ECA Academy
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GMP Certification Programme
Certified Quality Control Manager

Speakers

Emerich Grassinger
Takeda

Dr Reto Theis
Merck

Dr Thomas Storm
Novartis Pharma

Quality Control of Starting Materials (APIs and Excipients)

Live Online Training on 09/10 March 2021

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

Highlights

- 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

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

Objective

It is the aim of this Live Online Training to give practical oriented advice regarding the testing of APIs and excipients. You will learn

- who is responsible for the release or rejection of starting materials,
- how the incoming goods lab can be organised efficiently,
- which SOPs are necessary,
- in which cases test results can be taken over from the supplier's certificate of analysis,
- whether or not all test items of a pharmacopoeial monograph have to be analysed,
- whether the pharmacopoeial monographs are similar and in which cases different tests must be conducted for Ph. Eur., USP and JP,
- when a pharmacopoeial test method can be replaced by an alternative test method and in which cases this requires a variation application.

Background

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 main goal can also be achieved by applying reduced sampling/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.

However, 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.

Target Audience

This Live Online Training 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
- Common Technical Document (CTD)
- Certification Procedures:
  - EDQM Certificate of Suitability
  - Active Substance Master File
  - US - Drug Master File
- Quality Standards: How to discern a good starting material from a bad one?
- New requirements for excipients

Current GMP Requirements for APIs, Excipients and Drug Products

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

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)

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

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

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)

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

WORKSHOP II
Reduced Testing

- Different approaches for reduced testing
- Advantages and disadvantages
- Considerations of actual guidances and their practicability.

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

Speakers

Emerich Grassinger
Takeda, Vienna, Austria

Emerich Grassinger headed several labs within Boehringer Ingelheim where he also led several improvement projects throughout the supply chain involving the raw material releasing process. Thereafter he joined Haupt Pharma Wuelfing, where he was responsible for Quality Control, including the raw material laboratory and the sampling of incoming goods. Since 2019 he is head of Quality Control at Takeda in Vienna, Austria.

Dr Reto Theiss
Merck Healthcare, Darmstadt, Germany

Dr Reto Theiss works as Qualified Person at Merck Healthcare KGaA in Darmstadt, Germany, where he is responsible for releasing products of the generic branch to the market. His duties include as well 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

Dr Thomas Storm works in Inhalation Technical Development where he is currently leading the oral pharmaceutical development unit. His work areas include quality control of excipients, supplier qualification, quality control for development candidates, electronic raw data archival, HPLC, HPLC/MS, CDS, and inhalation pharmaceutical development of oral and inhaled dosage forms.

Your Benefit:
Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.


CERTIFICATE

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

D-69007 Heidelberg
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Reservation Form (Please complete in full)

Quality Control of Starting Materials (APIs and Excipients), Live Online Training on 09/10 March 2021

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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Date of the Live Online Training

Tuesday, 9 March 2021,
09.00 to approx 18.00 h CET
Wednesday, 10 March 2021,
09.00 to approx 15.00 h CET

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

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

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Gerhard Becker (Operations Director) at
+49(0)62 21/84 44 65, or at
becker@concept-heidelberg.de.

For questions regarding organisation please contact:
Mr Niklaus Thiel (Organisation Manager) at
+49(0)62 21/84 44 43, or at
thiel@concept-heidelberg.de.