

Reduced Sampling / Reduced Testing

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

SPEAKERS:



Emerich Grassinger
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*F. Hoffmann-La Roche,
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Dr Michael Möhlen
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Dr Bernd Renger
*Bernd Renger Consulting,
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Dr Martin Wesch
*Wesch & Buchenroth,
Law Office, Germany*



25-26 February 2019, Budapest, Hungary

LEARNING GOALS:

- 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 Multicompound Testing?



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Objectives

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 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.

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 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 rationale 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 Part 211 should be implemented in QA / QC.

Moderator: Dr Bernd Renger

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.

Moderator: Emerich Grassinger

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.

Moderator: Dr Gerald Kindermann

You will be able to attend 2 of these parallel sessions. Please choose the ones you would like to attend when you register for this Course.

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 prove equivalence?

Speakers



Emerich Grassinger

Aenova Group - Haupt Pharma Wülfig GmbH, Germany

Emerich Grassinger works since 1995 in various positions for the pharmaceutical industry. 2002-2010 he headed several labs within Boehringer Ingelheim and was

there also responsible for the Raw Material laboratory in which the testing and release of the APIs and Excipients was carried out. He led several improvement projects throughout the supply chain involving the raw material releasing process. In 2010, he joined Haupt Pharma Wülfig, where he is responsible for Quality Control and implements various Lean Lab instruments within the Aenova Group.



Dr Matthias Heuermann

NRW Centre for Health (LZG.NRW), Münster, Germany

Since 2004 Dr Heuermann is employed as head of the Official Medicines Control Laboratory (OMCL), today within the NRW Centre for Health of the federal state

North Rhine-Westphalia. He studied pharmacy and gained his PhD thesis at the University of Münster, Germany. Since 1995 Dr Heuermann is involved in national and international GMP inspections with a focus on QC laboratories and QA systems.



Dr Gerald Kindermann

F. Hoffmann-La Roche, Basel, Switzerland

Dr Gerald Kindermann is 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.



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 in 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.



Dr Martin Wesch

Wesch & Buchenroth, Law Office, 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. In 2007 he received the Wallhaeusser Prize for publications in that field from Concept Heidelberg.

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.



Easy Registration



Reservation Form:
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P.O. Box 10 17 64
69007 Heidelberg, Germany



Reservation Form:
+ 49 6221 84 44 34



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info@concept-heidelberg.de



Internet:
www.gmp-compliance.org

Date

Monday 25 February 2019, 09.00 - 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Tuesday, 26 February 2019, 08.30 - 15.30 h

Venue

Hilton Budapest City
Váci út 1-3.
1062 Budapest, Hungary
Phone +36 1 288 5500
Email info.budapest-city@hilton.com

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845

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.

Would you like to save money?

If you register for ECA's Education Course "Analytical Instrument Qualification" from 27 February to 1 March 2019 at the same time, you will receive a 350 € discount. This is not valid for EU GMP Inspectorates.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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.

Organisation and Contact

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

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For questions regarding content please contact:
Dr Günter Brendelberger (Operations Director) at
phone +49-62 21 / 84 44 40, or by e-mail at
brendelberger@concept-heidelberg.de.

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

ECA Course

Analytical Instrument Qualification

27 February - 1 March 2019, Budapest, Hungary

From 27 February to 1 March 2019, i.e. on Wednesday to Friday of the same week, the ECA Education Course Analytical Instrument Qualification will take place in the same hotel in Budapest. Topics to be covered will include:

- Regulatory Aspects of Instrument Qualification and USP <1058>
- Calibration Management
- Risk Assessment in Analytical Laboratories
- Qualification of GC Instruments
- Qualification of RAMAN, NIR, and FT-IR
- Balances and Weighing Processes
- Volumetric Apparatus
- Computer Validation
- HPLC / Chromatography Data Systems
- Validation of Excel Spreadsheets
- Data Integrity Challenges in Calibration and Qualification

Interactive Workshops will also be part of this course. Further information about this Education Course can be received at www.gmp-compliance.org.

Register simultaneously for both courses and receive a 350 € discount (not valid for EU GMP Inspectorates).

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.
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- until 2 weeks prior to the conference 10 %
- until 1 week prior to the conference 50 %
- 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 responsible for discount airfare penalties or other costs incurred due to a cancellation.
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.

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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 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.

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Reservation Form (Please complete in full)

- ☐ **Reduced Sampling / Reduced Testing**
25-26 February 2019, Budapest, Hungary
- ☐ **Analytical Instrument Qualification**
27 February - 1 March 2019, Budapest, Hungary

☐ Mr ☐ Ms

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

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