Best Compliance Practice in a GMP Regulated Testing Laboratory

Overview

This course provides detailed understanding regarding the implementation of respective cGMP requirements in a state-of-the-art quality control laboratory in a pharmaceutical company. The course does not just provide an overview about the most important cGMP regulations (OOS management, sample management, method validation, training, documentation, data management). In extensive workshops those regulations are further explained and extensively discussed within the group and solutions for the implementation are developed. Those results are further discussed with the trainers and with all attendees. This approach will not only provide the respective knowledge but also the ability to implement those solutions in the laboratory of the attendees.

Who Should Attend

The course should be attended by operators and supervisors in quality control laboratories of the pharmaceutical industry which are faced with the challenge to implement those, sometimes complex cGMP regulations into their daily business in an efficient and effective manner.

- Laboratory personal
- Head of quality control laboratories
- Supervisors
- Quality Assurance personal focusing on quality control topics, for example quality-on-the-floor personal

Learning Objectives

- Understanding how the most important cGMP requirements can be implemented in the quality control laboratory
- Development of approaches regarding the implementation of cGMP compliance within the quality control laboratory considering German and international regulations
- Competence regarding the implementation of data integrity compliance in the quality control laboratory, for example “audit trail review”.
- Self-contained management of OOS-results
- Development of sampling protocols using statistical tools
- Implementation of training programs in quality control laboratories

Faculty

Dirk Feldmann, *PhD, Head of Quality Operations, QP, Bausch & Lomb, Berlin*

Dirk Feldmann studied Pharmacy at the FU Berlin and finished his PhD thesis in Food Chemistry at the TU Berlin. In 1996 he became the laboratory head of several analytical laboratories of the German military forces in Berlin. Since 2006, he has held various positions at Bausch & Lomb, Berlin (Head of laboratory for bulk, finished goods and stability control and deputy head of QC, Head of Quality Assurance, Qualified Person, Head of Manufacturing). Currently Dirk Feldmann holds the position of Head of Quality Operations/Batch Release and QP at Bausch & Lomb, Berlin. Furthermore, between 2010 and 2012 he held the position of a pharmacist at Saint Luke Foundation / Kilimanjaro School of Pharmacy in Moshi, Tanzania as part of his work in an international development aid project.

Klaus von Jan, *PhD, CRS Compliance & Regulatory Services*

After his studies of chemistry at the TU Stuttgart and his PhD in Organic Chemistry about the synthesis and characterization of the structure of Oligonucleotides, Klaus von Jan joined Millipore BioSyntech GmbH, Hamburg, as Head of Quality Control and Quality Assurance in 1988. In 1995 he joined Chiron Vaccines Germany in Marburg as Director Quality Assurance Bulk Manufacturing Germany. Since 2006, Klaus von Jan is an independent consultant in the pharmaceutical industry focusing on aseptic manufacturing, vaccines and biologics, quality control, computer system validation, data management, FDA inspections and interims management. He has been the co-founder of Compliance Systems GmbH in 2006 as well as co-founder and co-owner of the Swiss-based pmc-support GmbH.

Thursday, 28 June 2018 — 9:00 – 17:00

9:00 **Welcome & Introduction**

9:45 **cGMP-Requirements in the Quality Control Laboratory - A Short Overview**

- OOS-management, aborted tests
- Method Validation / Method Verification
- Sample Management
- Sampling
- Data Management
- Documentation
- Training

10:45 **Coffee Break**

11:15 **Case Study 1 / Workshop: OOS-Management, Practical Example**

- Case explanation
- Expectation of the teamwork
- Presentation of results
- Best Practice discussion

12:30 **Lunch Break**

13:30 **The QP in the Quality Control Laboratory**

- Typical issues / failures in the daily business
- Failure during sampling
- Development of sampling protocols
- Statistical tools for determination of sample size

15:00 **Coffee Break**

15:30 **Case Study 2 / Workshop:**

- Development of a sampling protocol and determination of the sample size based on the presented methods
- Presentation of results and Best Practice discussion

17:00 **End of Day 1**

Friday, 29 June 2018 — 9:00 – 16:30

09:00 **Recap Day 1, Open Questions**

9:30 **Introduction to Data Management**

- 21 CFR Part 11, Annex 11
- Expectations of authorities (MHRA, FDA)
- Data integrity
- Batch related audit trail review
- Documentation and data security

10:45 **Coffee Break**

11:30 **Case Study 3 / Workshop**

- Management of an FDA 483 observation regarding data integrity
- Implementation and documentation of a batch related audit trail review
- Presentation of results and Best Practice discussion

12:30 **Lunch Break**

13:30 **Case Study 4 / Workshop**

- Method Validation / Method Specification
- Development of an activity protocol for the relocation of a sterility laboratory
- Presentation of results and Best Practice discussion

14:30 **Coffee Break**

15:00 **Case Study 5 / Workshop: Development of a Training Program for a Quality Control Laboratory**

- How can you organize a wide range of trainings in an efficient and effective manner
- Success controls
- Development of a training program

16:00 **Summary, Open Questions, Feedback**

16:30 **End of Training Course**