



Speakers



Dr Rainer Gnibl
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Aidan Madden
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Dr Gerald Kindermann
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Dr Ágnes Kis
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Complaint Handling and Recall Management

17/18 November 2020 | Heidelberg, Germany



How to implement EU-GMP Chapter 8 and FDA Requirements

Highlights

- Regulatory requirements
- Complaint Handling
 - Management
 - Documentation
 - Failure Investigation
- Quality Risk Management
 - Background
 - Implementation
 - Case Study
- GMP-GVP interface: the role of the QP and QPPV
- Recall
 - Management
 - Mock-Recalls
 - Decision Making Process

**Facing the GMP- GVP interface:
the role of the QP and the QPPV**

Objective

During this course, you will learn all relevant aspects to efficiently organise and improve your Complaint Handling and Recall System to **fulfil current GMP requirements and to get the best benefit for your daily business.**

Background

In principle, every complaint might cause a recall, and every complaint may provide an opportunity to improve.

According to the **EU-GMP Guide Chapter 8**, the pharmaceutical industry **must review all complaints** and other information concerning potentially defective products carefully according to written procedures. In order to provide for all contingencies, a system should be designed to investigate the need to **recall, if necessary, promptly and effectively products** known or suspected to be adulterated from the market-place.

According to the EU- GMP Guide, a person should be designated responsible for handling the complaints and deciding the measures to be taken. The **Qualified Person (QP)** should be made aware of any complaint, and be actively involved in the investigation and any subsequent recall.

The handling of technical complaints (also called non-medical complaints) triggers high demands on the process organisation and quality system. However, these complaints are also a chance for **continuous improvement** and to prevent the reoccurrence of future failures.

Reviewing **FDA's Warning Letters** of the last fiscal years reveals that Complaint Handling processes are a hot topic. Recent media coverage of recalls due to non-GMP operations and counterfeit products entering the supply chain are also an indication of how important it is to treat all complaints with the highest priority. The main failures can be found in the overall process and in inadequate investigations, as the following excerpts show:

- "Your firm failed to follow procedures for the handling of all written and oral complaints"
- "The inadequacy of your firm's quality oversight is demonstrated by the failure to perform thorough investigations of product failures and complaints."
- "The QCU failed to ensure customer complaints were adequately investigated"
- "Your firm failed to review and approve complaints"

Target Audience

This course is designed for all personnel involved in complaint handling and/ or recall activities at their company and all responsible persons like the Qualified Person / the Qualified Person for Pharmacovigilance (QPPV) and decision makers who want to improve the existing process.

Programme

Regulatory Requirements for Complaint Handling and Recalls - The Inspector's View

- EU Legislation on Complaints, Recalls & Falsification
- Real Intension of Complaint Handling
- Definition and Classification of Quality Defects
- Rapid Alert System - RAS
- What a Complaint Handling SOP should consider
- What a Recall SOP should consider

Complaint Handling Session

How to handle complaints - complaint management process

- Regulations
- How to organize the process
- The complaint sample and sample chain custody
- Pitfalls

How to handle complaints - complaint management quality system

- KPIs
- Reporting and trend evaluation
- Technical complaints versus safety signals
- The role of the QP and QPPV
- Counterfeits

A practical view:

Share experience - access to the root cause

Quality Risk Management Session

The Basics of Quality Risk Management

- Definitions and abbreviations
- Fundamentals
- Regulatory requirements and expectations
- Areas of application
- Construction of a QRM matrix

Implementation of a Quality Risk Management System in Complaint Handling

How to use real data from global issues to determine process understanding and customer satisfaction and to set priorities.



Workshop on Case Studies:
Quality Risk Management in Complaint Handling and Recall Procedures

Recall Session

The Handling of Recalls

- Implementation in the system
- The recall process
- Flow of information
- Documentation

How to perform a Mock Recall

Both FDA and EU GMPs call for regular evaluations of the effectiveness of the recall processes. This session will show you, how such an effectiveness check could be performed.

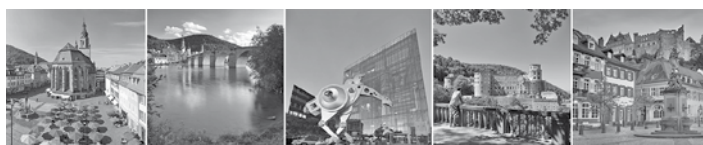


Workshop: When to recall or not to recall – apply root cause analysis

The participants will work through a single hypothetical scenario. Working in small groups the participants will need to decide what action to take, what information is needed, who should be involved, and ultimately decide if a recall is required and if so to what level.

Social Event

At the end 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.



Participants' comments



„Good mixture between lecture and workshops.“
Margit Watervall, CSL Behring, Switzerland (May 2016)

“Excellent conference – I would like to see a „Level 2“ on the same subject e.g. “Level 2 advanced”.
Jill Fern, Théa PHARMA S.A., Switzerland (June 2017)

Speakers



Dr Rainer Gnibl
GMP Inspector for EMA and
local Government, Germany

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP-inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.



Aidan Madden
FivePharma, Ireland

Aidan Madden is Managing Directive and Senior Consultant with FivePharma. Before that he was Quality Manager at Wyeth, Senior Microbiologist at Baxter and QC Manager at Fort Dodge Laboratories. He was also working at Teagasc, a government research laboratory and at the National University of Ireland in Galway.



Dr Gerald Kindermann
Formerly F. Hoffmann-La Roche,
Switzerland

Dr Gerald Kindermann was Product Quality Manager at the Global Quality Group at Roche working on quality systems. Before that he was Group Leader Quality Control and Quality Manager for the Supply Center. Since 2019 he is working as Senior Pharma Consultant at AGIDENS AG in Switzerland.



Dr Ágnes Kis
Compliance Consultant, formerly
F. Hoffmann La-Roche, Switzerland

Before starting working as a consultant in July 2018, Ágnes Kis was Global Complaint Lead Investigator and Global GMP Compliance Auditor at Roche. In a similar role, she was with Novartis Vaccines and Diagnostics. Before her industrial career, Ágnes Kis was Senior GMP/GDP Inspector for the Hungarian National Institute of Pharmacy and Nutrition (OGYÉI) and expert member in various working groups at EMA, PIC/S and the European Commission.



Dr Ulrich Kissel
European QP Association,
KisselPharmaConsulting, Germany

Ulrich Kissel is Qualified Person and Member of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

Complaint Handling and Recall Management, 17/18 November 2020, Heidelberg, Germany

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

CONCEPT HEIDELBERG
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Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

City

ZIP Code

Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions

If you cannot attend the conference you have two options:

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

2. If you have to cancel entirely we must charge the following processing fees:

- Cancellation until 2 weeks prior to the conference 10 %

- Cancellation until 1 week prior to the conference 50 %

- Cancellation within 1 week prior to the conference 100 %

CONCEPT HEIDELBERG reserves the right to change the materials, instructors,

or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible

and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be re-

sponsible for discount, airfare penalties or other costs incurred due to a cancel-

lation.

Terms of payment: Payable without deductions within 10 days after receipt of

invoice.

Important: This is a binding registration and above fees are due in case of can-

cellation or non-appearance. If you cannot take part, you have to inform us in

writing. The cancellation fee will then be calculated according to the point of

time at which we receive your message.

In case you do not appear at the event without having informed us, you will have

to pay the full registration fee, even if you have not made the payment yet. Only

after we have received your payment, you are entitled to participate in the con-

ference (receipt of payment will not be confirmed). (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Tuesday, 17 November 2020, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)

Wednesday, 18 November 2020, 9.00 – 15.00 h

Venue

Qube Hotel Bahnhof

Grüne Meile 21

69115 Heidelberg, Germany

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Email bahnstadt@qube-heidelberg.de

Fees (per delegate, plus VAT)

ECA Members € 1,590

APIC Members € 1,690

Non-ECA Members € 1,790

EU GMP Inspectorates € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference language

The official conference language will be English.

Certificate of Participation

Shortly after the event, you will receive your certificate of participation by email.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG

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For questions regarding reservation, hotel, organisation etc. please contact:

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