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EVENTS LIST

A Risk Based Scientific Approach to Analytical Methods Development and Validation Activities for FDA Regulated Industries

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Organizer : NYMT

Venue :

Location : TBASan Francisco, CAUnited States,
San Francisco, CA, US, ZIP: 0001

A Risk Based Scientific Approach to Analytical Methods Development and Validation Activities for FDA Regulated Industries

This Course introduces the schematics of Methods Development and Validation with a grassroot, conceptual standpoint, based on scientific rationale and a Method by Design approach, a concept akin to QbD. The aim is to lead the audience to the understanding, basic elements of analytical method, with a focus on Quality. At the outset, it implores the analytical chemist to grasp an Analytical Method as a process of measurement.

They are then lead to understand the concepts of measurement, errors, measurement uncertainty and measurement resolution. The extent of such errors needs to be explored, mitigated, minimized and established for the specific method, as it is being developed. Thus, it presents a goal oriented Method Development with a generic, iterative, sequential and modular approach, leading eventually to the establishment of the validation parameters at the validation stage. Following the initial development, the process continues thru optimization and subsequently to validation. Guidance from EP, USP, ICH Q2 (R)1, AOAC etc. will be discussed.

The presentation continually builds on from a conceptual level to practical applications, data handling, data integrity, validation protocol and other documentation, vis-a-vis regulatory

requirements. Discussions provide extensive guidance for preparing Methods Validation Protocols for the various stages of regulatory submissions, e.g. IND, NDA, ANDA, PAI CMC etc. Various aspects of laboratory controls, QC procedures, SOPs that cover calibration, standardization, qualification and validation, will be included, along with statistical tools, SQC, SPC for processing and monitoring of analytical data. Strategies for the development stability, indicating assays, are included.

This Course is highly interactive and participative. Attendees are encouraged to interact and be prepared to bring examples of Analytical Development and Validation issues, which will be discussed during the second day. A class breakout session (for about 2 hours) is normally included, wherein the attendees will be expected to participate in solving assignments of group exercise. This workshop style session requires and demonstrates the practical applications of the concepts learnt during the two days. Over the years, thousands of attendees have enjoyed and appreciated this breakout session immensely.

Learning Objectives:

- Increase your knowledge of conformity assessment, QC/QA in the pharmaceutical laboratory
- Increase your knowledge about cGMP/EMEA/ICH/WHO compliance issues
- Consult with a knowledgeable instructor about your current technical problems and preparation and requirements for submission of regulatory packages (NDA, ANDA, IND, MMA and others for FDA & OECD)
- Learn a generic approach for developing an analytical method and optimizing it
- Become acquainted with practical approaches for validating new analytical procedures
- Familiarize yourself with methods development and optimization in HPLC
- Be exposed to the latest international requirements and guidelines: ICH, ISO 17025, OECD, & FDA guidelines for analytical validation
- Learn about the FDA’s new initiatives in systems-based inspection and risk-based assessment
- Understand the training and supervision requirements of chemists and technicians and other lab personnel for GLP
- Receive helpful hints to help prepare you for a visit from an auditor’s perspective
- Learn about general validation and qualification requirements for analytical instruments such as HPLC, TOC, CE, LC-MS, AA, UC/VIS, dissolution and other emerging techniques

Areas Covered:

- An overview of global compliance issues, global harmonization initiatives, role of ICH, relevance of Validation activities & the Paradigm Shift
- Quality Control and Quality Assurance in Analytical, R&D, QC, PD laboratories: General considerations, Quality Systems, QC procedures, QA oversight, Process Control Measure.
- Perspectives of ICH ISO Integration: ICH Q1 (Stability Studies), Q2 (Analytical Methods),

Q3 (Impurities), Q7 (Pharma Process), Q9 (Risk Assessment), Q10 (Quality Systems), etc.
- Measurement, Measurement Uncertainty, Measurement Resolution, Total Error, Bias
- Analytical Measurement: Process Model & Risk Assessment (REMS)
- A generic, science based outline of Methods Development & Validation [ab initio]
- Perspectives of QbD, PAT directives: online measurements vs. offline
- Validation parameters, their generic definitions and their practical applications to various methods
- Highlights of the guidelines derived from International Standards – ISO 17025, AOAC, WHO, GLP, GMP, EMEA, USP/EP/JP, etc.
- Standardization/Qualification/Verification/Validation: the implicit continuum
- A generic approach to Analytical Method Optimization during development
- Some case histories and applications for improvement of Validation characteristics
- Data integrity and statistical evaluation of analytical data: SQC, control charts
- Methods Development and Optimization in HPLC, UV-VIS including assessment of peak purity, as examples of the most recent techniques widely used in analytical laboratories
- Phase Appropriate Validation & Regulatory submissions: IND/ ANDA/ NDA/ CMC

Who will Benefit:

- Scientists
- Managers
- R&D Personnel
- Quality Assurance, Quality Control Staff and Managers
- Validation Coordinators
- Production and Packaging Personnel
- Regulatory/Compliance Managers
- Warehouse Managers
- Distribution Chain
- Qualified persons (EMEA)
- Distributors
- Supply and Purchasing Managers
- Shippers

AGENDA

DAY 01(8:30 AM - 4:30 PM)

- 8:30 AM - 8:59 AM: Registration, Meet & Greet.
- 9:00 AM - 10:30 AM:
    - Section I - Quality Systems, Paradigm Shift, Global Perspectives
    - Section II - QA/QC Validation, Laboratory Controls
        - In these sessions we will cover the general info, FDA Directives, Harmonization and CFR Clauses Requiring Methods Validation. PAT Platform, Basics of

QC/QA, MVP, REMS

- 10:30 AM - 10:45 AM: Break
- 10:45 AM - 12:15 PM:
  - Section III - Risk Assessment, Strategy & Process Model
  - Section IV - Measurement Resolution, Errors and Uncertainty
    - During these sessions we will cover Identifying and Mitigating Risks, Integration with QS.
- 12:15 PM - 1:00 PM: Lunch
- 1:00 PM - 2:30 PM:
  - Section V - Rationale of Methods Development and Validation, A Generic Approach
    - During this session we will cover the Pathway of a Generic, Sequential and Modular Approach, Goal Oriented Methods Development, Stages in Opt/Validation
- 2:30 PM - 4:00 PM:
  - Section VI - Guidelines of Method Development, Optimization and Validation Approaches.
  - Section VII - Generic Definitions: Validation Parameters
    - During this session we will cover Understanding Validation Parameters as Method CQA's, Initial Exploration: A Road Map
- 4:00 PM - 4:30 PM: Q&A Session

DAY 02(8:30 AM - 4:30 PM)

- 9:00 AM - 10:30 AM: Review of Parameters, Axioms & General Practices
  - Section VIII - Validation Guidelines: ICH, USP, Eurachem, AOAC, ISO 17025
- 10:30 AM - 10:45 AM: Break
- 10:45 AM - 12:00 Noon
  - Cont. of session VIII
  - This session will cover Guidelines from US FDA, EMEA, WHO, USP, JP etc. on Methods Validation
- 12:05 PM - 1:00 PM: Lunch
- 1:00 PM - 3:15 PM: Class Breakout Discussion - Group Exercise
  - The attendees solve assigned Analytical Development problems and come up with Validation Protocol using the concepts learned
- 3:15 PM - 4:00 PM:
  - Section IX - Regulatory & Data Requirements
  - In this section we will discuss about Examples of FDA Enforcement Actions and other Reg. concerns
- 4:00 PM - 4:30 PM: Q&A Feedback

SPEAKER

Dr. Shib Mookherjea
Validation Expert, Management Consultant at ValQual International, Inc.

Dr. Shib Mookherjea is the Principal of ValQual International, Inc. (www.valuqlaintl.com) and is a globally acclaimed Speaker and Consultant. He has extensive experience in R&D, Validation and Compliance Issues for Pharma, Biotech and Medical Device Industries; Quality Assurance, Quality Management and Quality Control in Pharma and Medical Device.

He is an SME in the areas of Methods Development and Validation of Analytical Methods, QA / Conformity Assessment in the Analytical Laboratory, as well as Analytical Development; Qualification and Validation of Laboratory Instruments and Equipment for Regulatory and QS Compliance (IQ, OQ, PQ); Laboratory (Methods, Systems, Equipment Qualification), and Drug /Devices Development. He offers Consulting / Advisory on various aspects of cGMP /GLP/ISO 13485, ISO 9001, CAPA. He also conducts various audits for GMP & GLP (FDA/OECD); ISO 17025; Pharmaceutical Development (ICH Q6, Q7A, Q8). He has conducted GLP Studies (FDA/FIFRA) and has conducted hundreds of training sessions, workshops and short courses in diversified forums (for both public and in-house companies) covering various aspects of Quality / QA / Validation for Compliance to cGMP/GLP/WHO/EMEA/ICH etc. over the last 30 plus years, both in the continental U.S. and abroad.

Over the last 20+ years, he has conducted hundreds of these Training sessions in more than 25 countries, to more than 8,000 attendees. Apart from collaborating with several training organizations including the American Chemical Society, EAS, PITTCON, CFPA, Sindusfarma (Brazil), Separation Science (UK), CII, he has been engaged over the years in Training and Advisory roles inside many Governmental Agencies and Organizations including FDA, DEA, EPA, Walter Reed etc. and both large multinational as well as small companies across the Pharma/Biotech/Medical Devices.

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