Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

GMP for Quality Control and Contract Laboratories

Zurich, Switzerland

November 29th & 30th, 2016

9:00 AM to 6:00 PM

Price

(Without Stay) Price: **$1,895.00**

(Seminar for One Delegate)

(With Stay) Price: **$2,295.00**

(Seminar for One Delegate)

Register for 5 attendees (With stay)

Price: **$5,853.00** You Save: $5,622.0 (49%)*

~~$11,475.00~~

ENROLL

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

Ludwig Huber

Chief Advisor -
Global FDA compliance, Labcompliance

- Chairman, presenter and panel discussion member at US-FDA Industry Training sessions and conferences
- Served as team member of PDA's task forces "21 CFR Part 11", of US-FDA internal documents, and of the GAMP® special interest group on Laboratory Systems.
- Presenter of the Year of the Institute for Validation and Technology
- Director and chief editor of www.labcompliance.com, the global on-line resource for validation and compliance issues for laboratories.

Overview :

Quality control and related contract laboratories are considered at high risk because after testing and approval, drug products and Active Pharmaceutical Ingredients (APIs) are released to the market without further check. That's the reason why the FDA and other agencies put highest emphasis on inspections of QC laboratories. Even though cGMP regulations have been in place since long time, the large number of QC related 483's and warning letters demonstrate that companies have problems with implementation.

This two day interactive in-person seminar will provide participants the regulatory background and guidelines through all critical areas of GMP compliance. This course helps attendees understand the latest requirements and also provides them templates and examples to develop inspection ready documentation.

Seminar Pricing Includes (With Stay)

- 2 Days Stay
- Pick-up and Drop Facility (Nearest Airport)
- Break-Fast and Lunch
- High Tea
- Pack of 3 Webinars will be provided which has been done in the past on similar subject

Agenda:

Day One

Lecture 1 : FDA Regulations and Requirements Overview

- FDA 21 CFR Part 211 and 21 CFR Part 11
- Most frequently cited FDA 483s and warning letters
- Requirements overview from sampling to archiving
- Quality system requirements, e.g., ICH Q10
- The concept and practice of risk based compliance

Lecture 2 : Planning for quality and cGMP compliance

- Developing and using a validation master plan
- Scope, objectives and key elements of the master plan
- Developing and using FDA compliant SOPs
- Using templates to generate inspection ready documentation
- Planning for efficiency cost-effectiveness

Lecture 3 : Calibration and Qualification of Laboratory Equipment

- FDA requirements
- USP chapter <1058> for instrument qualification
- Going through examples for qualification steps(DQ, IQ, OQ, PQ)
- SOPs and deliverables for three instrument categories
- Developing calibration and qualification protocols

Lecture 4 : Equipment Maintenance and Change control

- Preventive maintenance; tasks, documentation
- Planned and unplanned changes
- Changing hardware, firmware, documentation
- Definition and handling of like-for-like changes.
- Requalification: time and event based

Lecture 5 : Validation of Laboratory Computer Systems

- Going through the new GAMP® guide: "A Risk based Approach to Laboratory Computerized Systems"
- Going through a complete laboratory computer system validation from beginning to end
- Integration the GAMP® guide with USP <1058>
- Periodic evaluation to reduce revalidation efforts
- Revalidation: why, what, when

Lecture 6 : Validation of Analytical Methods and Procedures

- Parameters and tests according to ICH Q2
- Developing a validation plan, protocols and a report
- Setting acceptance criteria for different applications
- Verification of compendial methods according to USP <1226>
- Transfer of analytical procedures according to the new USP <1224>

Day Two

Lecture 1 : Sample Testing: Preparation, conduct, documentation

- Preparing the equipment
- Setting specifications and acceptance criteria
- Documentation of test results
- Review and approval
- Not to forget: Review of electronic audit trail

Lecture 2: Handling out of specification (OOS) test results

- Going through the FDA OOS guide
- Learning from recent FDA warning letters
- Going through an OOS checklist
- Using out of trend (OOT) data to avoid OOS results
- Documentation and follow-up: root cause, corrective action plan, preventive action plan

Lecture 3: Quality assurance of reference standards and other supplies

- Supplier qualification vs. sample testing
- Selection and assessment of suppliers
- Retesting of materials
- Preparing working standards from reference standards
- Correct labeling of chemicals

Lecture 4: Training for GMP compliance

- FDA requirements
- Identification of training needs
- Developing a training plan
- Making GMP training interesting
- Documenting effectiveness of training

Lecture 5: Ensuring Integrity of Raw Data and Other records

- FDA Part 11 and EU-PIC/S Annex 11 requirements
- Definition of Raw Data: Electronic vs. paper
- Acquisition and recording of raw data
- The importance of electronic audit trail
- Archiving of electronic records for 'ready retrieval'

Lecture 6: Internal audits in preparation for FDA inspection

- Scheduling of audits
- FDA Inspections as model for laboratory audits
- Going through a typical FDA laboratory inspection
- Responding to Typical inspectional/audit deviation
- How to avoid FDA 483s and warning letters

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
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

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

GlobalCompliancePanel