

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

20 - 21 February 2014, Prague, Czech Republic

#### **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



## Quality Control of Raw Materials

### 20 - 21 February 2014, Prague, Czech Republic

#### **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 PhEur, 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, 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.

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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 your payment, y be confirmed)! Date

Thursday, 20 February 2014, 9.00 h - 18.00 h (Registration and coffee 8.30 h - 9.00 h) Friday, 21 February 2014, 8.30 h - 16.00 h

#### Venue

Corinthia Hotel Prague Kongresova 1 14069 Prague 4 Czech Republic

+ (0) 420 261 191 111 Phone +(0) 420 2261 225 011 Fax

#### Fees

ECA Members € 1,490.- per delegate plus VAT APIC Members € 1,590.- per delegate plus VAT Non-ECA Members € 1,690.- per delegate plus VAT EU GMP Inspectorates € 845.- per delegate plus VAT 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**

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#### For questions regarding content:

Dr Günter Brendelberger (Operations Director) at phone +49-62 21 / 84 44 40, or per e-mail at brendelberger@concept-heidelberg.de. For questions regarding reservation, hotel, organisation etc.:

Marion Grimm (Organisation Manager) at +49-62 21 / 84 44 18, or per e-mail at grimm@concept-heidelberg.de.

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