Quality Control of Starting Materials
(APIs and Excipients)

SPEAKERS:

Emerich Grassinger
Aenova Group - Haupt Pharma Wülfing

Armin Groh
CSL Behring

Dr Reto Theiß
Merck

Dr Thomas Storm
Novartis Pharma

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

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

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

7 - 8 February 2019, Copenhagen, Denmark

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 „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, 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
- New challenge: risk assessment for excipients

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, reduced sampling and reduced testing, ABC analysis)

EMERICH GRASSINGER, Aenova Group - 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
- USP General Chapter <1226> Verification of Compendial Methods

DR THOMAS STORM, Novartis Pharma AG

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, Aenova Group - Haupt Pharma
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, Aenova Group - Haupt Pharma Wülfing GmbH

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)
- Measurement system analysis
- Documentation
- Retests
EMERICH GRASSINGER, Aenova Group - Haupt Pharma Wülfing GmbH

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
ARMIN GROH, CSL Behring

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 within QA and QC. 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 Wülfing, where he is responsible for Quality Control, including the raw material laboratory and the sampling of incoming goods.

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.
Reservation Form (Please complete in full)

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Organisation and Contact

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

For questions regarding organisation: Dr. Clausen, Tel.: +49 (0) 62 21/84 44 34, e-mail: clausen@concept-heidelberg.de

For questions regarding accommodation: Mr. Thiel, Tel.: +49 (0) 62 21/84 44 43, e-mail: thiel@concept-heidelberg.de

ECA Members € 1,490
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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

For questions regarding accommodation, dinner on the first day, lunch on both days and all refreshments, VAT is reclaimable.

Fees (per delegate plus VAT)

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Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark

Phone: +49-3396 50 00

Registration and coffee 8.30 h - 9.00 h
Friday 8 February 2019 8.30 h - 16.00 h