ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

## Speakers

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# Quality Control of Starting Materials (APIs and Excipients)

## 18/19 March 2026 | Vienna, Austria

*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

Participate in 2 Workshops:
- Sampling
- Reduced Testing

## Objectives

It is the aim of this GMP Education Course 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 GMP 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
- 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

### 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

### 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)

### 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 prove comparability?
- Advantages of instrumental methods versus visual methods
- Handling of deviations (Out-of-Specification results and complaints)
- Measurement system analysis
- Documentation
- Retests

### 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.

# 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.

Veronika Käser
Merck Healthcare KGaA,
Darmstadt, Germany

Veronika Käser is a pharmacist with several years of experience in the Quality Control at the pharmaceutical industry where she gained a broad range of experiences in quality topics and operational tasks in the GMP field including raw material laboratory and stability management. Currently she is team lead at the stability management team at Merck Healthcare.

Dr Reto Theiss
Merck Healthcare KGaA,
Darmstadt, Germany

Reto Theiss has more than 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.

# Social Event

In the evening 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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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

# Quality Control of Starting Materials (APIs and Excipients)
# 18/19 March 2026, Vienna, Austria

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)

**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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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 payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

**Privacy Policy**: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

## Date
Wednesday, 18 March 2026, 09.00 - 18.00 h
(Registration and coffee 08.30 - 09.00 h)
Thursday, 19 March 2026, 09.00 - approx. 15.15 h

## Venue
Doubletree by Hilton Vienna Schönbrunn
Schlossallee 8
1140 Vienna
Austria
Phone: +43 1 / 89 110
Email: info@doubletree-schonbrunn.at

## Fees (per delegate, plus VAT)
ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
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. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

## Presentations / Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

## Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22168.

## 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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