ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Heiko Brunner
Hamburg, Germany

Dr Brunner is a chemist who started his career in the pharmaceutical industry in 1991. He worked for various originator companies in the field of early and late phase product development. In 2008, he transitioned to the generic industry. In addition to holding leadership roles in product development, he also took on key positions in project management and served as Head of Quality Control and acted as a lead GMP auditor.

Dr Gerd Jilge, Retired Head of a Method Development Laboratory at Boehringer Ingelheim Pharma, Germany

In 1991, Dr Jilge came to Boehringer Ingelheim working in drug product development, where he was responsible for method development and validation for the application of analytical procedures. In 2000, he took a position in Drug Regulatory Affairs of Boehringer Ingelheim GmbH with the focus on CMC documentation for the submission of new and registered drug products. From July 2007 to January 2022, he was working in Quality Control in the method development group for drug substances. Dr Jilge is Member of the ECA Analytical Quality Control Group Advisory Board.

System Suitability Tests (SST) and Troubleshooting for HPLC Methods

Live Online Training on 04 November 2025

Highlights

- Importance of the system suitability test (SST) and regulatory requirements of chromatographic analytical methods
- Current changes in the pharmacopoeial SST chapters
- SST parameters and their acceptance criteria with a focus on chromatographic methods
- Dos and don'ts of the SST
- Why the SST alone is not suitable for device qualification
- Evaluation and troubleshooting of HPLC methods
- Troubleshooting approaches and solution strategies
- Case studies

Programme

Objectives

This Live Online Training provides a comprehensive insight into the requirements of SST criteria, including their acceptance limits. The event combines theoretical concepts and case studies with practical exercises to equip participants with a thorough understanding of HPLC method evaluation and troubleshooting.

Background

The SST is an essential part of any GMP analysis, particularly when applying chromatographic methods. It ensures the proper functioning of both the analytical system and the corresponding analytical procedure, including sample preparation.
Before establishing new HPLC methods in one's own laboratory, a thorough review and evaluation are necessary. Potential sources for new methods include external laboratories (as part of method transfer), literature descriptions, pharmacopoeial monographs, or in-house developments. A detailed analysis of potential weaknesses can help prevent later issues, including variation applications in regulatory approvals. If difficulties arise when applying a new method, troubleshooting can often be time-consuming and costly.

Target Audience

This Live Online Training is designed for participants who wish to expand their knowledge of SST and troubleshooting of HPLC methods. It is particularly aimed at:

- Heads of Quality Control
- Qualified Persons (QP)
- Laboratory Managers
- and all laboratory staff in pharmaceutical quality control and analytical development.

It is also relevant for professionals from control departments of active pharmaceutical ingredient (API) and excipient manufacturers, as well as contract laboratories. Furthermore, this Live Online Training is of interest to employees and managers in quality assurance.

Programme

System Suitability Test (SST)

- Importance of SST – Why is the system suitability test so important?
- Regulatory requirements
- Current changes in the pharmacopoeial SST chapters
- SST parameters and their acceptance criteria
- How to obtain the optimal SST (development of SST)?
- Dos and Don'ts of SST
- How can SST contribute to the "Analytical Life Cycle"?
- Why is SST not sufficient for the qualification of analytical systems?
- Examples of System Suitability Tests for other chromatographic and non-chromatographic analytical methods
- Is an SOP required for SST?

Evaluation and Troubleshooting of HPLC Methods

- Common issues and their causes
- Evaluation criteria for HPLC methods
- Choosing the right method parameters
- Diagnostic tools, checklists, and performance monitoring
- Assessment of chromatograms
- Approaches to error correction and solution strategies

Interactive Learning Components

- Quiz – deepening knowledge
- Case studies – practical examples on troubleshooting
- Interactive workshop – group work: troubleshooting an HPLC method

Date of the Live Online Training

Tuesday, 04 November 2025
09.00 – 17.00 h CET

Technical Requirements

We use WebEx for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

Non-ECA Members € 1,290
ECA Members € 1,090
APIC Members € 1,190
EU GMP Inspectorates € 645
The conference fee is payable in advance after receipt of invoice. VAT is reclaimable.

Registration

Please register online at **www.gmp-compliance.org under the number 22319.**

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.

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