20 YEARS ECA Academy Your GMP/GDP Information Source

# Quality Control of Starting Materials

## (APIs and Excipients)

Actual Challenges :
- Risk Assessment for Representative Sampling
- New Requirements for Excipients

SPEAKERS:

Emerich Grassinger
*Shire*

Armin Groh
*CSL Behring*

Dr Reto Theiß
*Merck*

Dr Thomas Storm
*Novartis Pharma*

Testing and Sampling of Incoming Active Pharmaceutical Ingredients (APIs) and Excipients

7 - 8 February 2019, Copenhagen, Denmark

PROGRAMME:

- Regulatory Requirements for APIs and Excipients
- Current GMP Requirements for APIs, Excipients and Drug Products
- Laboratory Organisation
- Pharmacopoeias
- Sampling of Incoming APIs and Excipients
- Reduced Testing of Supplied APIs and Excipients
- Analytical Methods
- NIR (Near InfraRed Spectroscopy) for an Efficient Control of Starting Materials

This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager“.
Please find details at www.gmp-certification.eu

# Quality Control of Starting Materials (APIs and Excipients)

7 - 8 February 2019, Copenhagen, Denmark

## Objectives

Testing active pharmaceutical ingredients and excipients 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 starting materials are released only after their quality was judged as satisfactory. This GMP Education Course about the incoming goods control of APIs and excipients will give you a comprehensive overview of the specific tasks and questions of the „starting materials lab" and show you real-life solutions and answers.

This course will deal among others with the following questions:

- Who is responsible for the release or rejection of starting materials?
- How can the incoming goods lab be organised efficiently?
- Which SOPs are necessary?
- In which cases can test results be taken over from the supplier's certificate of analysis?
- Do all test items of a pharmacopoeial monograph have to be analysed?
- Are the pharmacopoeial monographs similar, or must different tests be conducted for Ph.Eur., USP and JP?
- Can a pharmacopoeial test method be replaced by an alternative test method? Does this require a variation application?
- How can the EU Guideline 2015/C 95/02 on risk assessment for excipients be implemented?

It is the aim of this GMP Education Course to give answers to these and many other important questions relating to the testing of APIs and excipients and to serve as a forum for an intensive experience exchange.

## Target Group

This 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 the starting materials used (= APIs and excipients).

This course is also of interest to personnel from quality assurance and to those employees from API and excipient manufacturers who want to inform themselves about the requirements of the pharmaceutical industry on the testing of these starting materials.

## Programme

### Regulatory Requirements for APIs and Excipients

- Definition of APIs and excipients
- EU Requirements
- FDA Requirements, e.g. FDA Draft Guidance "Drug Product"
- Common Technical Document (CTD)
- Certification Procedures:
  - EDQM Certificate of Suitability
  - Active Substance Master File
  - US Drug Master File
- Quality Standard: How to discern a good starting material from a bad one?
- New requirements for excipients

DR RETO THEISS

### Current GMP Requirements for APIs, Excipients and Drug Products

- Relevant ICH guidelines
- EU regulations for Drug Products and API
- GMP for excipients – current expectations
- IPEC (International Pharmaceutical Excipients Council) Guideline for excipients
- Upcoming EU GMP regulation for excipients
- GMP aspects of supplier/manufacturer qualification
- New challenge: risk assessment for excipients

DR THOMAS STORM

### Laboratory Organisation

- Role of the raw materials laboratory within the pharmaceutical supply chain
- Optimization of the analytical laboratory with respect to costs, time and resources (economic order size, costs of analysis vs stock keeping costs, reduced sampling and reduced testing, ABC analysis)

EMERICH GRASSINGER

### Pharmacopoeias

- Regulatory background
- Pharmacopoeial institutions – Ph.Eur., USP/NF, JP
- CEPs
- Implementation of pharmacopoeial monographs in your laboratory
- Multi-compendial testing
- Validation of pharmacopoeial testing methods
- USP General Chapter <1226> Verification of Compendial Methods

DR THOMAS STORM

### Sampling of Incoming APIs and Excipients

- Regulatory requirements
- Reduced Testing
- Sampling plans
- Rational for representative sample and risk analysis
- Training
- GMP-compliant documentation of sampling operations
- Practical examples

EMERICH GRASSINGER

**WORKSHOP I**
**Sampling**

- Examples for generating sample procedures
- Risk assessment and Rational for representative sampling
- Calculating different optimizations (reduced sampling, reduced testing, economic order size)

Moderator: EMERICH GRASSINGER

### Reduced Testing of Supplied APIs and Excipients

- What guidance is available on reduced QC testing?
- EU and FDA expectations?
- Supplier qualification as a prerequisite
- Other information required before you start reducing
- Can APIs and excipients be covered within the same approach?
- Who is in the driver seat, who must be involved?
- Practical execution

DR RETO THEISS

**WORKSHOP II**
### Reduced Testing

Apart from any guidance, it is still much up to the manufacturer to decide which APIs and which excipients might be subject of a reduced testing procedure. Since the quality of the substance has to be assured without compromise, multiple factors must be considered before the full testing of every single batch can be reduced. It is the aim of this workshop to exchange information about different approaches and to discuss their advantages and disadvantages respectively considering the actual guidance as well as their practicability.

Moderator: DR RETO THEISS

### Analytical Methods

- Use and validation of non-compendial methods
- How to proof comparability?
- Advantages of instrumental methods versus visual methods
- Handling of deviations (Out-of-Specification results and complaints)
- Measurement system analysis
- Documentation
- Retests

EMERICH GRASSINGER

### NIR (Near InfraRed Spectroscopy) for an Efficient Control of Starting Materials

- A short introduction to NIR Spectroscopy
- NIR as a pharmacopoeial monograph
- NIR for single container identification
- Costs vs. benefit
- NIR vs. ATR vs. Raman

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## Speakers

**Emerich Grassinger**
*Shire, Austria*
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. 2010 – 2018 he works as Director of Quality Control for the Aenova site Haupt Pharma Wülfing in Gronau, a contract manufacturer for sterile products and solid dosage forms. He led several improvement projects throughout the supply chain and implemented Lean Lab at several sites. Since 2019 he is responsible for Quality Control for Shire in Vienna, Austria.

**Armin Groh**
*CSL Behring, Bern, Switzerland*
Armin Groh worked many years as manager of several laboratory groups in the QC unit of Takeda in Singen, Germany. He was responsible for the release of starting materials and for various analytical methods like HPLC, GC, FT-IR and FT-NIR, titrations, and other pharmacopoeial methods. In April 2018 he joined CSL Behring as Global Lead Auditor.

**Dr Reto Theiß**
*Merck KGaA, Darmstadt, Germany*
Dr Reto Theiss started his career in the pharmaceutical industry in 1999. Since 2002 he is with Merck KGaA in Darmstadt, Germany, acting as a Qualified Person where he was initially responsible for releasing products of the generic branch to the market. Since 2005 his duties include the QA supervision of solid dosage forms during the whole production chain. Furthermore, he is performing supplier and CMO audits as part of the supplier qualification.

**Dr Thomas Storm**
*Novartis Pharma AG, Basel, Switzerland*
Thomas Storm studied Chemistry and Physics, PhD in Environmental Technology, TU Berlin. Worked since 2001 as Head of Laboratory in Analytical Development at Schering AG / Bayer Schering Pharma AG, Berlin. Joined Novartis Pharma AG in Basel in Inhalation Technical Development in 2008, currently leading the oral pharmaceutical development unit. Work areas included quality control of excipients, supplier qualification, quality control for development candidates, electronic raw data archival, HPLC, HPLC/MS, CDS, and pharmaceutical development of oral and inhaled dosage forms.

## 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.

**Easy Registration**

**Reservation Form:**
**CONCEPT HEIDELBERG**
**P.O. Box 10 17 64**
**69007 Heidelberg**
**Germany**

**Reservation Form:**
**+ 49 6221 84 44 34**

**e-mail:**
**info@concept-heidelberg.de**

**Internet:**
**www.gmp-compliance.org**

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

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

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**Quality Control of Starting Materials (APIs and Excipients)**
7 - 8 February 2019, Copenhagen, Denmark

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

**Important: Please indicate your company's VAT ID Number** **P.O. Number, if applicable**

Street/P.O. Box

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 %,
- until 1 weeks prior to the conference 50 %
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**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

Thursday, 7 February 2019, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Friday, 8 February 2019, 8.30 h – 16.00 h

## Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 3396 50 00
Scandinavia.meetings.events@radissonblu.com

## Fees (per delegate plus VAT)

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

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 with all further information when you have registered for the event. 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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