Participate in 2 Workshops:
- Sampling
- Reduced Testing

# Quality Control of Raw Materials (APIs and Excipients)

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

26 – 27 February 2015, Copenhagen, Denmark

SPEAKERS:

Emerich Grassinger
*Haupt Pharma Wülfing*

Armin Groh
*Takeda*

Dr Reto Theiß
*Merck*

Dr Thomas Storm
*Novartis Pharma*

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 Raw Materials

ECA ACADEMY

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

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## 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 „raw 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?

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?

DR RETO THEISS, *Merck KGaA*

### 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

DR THOMAS STORM, *Novartis Pharma AG*

### 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, involvement of RM suppliers in the SC)

EMERICH GRASSINGER, *Haupt Pharma Wülfing GmbH*

### 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
- New USP General Chapter <1226> Verification of Compendial Methods

DR THOMAS STORM, *Novartis Pharma AG*

### Sampling of Incoming APIs and Excipients

- Regulatory requirements
- Are the requirements the same for active and excipients?
- Sampling plans
- Training
- GMP-compliant documentation of sampling operations
- Practical examples

EMERICH GRASSINGER, *Haupt Pharma Wülfing GmbH*

**WORKSHOP I**
**Sampling**
- Examples for generating sample procedures
- How to deal with the unexpected?
- How to deal with deviations on the delivery like incorrect temperature control, stacked up pallets, etc.?

Moderator:
EMERICH GRASSINGER, *Haupt Pharma Wülfing GmbH*

### 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, *Merck KGaA*

**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, *Merck*

### 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)
- CAPA process
- Measurement system analysis
- Documentation
- Retests

EMERICH GRASSINGER, *Haupt Pharma Wülfing GmbH*

### NIR (Near InfraRed Spectroscopy) for an Efficient Control of Raw Materials
- A short introduction to NIR Spectroscopy
- NIR as a pharmacopoeial monograph
- NIR for single container identification
- Costs vs. benefit
- NIR vs. ATR

ARMIN GROH, *Takeda GmbH*

## Speakers

**Emerich Grassinger**
***Haupt Pharma Wülfing GmbH, Member of the Aenova Group, 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. 2010 he joined Haupt Pharma Wuelfing, where he is responsible for Quality Control, including the raw material laboratory and the sampling of incoming goods.

**Armin Groh**
***Takeda GmbH, Singen, Germany***
Armin Groh works as head of laboratory in the QC unit of Takeda in Singen, Germany. He is responsible for various analytical methods like HPLC, GC, FT-IR and FT-NIR, titrations, and other pharmacopoeial methods.

**Dr Reto Theiß**
***Merck KGaA, Darmstadt, Germany***
Dr Reto Theiß started in 1997 at Temmler Pharma in Marburg. In 1999 he became deputy Head of Temmler's Quality Control department. In 2002 he changed to Merck in Darmstadt serving as QP responsible for releasing products of the generic branch for the market. Since January 2005 his duties include the QA supervision of solid dosage forms during the whole production chain.

**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 in 2008 as Head of Laboratory in Inhalation Development and Technology. Work areas included quality control of excipients, introduction of novel excipients, supplier qualification, quality control for development candidates, electronic raw data archival, HPLC, HPLC/MS, CDS, and, recently, inhalation specific analytics.

## 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)

+ 49 6221 84 44 34

**Quality Control of Raw Materials (APIs and Excipients)**
26 – 27 February 2015, 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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**Terms of payment**: Payable without deductions within 10 days after receipt of invoice.
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### Date

Thursday, 26 February 2015, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Friday, 27 February 2015, 8.30 h – 16.00 h

### Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 33 96 50 00
Fax +45 33 96 55 55

### 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 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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