ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers

Emerich Grassinger
Takeda, Austria

Dr Gerald Kindermann
GxP Consulting, Switzerland

Dr Michael Möhlen
Valneva Austria, Austria

Dr Bernd Renger
Bernd Renger Consulting, Germany

Prof Dr Martin Wesch
Wesch & Buchenroth, Law Office, Germany

Reduced Sampling / Reduced Testing

17/18 October 2023 | Heidelberg, Germany

Highlights

- Regulatory Requirements for Sampling
- Design and Qualification of Sampling Areas
- Supplier Qualification as an Important Prerequisite for Reduced Sampling/Reduced Testing:
  - Supplier Audits
  - Quality Agreements
  - Specifications/Monographs/Supplier CoA
- How to Define and Optimise Sampling and Testing Procedures for
  - APIs
  - Excipients
  - Primary Packaging Materials
  - Secondary Packaging Materials
- Options for Reduced Sampling
- Options for Reduced Testing
- How to Deal with Multicompendial Testing?

cGMP-compliant Sampling and Testing of Starting and Packaging Materials – how to meet EU and FDA Requirements and safe Costs in QA/QC

Programme

Objective

The aim of this course is to demonstrate the process of the qualification of starting materials (APIs and excipients) and packaging materials (primary and secondary) and to define the prerequisites for implementing a system for reduced sampling and reduced testing for these products. This system has to be in compliance with the actual GMP requirements in Europe and in the US, though. Case studies will show how to define and optimise sampling and testing procedures and you will discuss further details in a parallel session with 3 workshops.

Background

Testing active pharmaceutical ingredients, excipients and packaging materials is one of the main tasks of the quality control units in the pharmaceutical industry. It must be ensured that the necessary tests are conducted on the incoming goods and that the materials are released only after their quality was judged as satisfactory.

According to Chapter 5 – Production – of the EU GMP Guide, the selection, qualification, approval and maintenance of suppliers has to be documented and the level of control has to be proportionate to the potential risks posed by the individual materials. Manufacturers of medicinal products are responsible for testing the starting and packaging materials as described in the marketing authorisation dossier. However, it is explicitly accepted to outsource these testing activities, if the following requirements are fulfilled:

a. Distribution controls (transport, wholesaling, storage and delivery) to ensure the maintenance of the quality characteristics of the starting materials
b. Audits performed at appropriate intervals at the sites carrying out the testing
c. A certificate of analysis signed by a designated person with appropriate qualifications and experience
d. Significant experience in dealing with the starting material manufacturer ("history of compliance")
e. Full analyses that are performed regularly by the medicinal product manufacturer or a contract laboratory acting on behalf of the manufacturer to compare the results with the supplier's certificate of analysis.

It is the aim of this GMP Education Course to show how these requirements can be put into practice.

Other focus areas of this course are the regulatory requirements for sampling, the design and qualification of sampling areas and the handling of varying specifications in the different pharmacopoeias for identical APIs and excipients used for finished drug products dedicated for the markets in Europe, in the US, and in Japan. Must different tests be conducted according to EP, USP, and JP, respectively?

The course programme will be completed by a lawyer's presentation about the legal and contractual liability of suppliers for defect products.

Target Audience

This GMP Education Course is directed at all those employees from quality control units in the pharmaceutical industry (including heads of quality control and laboratory managers) who are competent or responsible for sampling, testing and release of starting materials (APIs and excipients) and packaging materials (primary and secondary). This course is also of interest to personnel from quality assurance and to those employees from API, excipient or packaging material suppliers who want to inform themselves about the requirements of the pharmaceutical industry on the testing of these materials.

Programme

Regulatory Requirements for Sampling Procedures

- API and finished goods sampling
- Regulatory requirements
  - EU GMP Part 1, Chapters 4, 5, 6
  - EU GMP Part 2, Chapter 7
  - EU GMP Chapter 4
  - EU GMP Annex 8
  - EU GMP Annex 19
- Other regulations
  - US/FDA Requirements
  - WHO - PIC/S - ISO 2859-1 (former Military Standard)
- Supplier qualification and audits
  - Reduced testing

Design and Qualification of Sampling Areas for Incoming Goods Products

- Sampling area for raw materials, APIs and excipients
- Layout and design of premises and equipment
- "Cleanroom"-like classification?
- What are the appropriate environmental requirements for sampling areas?
- How to qualify and maintain sampling areas?
- Is a change of pallets/removal of cart boxes required?
- Are expectations increasing? - Lessons learned during inspections

Supplier Qualification and Supply Chain Traceability: an important Prerequisite for Reduced Sampling and Reduced Testing

- Prerequisites
- Qualification of packaging materials
- Qualification of APIs and excipients
- Supplier qualification/Supplier audits
- Quality Agreements
- Specifications/Pharmacopoeial monographs/Supplier CoA
- Complaint Handling

Social Event

On 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.

Sampling and Documentation to make the Supplier liable for Defect Products

- Legal and Contractual Liability
- Definition of a Product Defect
- Express Warranty
- Admissible Evidence
- Insurability

Case Study I: How to Define Inspection Procedures for Packaging Materials (Primary and Secondary) in the Incoming Goods Control

- Sampling Plans for printed packaging materials, glass containers, plastic containers, etc.
- AQL (Acceptable Quality Level)
- Tests required according to Ph.Eur./USP
- Options for reduced sampling
- Options for reduced testing
- Skip lot testing

Case Study II: How to Define and Optimise Sampling and Testing Procedures for APIs and Excipients in the Incoming Goods Control

- Sampling of APIs and excipients
- Risk assessment and rational for different sampling plans and sampling procedures
- Options for reduced ID testing
- Options for reducing analytical costs (economic order size and accepting CoA from suppliers)
- Optimization of ID testing using NIR/RAMAN

Parallel Sessions: Working on specific Tasks

1. Strategies/Prerequisites for Reduced Testing/Reduced Sampling

The aim of this workshop is to evaluate in small discussion groups how the opportunities and requirements of EU GMP Chapter 5, Annex 8 and 21 CFR Parts 211 should be implemented in QA / QC.

2. Reduced Testing/Reduced Sampling for APIs/Excipients

Participants will discuss and calculate benefits of different measures in small groups. Scenarios of different materials/suppliers/qualification status, use of NIR/RAMAN for identity testing and optimization of the order size to reduce testing effort will be evaluated including their impact on the sampling and testing plans for APIs and excipients.

3. Reduced Testing/Reduced Sampling for Primary and Secondary Packaging Materials

Participants will discuss in small groups scenarios of different materials/suppliers/qualification status/etc. and their impact on the sampling and testing plans with regard to reduced sampling and reduced testing for packaging.

How to Deal with Divergent Compendial Method Requirements

- ICH QB4 and the Pharmacopoeial Discussion Group
- Divergent and conflicting pharmacopoeial requirements
- CDER's MAPP 5310.7 "Acceptability of Standards from Alternative Compendia"
- How to proceed in case of missing harmonization?
- How to proof equivalence?

Speakers

Emerich Grassinger
Takeda, Vienna, Austria

Emerich Grassinger headed several labs within Boehringer Ingelheim where he also led several improvement projects throughout the supply chain involving the raw material releasing process. Thereafter he joined Haupt Pharma Wuelfing, where he was responsible for Quality Control, including the raw material laboratory and the sampling of incoming goods. Since 2019 he is head of Quality Control at Takeda in Vienna, Austria.

Dr Gerald Kindermann
GxP Consulting, Switzerland

Dr 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. He worked as a Senior Pharma Consultant at AGIDENS AG and Capgemini Engineering, Switzerland. In May 2023, he joined GxP Consulting, in Basel, Switzerland as a Senior Consultant in the GMP area.

Dr Michael Möhlen
Valneva Austria GmbH, Vienna, Austria

Dr Möhlen is the Head of Technical Operations at Valneva Austria GmbH in Vienna and responsible for industrialisation of Vaccine candidates. This includes oversight as well to Quality Control and Clinical Serology. Until 2009 Dr Möhlen held various management positions in the Quality Control arena with Chiron and later Novartis Vaccines, including responsibility for raw material sampling and testing.

Dr Bernd Renger
Bernd Renger Consulting, Germany

Dr Bernd Renger was a member of the European Compliance Academy (ECA) Advisory Board and Immediate Past Chair of the European QP Association. Since 2011 he is running his own consultancy business. Before that he was VP of Quality Control at Vetter Pharma-Fertigung. He started his career 1977 at Hoechst AG as a research and development chemist. Since then, he has held several quality management positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna.

Prof Dr Martin Wesch,
Wesch & Buchenroth, Law Office,
Stuttgart, Germany

Prof Dr Martin Wesch is a lawyer specialised in medical and industrial law and working for the Stuttgart-based firm of lawyers Wesch & Buchenroth, which he founded in 2001. Since April 2002, he has been teaching industrial law at the University of Stuttgart. He is author of several publications, both in journals and books, to legal demands on quality assurance in manufacturing pharmaceuticals.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Reduced Sampling / Reduced Testing | 17/18 October 2023, Heidelberg, Germany

Please choose TWO parallel sessions:

☐ *Strategies/Prerequisites for Reduced Testing /Reduced Sampling*
☐ *Reduced Testing / Reduced Sampling for APIs / Excipients*
☐ *Reduced Testing / Reduced Sampling for Primary and Secondary Packaging Materials*

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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 cancellation 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 conference (receipt of payment will not be confirmed)! (As of July 2022).
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 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 October 2023, 09.00 - 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 18 October 2023, 08.30 - 15.30 h

Venue
Heidelberg Marriott Hotel
Vangerowstr. 16 | 69115 Heidelberg
Phone:.+49 6221 908 0
E-mail: info.heidelberg@marriott.com

Fees (per delegate, plus VAT)
ECA Members EUR 1,690
APIC Members EUR 1,790
Non-ECA Members EUR 1,890
EU GMP Inspectorates EUR 945
The course 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.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

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

CONCEPT HEIDELBERG
P.O.Box 10 17 64 | 69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0 | Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Markus Funk (Operations Director) at
+49(0)62 21/84 44 40, or at
funk@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc. please contact:
Mr Rouwen Schopka (Organisation Manager) at
+49(0)62 21/84 44 13, or at
schopka@concept-heidelberg.de