ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers

Emerich Grassinger
Takeda, Austria

Dr Gerald Kindermann
AGIDENS, Switzerland

Dr Michael Möhlen
Valneva Austria, Austria

Dr Bernd Renger
Bernd Renger Consulting, Germany

Dr Martin Wesch
Wesch & Buchenroth, Law Office, Germany

Reduced Sampling / Reduced Testing

Live Online Training on 17/18 June 2021

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

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?

Q&A session after each presentation

Objective

The aim of this Live Online Training 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. You will also discuss further details and get to know practical approaches. Q&A sessions after each presentation ensure interaction and that your questions are answered.

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 the revised Chapter 5 – Production – of the EU GMP Guide in operation since March 2015, 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.

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

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

Practical Approaches

1. Strategies/Prerequisites for Reduced Testing /Reduced Sampling

Learn 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

Discuss and calculate benefits of different measures. 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

Get to know 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
AGIDENS AG, 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. Since August 2019 he works as a Senior Pharma Consultant at AGIDENS AG in Switzerland.

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 has held several quality management positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna.

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

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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Reservation Form (Please complete in full)

Reduced Sampling / Reduced Testing
Live Online Training on 17/18 June 2021

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:
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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 of the Live Online Training

Thursday, 17 June 2021, 09.00 – 17.45 h
Friday, 18 June 2021, 08.30 – 15.30 h
All times mentioned are CEST.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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.

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 will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

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

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