ComplianceOnline
The Largest GRC Advisory Network

2-day In-person Seminar

# GMP Compliance for Quality Control and Contract Laboratories

By: **Dr. Ludwig Huber**, Chief Advisor - Global FDA Compliance, Labcompliance

**Location:** December 5-6, 2017 | Amsterdam, Netherlands



## SPEAKER

**Dr. Ludwig Huber**, Chief Advisor - Global FDA Compliance, Labcompliance

Dr. Ludwig Huber is Director and Chief Editor of www.labcompliance.com, the global on-line resource for validation and compliance issues for laboratories. Mr. Huber is an expert for FDA and equivalent international compliance and for ISO/IEC 17025 laboratory accreditation. He is also the Chairman, presenter and panel discussion member at US-FDA industry training sessions and conferences.

He served as a 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 equipment. In addition, he was awarded as Presenter of the Year of the Institute for Validation and Technology. He is the author of the books “Validation and Qualification in Analytical Laboratories, and "Validation of Computerized Analytical and Networked Systems", Interpharm Press.

For more information, visit www.ludwig-huber.com

## LEARNING OBJECTIVES

- Learn about the regulatory background and GMP requirements for quality control and contract laboratories.
- Understand and be able to explain your company’s quality plan or laboratory compliance master plan.
- Understand the difference between GMP and non-GMP laboratories.
- Learn how to develop inspection ready documentation.
- Be able to train others in your organization on GMP requirements.
- Learn how to avoid and/or respond to the FDA inspectional observations and warning letters.

# COURSE DESCRIPTION

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.

Practical examples and interactive exercises will be dispersed into and between the presentations while 50% of the total time will be dedicated to practical sessions. During the seminar, participants will work in small groups on case studies and prepare the answers using prepared fill-in templates. After the course a large variety of tools such as SOPs, validation examples and checklists will be readily available on a dedicated website that can be used to easily implement what they have learned from the course.

# AGENDA

DAY ONE: 8:30 AM - 5:00 PM

**08:30 AM - 09:00 AM: Registration**
**9:00 AM: Session Start**

- **09.00 - 09.45: 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
- **09.45 - 10.30 (*): 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
- **10:45 - 11:00: Break**
- **11.00 - 12.00 (*): 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
- **12.00 - 12.30 (*): 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
- **12:30 - 13:30: Lunch**
- **13.30 - 15.00: 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
- **15:00 - 15:30: Break**
- **15.30 - 17.00 (*): 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>

# AGENDA

DAY TWO: 8:30 AM - 4:30 PM

- **08.30 - 09.00: 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
- **09.00 - 10.00 (*): 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
- **10:00 - 10:30: Break**
- **10.30 - 11.15 (*): 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
- **11.15 - 12.00: Training for GMP compliance**
  - FDA requirements
  - identification of training needs
  - Developing a training plan
  - Making GMP training interesting
  - Documenting effectiveness of training

**Note:** Sessions indicated with (*) include one or more workshop exercises.

- **12:00 - 13:00: Lunch**
- **13.00 - 14.30 (*): 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'
- **14:30 - 15:00: Break**
- **15:00 - 16.15 (*): 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
- **16.15 - 16.30: Wrap up – Final questions and answers**

# WHO SHOULD ATTEND

This seminar will be beneficial to the following personnel in FDA regulated laboratories:

- Analysts and lab managers
- QA managers and personnel
- Validation specialists
- Regulatory affairs
- IT professionals
- Human resources (HR) managers and staff
- Training departments
- Documentation department
- Consultants& teachers

# Registration Form

## Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-888-717-2436.
- Call Toll Free: +1-888-717-2436 (USA), 8000-3570-2845 (Middle East) or Fax your PO: 650-565-8542.
- Pay your check to (payee name) "MetricStream Inc" our parent company and Mail the check to: ComplianceOnline (MetricStream, Inc), 2479 East Bayshore Road, Suite 200, Palo Alto, CA 94303.
- Please fill this form with attendee details and payment details and fax it to 650-565-8542

### Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ Toll Free: +1-888-717-2436 (USA), 8000-3570-2845 (Middle East) or email us @ editor@complianceonline.com

### Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $300 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($300) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

**Seminar Topic:** GMP Compliance for Quality Control and Contract Laboratories

Date & Location: .....

Attendee Details:

| | Name | Title | Email |
|---|---|---|---|
| Attendee 1 | | | |
| Attendee 2 | | | |
| Attendee 3 | | | |
| Attendee 4 | | | |

*Email address (so you can receive order acknowledgements, updated news, product information and special offers)*

### Company Information

Organization .....

.....

Address .....

.....

City .....

State ..... Zip.....

Country .....

Phone ..... Fax .....

### Payment Options

☐ Check enclosed, payable in U.S. funds to ComplianceOnline (MetricStream, Inc.)

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

Total amount $ .....

Signature .....
*(Signature required on credit card and bill-me orders.)*

Print name.....

☐ Bill me/my company $ .....

Purchase order # .....
*(Payment is required by the date of the conference.)*

*Please fill this form with attendee details and payment details and fax it to 650-565-8542*

ComplianceOnline
The Largest GRC Advisory Network

www.complianceonline.com
2479 East Bayshore Road, Suite 200, Palo Alto, CA 94303
Ph: +1-888-717-2436 | Fax: 650-565-8542