I. Validation as part of the Quality Management System (based on PICS)

II. Validation Master Planning

Validation master planning includes the following topics:
- Process control
- Equipment control
- Data Computers
- Training
- Documentation
- Change Control
- Role of QA

III. Workshop case study:
Participants work in groups to develop a computer validation master plan for an oral liquid product

Session 2

I. Regulations
- Summary of the PICS regulations for computerised systems
- Requirements of EU Annex 11 for Computerised Systems
- PICS requirements for quality management systems and validation

II. Validation Documentation Hierarchy and Contents
- Corporate policy
- Computer Validation Master Plan (VMP) and computer inventory
- User requirements specification
- Individual validation plans
- Risk analysis

III. Document Management

IV. Other Key Documents
- Specifications
- Verification Testing Protocols including IQ/ OQ/ PQ
- Validation results
- Validation reports

V. Workshop case study:
Participants develop the documentation for an example project
Gap Analysis for Computer Systems Validation (PIC/S)

I. Learn How to Plan a Gap Analysis
   - Develop a gap analysis
   - Plan conduct the gap analysis
   - Roles and responsibilities
   - Tools for a typical assessment
   - Determine the methodology to use
   - Prepare for issues that may be found

II. What Inspectors Are Looking For
   - Current requirements and expectations
   - Policies, plans, test protocols, risk analysis
   - Lifecycle approach to process computer validation

III. Correcting Deficiencies
   - Identify documentation deficiencies
   - Apply risk-based remediation
   - Record observations and addressing problem areas
   - Revalidation planning
   - How to determine if you are compliant

IV. Workshop case study: Participants carry out a gap analysis of a previous validation program

The Importance of Good Specifications for Computer Systems

I. Regulations (PICS requirements) concerning specifications

II. Content of Specifications for Computer Systems dealing with
   - Process
   - Packing
   - Critical data
   - Equipment
   - Laboratory
   - specifications are reviewed for critical process parameters and critical quality attributes

III. Workshop case study: Participants review a specification to determine critical parameters

Applying a Risk Based Approach to Computer Systems Validation

I. Defining the Process – What is the Process to Be Validated?
   - Risk management of an example process
   - Critical process parameters
   - Critical quality attributes
   - Requirement specifications (define "fit for use")
   - Determine what to validate and the approach taken
   - Answer the key question-Does it need to be validated?
   - Supplier (Vendor) assessment

II. Defining the Equipment and Systems that need to be validated
   - Types of equipment and computer systems

III. Testing
   - Extent and types of testing required based on risk assessment
   - Commissioning and Qualification, the ISPE Model
   - Use of Supplier testing

IV. Documentation
   - What documents do you REALLY need?

V. Workshop case study: Participants carry out a risk assessment of part of the process

Session 3
Duration: 3 hours

Session 4
Duration: 3 hours

Session 5
Duration: 3 hours
Session 6

How to define effective Computer Systems Validation Test Specifications & Reports

I. Regulatory Requirements for Testing
- PICS requirements

II. Testing requirements for:
- Process Control
- Packing
- Critical data
- Equipment
  - including critical process parameters and critical quality attributes

III. What to Do When Things Go Wrong
- Review different levels of exceptions - test failures
- Differentiate between critical and non-critical
- Determine the risk and impact of the exception

IV. Validation Reports
- How to write a summary report

V. Workshop case study:
Participants develop a test specification or test protocol for different types of computer system

Session 7

Understanding the Regulators Concern for Data Integrity

I. Introduction
- Regulations and GMP requirements
- Advantages of electronic records (e-records)
- Risks to e-records, risk assessment and control
- The importance of data integrity
- Managing e-records
- IT requirements

II. Ensure Data Integrity During the Validation Process
- Data integrity as part of:
  - specification
  - risk assessment
  - requirements
  - testing

III. Ensure Data Integrity During Production Use
- Standard Operating Procedures (SOPs)
- The role of training
- The role of system monitoring
- Data integrity as part of system retirement

IV. Workshop Case Study
In this activity, the attendees identify possible data integrity concerns for a typical CAPA system.

Session 8

Incorporating Risk Management to Change Control Processes

I. Regulations and GMP requirements
- Changes to process
- Changes to equipment
- Changes to computer systems

II. Change Control Processes
- Procedures
- Types of change

III. Use of Risk Assessment
- Risk assessment techniques and risk management
- How to apply risk assessment to change control
- Examples of the use of risk assessment for different types of change control and different types of computer systems

IV. Workshop case study:
Participants work in groups on different change case studies for Computer Systems