Design
- Risk Assessment on Extractables and Leachables
- Safety Evaluation
  - Toxicological Assessment
  - EMA guideline on Genotoxic Impurities
  - PQRI Threshold
- Practical Case Studies on
  - Pre-filled Syringes
  - Lyophilized Drug Products
  - Injectables
  - Large Volume Parenterals
  - Disposable and Single-Use Systems
  - Single Use Equipment Process Validation Requirements

14. PROCESS & PRODUCT VALIDATION – SINGLE USE SYSTEM QUALIFICATION & VALIDATION

Module Length: One full day

Number of trainers: One / Two

Tailoring option available: Yes

Final Evaluation Quiz: Yes

Training Agenda:

- International Regulatory Context
  - Requirements (PDA, EMEA and FDA)
  - Material Qualification Documentation
  - Single Use Equipment Process Validation Requirements
- Process Validation Studies
- Process Review
- Validation Test Overview
  - Compatibility
  - Adsorption
  - Extractables & Leachables
  - Stability Studies
- Toxicological Risk Assessment
- Bracketing and Grouping
- Process Revalidation
- Future Regulatory Trends

15.PROCESS & PRODUCT VALIDATION – PRIMARY PACKAGING QUALIFICATION

Module Length: One full day

Number of trainers: One/Two

Tailoring option available: Yes

Final Evaluation Quiz: Yes

- International Regulatory Context
  - Requirements (USP, EPh, ISO and ICH regulations)
- Qualification Risk Assessment
- Material Qualification
  - Process Material in contact with the drug formulation
  - Primary, Secondary and Tertiary Container Packaging
- Validation Matrix Development
- Toxicological Assessment
- Practical Case Studies
- Container Closure Integrity (CCI)
- Container Closure Test Methodology
- Development and Validation of Integrity Test Methods
  - Testing Requirement definition
  - Testing Strategy Development
  - Method Validation Strategy
  - Practical Case Study
- Practical Workshop (Optional)

16. PROCESS & PRODUCT VALIDATION – CONTAINER CLOSURE INTEGRITY TESTING

Module Length: One full day

Number of trainers: One / Two

Tailoring option available: No

Final Evaluation Quiz: Yes

Training Agenda:

- International Regulatory Context
  - USP <1207>, EPh, ICH
  - PDA TR 27

- Container Closure Integrity Test Methodologies
  - Classification
  - Microbial and Physicochemical methods
  - Limit of detection

- Development of Container Closure Integrity Testing Strategy
  - Requirement definition
  - Strategy Development

- Container Closure Integrity Testing Method Selection
  - Selection guidance
  - Selection consideration

- Development and Validation of Integrity Test Methods
  - Best Practices
  - Validation Strategy

- Case Studies

17.PROCESS & PRODUCT VALIDATION - CLEANING VALIDATION

Module Length: One full day

Number of trainers: One / Two

Tailoring option available: No

Final Evaluation Quiz: yes

Training Agenda:

- Cleaning Validation Concepts
  - International Regulatory Context
  - Maximum Allowable Limits of Carry Over (MACO)
  - Cleaning Validation Documents

- Special Aspects of Cleaning Validation
  - Bracketing, worst case rating
    - Bracketing of products
    - Bracketing of equipment
  - Acceptance criteria
- Cleaning Validation in
  - Biotech API Production Plants
  - Chemical API Production Plants

- Technical and Organizational Aspects on Equipment Regarding Cleaning Procedures
  - Design and cleaning principle
  - Validation and maintenance for efficient cleaning
  - Case studies

- Good practice to write a cleaning validation protocol
  - Current GMP Requirements
  - How to write a cleaning protocol
  - Summary

- Practical Workshop (Optional)

18.RAPID MICROBIOLOGY

Module Length: half a day

Number of trainers: One

Tailoring option available: No

Final Evaluation Quiz: Yes

Training Agenda:

- History of microbiology methods
- International regulatory context overview
- Rapid Microbiology technology overview
    - Growth Based
    - Viability Based
    - PCR based
- Validation Strategies
- Rapid Method Qualification
    - IQ
    - OQ
    - PQ