The GMP Compliance Manager

04/05 November 2020 | Barcelona, Spain

Highlights

- Current Regulatory Requirements and Expectations
- Compliance Strategies
- Deviations and CAPA
- Data Integrity
- Documentation Systems, Review and Approval
- Risk Analysis
- Monitoring
- Quality Review

With 3 Workshops:
- Deviations and CAPA
- Quality Metrics and KPIs
- Risk-based Supplier Qualification
Objectives

During this Course you will learn how the various pharmaceutical quality and documentation systems work and how they interact. Experts from the pharmaceutical industry will show you possibilities to improve your systems and how to run them efficiently and in compliance with (c)GMP.

Background

Pharmaceutical Quality Assurance and GMP Compliance Managers are continuously facing new challenges due to changing regulatory requirements and at the same time increasing needs for efficiency.

In this context, QA and GMP-Compliance Managers must be familiar with many GMP-related aspects and systems like:
- Non-Conformance Management
- Quality Risk Management
- Document and Data Governance
- Monitoring and Quality Reports

And these are not stand alone systems. They are all linked to each other: A Deviation causes a Failure Investigation which is followed by a CAPA that can lead to a Change and Change Control. All relevant information must be documented in Quality Reviews and Risk Management is the key to almost everything. And everything should be documented and data handled in an integer way.

Companies should have all these systems in place. Let’s find out how we can get the most out of them!

Target Audience

This Course is designed for all persons in pharmaceutical, biopharmaceutical and API industry’s production and quality units who establish, manage and improve quality and documentation systems.

Moderator

Wolfgang Schmitt
CONCEPT Heidelberg (on behalf of ECA)

Programme

Current Regulatory Developments and their Impact on the Quality Management System: Challenges and Opportunities
- New and relevant EU GMP requirements for the Quality Management System
- ICH Q8, Q9 and Q10 – approach and implementation

Deviation - Investigation – CAPA
- GMP requirements and expectations
- Deviation management: best industry practice
- Performing Failure Investigation
- Elements of investigations
- CAPA-System and elements
- Success factors for an integrated system
- Industry approaches for CAPA systems

Risk Analysis and Management
- The Principles of Risk Analysis
- A detailed look at FMEA and HACCP
- How to apply ICH Q9 "Quality Risk Management"
- Process improvement with Risk Analysis

Data Integrity
- What’s it all about (where does the hype come from)
- What you need to know about it
- What are inspectors looking for?

Compliance Strategy und Compliance Project Management
- Setting up a strategy for compliance management
- Quality oversight
- Business case study

Documentation Systems as a Foundation
- Regulatory requirements
- Document change management: Maintaining compliance
- Records retention
- Archiving
- How to keep track of raw data/GMP relevant documentation
- Language: local language vs. English; quality of translation
- Issue/training/effective date vs. new document version
How to control the Flow of Documents

- Review and approval of Documents
- Batch Record Review process
- GMP process and data flow
- Documentation vs. Data integrity issues

Product Quality Review and Annual Product Review as Quality Enhancement Tools

- Best practices in combining the two reviews
- Statistical background and trending
- Timing of PQRs
- Responsibilities: who is responsible for generation of particular parts of the report, analysis and final conclusion
- Site specific versus product specific PQR
- Challenges and recommendations to overcome challenges
- Examples and case studies

Case Study: How to monitor Suppliers

- Key Quality and Performance Indicators
- Reporting and Monitoring (trend analysis and targets)
- Who is involved – who is responsible?
- Outlook: the FDA Guidance on Quality Metrics

3 parallel Workshops:

1. Deviations - Failure Investigation - CAPA
2. Quality Metrics and KPIs: from Data Collection to Continuous Improvement
3. Risk Management in Supplier Qualification: How to reduce the effort of qualification without losing control and become non-compliant

You will be able to attend 2 of these workshops. Please choose the ones you like to attend when you register.

Speakers

Ingo Ebeling
Abbott Laboratories
Ingo Ebeling is Head of MST (Technology Center) and Engineering.

Melanie Kinzner
Sandoz International GmbH
Melanie Kinzner is Manager Global QA Development. Before that she was Compliance Expert at Sanofi.

Dr Ulrich Kissel
European QP Association
Ulrich Kissel is Qualified Person and Chairman of the Board of Directors of the European Qualified Person Association (EQPA). Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Katja Kotter
Vetter Pharma-Fertigung GmbH & Co. KG
Katja Kotter is Vice President Regulatory Affairs/ Quality Compliance.

Sue Mann
Sue Mann Consultancy, U.K.
Sue Mann is a consultant and has more than 35 years experience in the Pharmaceutical Industry, mainly in Quality Assurance, Clinical Trials supply and production support. In her last position, Sue was Vice President of International Quality Assurance at Shire Pharmaceuticals.

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.
General terms and conditions

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1. We are happy to welcome a substitute colleague at any time.
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