

**USFDA India Seminar 2011 at Mumbai**

# **VALIDATION OF METHODS AND PROCESSES**

by **Dr. Steven S Kuwahara, Ph.D.**

On 5th, 6th and 7th December, 2011 at The Leela Kempinski at Mumbai



## **About GlobalCompliancePanel:**

GlobalCompliancePanel is an online training provider of Regulatory and Quality compliance. We deliver a broad range of high quality regulatory and compliance-related services.

At GlobalCompliancePanel, we offer extensive and high quality training for Risk Management, Regulatory Compliances, Corporate Governance and Quality Management. We have been serving our customers for the past three years, during which we have successfully completed over 350 training courses, from which more than 15,000 professionals have benefited. Many of these sessions have had over 100 participants. Over 100 well-versed Experts from various industries with several decades of collective experience are associated with us.

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**Global  
CompliancePanel**

## **Dr. Steven S Kuwahara**

Founder & Principal, GXP Biotechnology

### **About Speaker:**

Dr. Kuwahara currently heads GXP BioTechnology . He is an experienced analytical biochemist who has applied his knowledge to the quality control area of pharmaceuticals. His work has dealt with all aspects of GMP and GLP in relation to drugs and biopharmaceuticals. He has worked with small molecules, proteins, cells, gene therapy vectors and nutritional supplements.

Dr. Kuwahara has written many papers and book chapters, and serves on the editorial advisory boards of BioPharm, BioQuality, Journal of Validation Technology, and Journal of GXP Compliance. For the last of these, he also writes a column called "The GLP Forum."

He has held certifications such as CQA, CQT, and CQE from the American Society of Quality, and was certified RAC by the Regulatory Affairs Professionals Society.

### **Past Seminars**



### **Date and Venue:**

**December 5th, 6th and 7th, 2011**

**The Leela Kempinski at Mumbai  
Sahar**

**Mumbai, Maharashtra 400 059, INDIA**

**Contact number: 022 66911324**

## Seminar Content:

Conference timings: 9:00 am - 6:00 pm

### Day 1 - 26th October 2011

#### ✓ Lecture 1

- ▶ Introduction to Validation and Calibration
- ▶ Regulatory Requirements for Validation
  - Brief Description of Types of Validations
  - Cleaning Validation
  - Shipping Validation and Cold Chain Management
  - Sterility Validation
  - Test Method Validation
  - Process Validation
  - Critical Utility and Facility Validation/Qualifications
  - Equipment Qualification

#### ✓ Lecture 2: Validation Master Plans

- ▶ Validation Methodology and Documentation
- ▶ Internal Review of Validation

#### ✓ Lecture 3: Risk-Based Validation

- ▶ Roles and Responsibilities in Validation
- ▶ Risk assessment
- ▶ Validation Protocols

#### ✓ Lecture 4: Cleaning and Sterility

- ▶ Cleaning Validations
- ▶ Sterilization and sanitization validations

### Day 2 - 27th October 2011

#### ✓ Lecture 5: Equipment Qualifications

- ▶ The USP definitions and procedures.
- ▶ Analytical Instrument Qualification (AIQ)
- ▶ Part 11 and Computer Validation

#### ✓ Lecture 6: Test Method Validation, Part 1

- ▶ Definitions
- ▶ Methodology and statistics

#### ✓ Lecture 7: Test Method Validation, Part 2

- ▶ Methodology and Statistics
- ▶ Handling the different types of test methods
- ▶ Input from the Guidance on Process Validation

#### ✓ Lecture 8: Process Validation

- ▶ The guidance documents, Part 1
  - Definitions
  - Stage 1 – Process Design

### Day 3 - 28th October 2011

#### ✓ Lecture 9: Process Validation

- ▶ The guidance document, Part 2.
- ▶ Stage 2 – Process Qualification
  - Facility Design and Qualification of Equipment
  - Process Performance Qualification (PPQ)
- ▶ Stage 3 –Continued Process Verification

#### ✓ Lecture 10: Process Validation, Part 3

- ▶ Validation Reports and System Release
- ▶ Concurrent Release
- ▶ Release Under PAT

#### ✓ Lecture 11: Validation Deviation Reporting and Resolution

- ▶ Internal assessment of the validation study.
- ▶ Deviations and Consistency
  - Really?
  - Change control and validations

#### ✓ Lecture 12: Vendor Qualification Auditing

- ▶ Service Vendors
  - Distribution
  - Test Facilities
  - Other Contractors
- ▶ Raw Material and API Vendors
- ▶ General Auditing Procedures

## What you get:

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals



### Companies that will benefit:

- Small molecule drug companies
- Biologic companies
- API and generics manufacturers

## Pricing List:

1. Price for One Delegate pass – INR 20000 + 10.3% tax  
(Between November 6th to December 4th)

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2. Early bird price for one Delegate pass – INR 18000 + 10.3% tax  
(Between October 4th to November 5th)

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3. Group Delegate pass (5 & above) – 10% discount on total amount.

## Professionals who will benefit:

- End-users responsible for applications that need to be validated
- QA managers and personnel
- Validation specialists
- Engineers
- Senior Quality, Facilities and R&D Management
- Regulatory Affairs staff
- Quality System Auditors
- Operations managers
- Training departments
- R&D Directors

## How to Register:

- Step 1: Download the registration form from GlobalCompliancePanel website.
- Step 2: Fill in the requested information and fax us or email a scanned copy of the same.
- Step 3: Send us the cheque with the purchase document which comes with the registration form.
- Step 4: We will send you a confirmation letter within 1 week after we receive the check.
- Step 5: Bring the confirmation letter with you on the 1st day of the seminar and submit it at the registration counter to receive your seminar kit and join the seminar.

## Contact Information:

### Event Coordinator

Toll free: 1800 425 9409

Phone number: +91 80-3247-3694 / +91 80-3201-4957 / +91 80-3221-3341.

Email: [customersupport@globalcompliancepanel.com](mailto:customersupport@globalcompliancepanel.com)

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Kindly get in touch with us for any help or information.  
Look forward to meeting you at the seminar  
Team GlobalCompliancePanel