



## Speakers



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# Quality Control of Starting Materials (APIs and Excipients)



Live Online Training on 15/16 February 2022



*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
- Pharmacopoeias
- Laboratory Organisation
- 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

## Objectives

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

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- 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

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- 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

### Pharmacopoeias

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- 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

### Laboratory Organisation

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- 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)

### Sampling of Incoming APIs and Excipients

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- 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



Q&A sessions will ensure interaction and that your questions will be answered.



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 Wuefing, 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

Reto Theiss has 25 years of experience in the pharmaceutical industry and more than 20 years as a Qualified Person. Holding several QA functions in the past he is currently working as QP for Merck Healthcare KGaA in Darmstadt, Germany. Furthermore, Mr Theiss is a qualified auditor for Merck Healthcare.



Dr Thomas Storm  
Sandoz, Basel, Switzerland

Dr Thomas Storm is Global Program Head for Respiratory Programs in Sandoz Product Development. Before that, he worked in Inhalation Technical Development at Novartis Pharma AG, Basel, Switzerland where he was 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.



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## Quality Control of Starting Materials (APIs and Excipients) Live Online Training on 15/16 February 2022



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## Date of the Live Online Training

Tuesday, 15 February 2022, 09.00 to approx 18.00 h

Wednesday, 16 February 2022, 09.00 to approx 15.00 h

All times mentioned are CET.

## Technical Requirements

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## 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](http://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.

## Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at [www.gmp-compliance.org/recordings](http://www.gmp-compliance.org/recordings). These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

## Organisation and Contact

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

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