Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

A Risk Based Strategy for the Development & Validation of and Validation of Analytical Methods with a QbD Approach

Baltimore, MD

April 5th & 6th, 2018

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

Register for 10 attendees

Price: **$8,222.00** You Save: $6,728.0 (45%)*

~~$14,950.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Shib Mookherjea

Senior Director, ValQual International

Shib Mookherjea is a globally acclaimed speaker and consultant and has extensive experience in R&D, quality assurance, and quality management and teaches Methods Development, Validation Procedures, and Conformity Assessment in the Analytical Laboratory; Qualification and Validation of Laboratory Instruments and Equipment for Regulatory and QS Compliance (IQ, OQ, PQ); and the webcast Cleaning Validation and Compliance Issues for Pharma, Biotech and Medical Device Industries.

Overview :

Following the initial development, the steps further continues thru optimization and subsequently to Validation, leading to the understanding of Validation Parameters and their generic definitions. 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 leading to 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 (CGMP), 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 will be touched along with a discussion on Methods Transfer, Spec setting, QC Batch Release, Potency Assays etc.

Agenda:

Day One

Lecture 1 :

- Quality Systems, Paradigm Shift, Global Perspectives
- QA/QC Validation, Laboratory Controls

(Sections I & II)

Lecture 2 :

- Risk Assessment, Strategy & Process Model
- Measurement Resolution, Errors and

(Sections III & IV)

Lecture 3:

- Rationale of Methods Development and Validation, A Generic Approach

(Sections V)

Lecture 4:

- Guidelines of Method Development, Optimization and Validation Approaches [ab initio]
- Generic Definitions: Validation Parameters

(Sections VI & VII)

- Q&A

Why you should attend:

"For various Analytical and Test Methods, a goal oriented pathway with proper design prior to development activities will help build Quality into the Method from the inception (QbD) and Validation helps to demonstrate that the desired Method is Fit For The Purpose. A Risk based strategy is needed to Develop and apply them for their intended purpose during the entire Life Cycle of such Methods" This presentation follows a progressive, time tested structure over the duration of 2 Days with a Breakout session for 2andHalf Hours on the 2nd Day, which involves Group participation ,with real analytical problem solving and Method Development and generate an appropriate Validation schematics and the Validation Protocol.

(From ACS site) Learn the fundamentals of quality assurance, quality control, and analytical methods validation and how to improve your FDA, WHO and OECD regulatory compliance directives for analytical data submissions.

Day Two

Review of Parameters, Axioms & General Practices

Lecture 1 :

- Validation Guidelines: ICH, USP, Eurachem, AOAC, ISO 17025

(Section VIII)

Lecture 2:

- (CONT.) Validation Guidelines: ICH, USP, Eurachem, AOAC, ISO 17025

(Sections VIII)

Lecture 3:

- Class Breakout Discussion - Group Exercise

Lecture 4:

- Regulatory & Data Requirements
- Optimization and Validation in HPLC

(Sections IX & X)

Areas Covered in the Session:

- 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) in Methods Dev.
- A generic, science based outline of Methods Development & Validation [ab initio]
- Perspectives of QbD, PAT directives: online measurements /offline and the Paradigm Shift.
- Validation Parameters, their generic definitions and their practical applications.
- Highlights of the guidelines derived from International Standards - ISO 17025, AOAC, WHO, GLP, GMP, EMEA, USP/EP/JP, etc.

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Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
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What You will get

1. Learning Objectives
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Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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