ECA Academy
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GMP Certification Programme
Certified Quality Control Manager

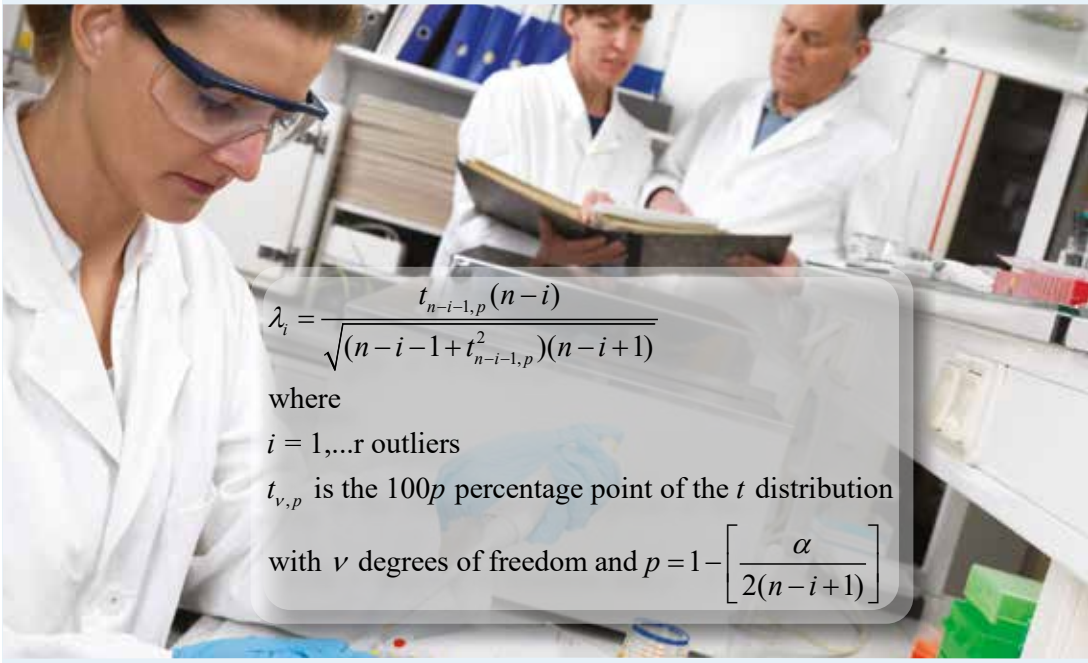
Speakers

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Practical Statistical Tools for Analytical Laboratories

Live Online Training on 07/08 October 2025



Performance Evaluation and Monitoring for compliant Analytical Procedures and Processes

Highlights

- Participants should gain an understanding of
  - basic statistical fundamentals
  - distribution of data and its parameters
  - accuracy and precision
  - variability and precision levels
  - reportable result
  - linear and non-linear models
  - performance requirements for analytical procedures
- Participants will be shown how to
  - apply statistical principles scientifically and pragmatically in their day-to-day business
  - use statistical simulations
  - optimise the reportable result for minimum variability
  - trend data
  - compare data and methods
  - establish reliable reporting/quantitation limits

Objectives

This Live Online Training will provide the participants with recommendations, tools and examples to apply scientifically and pragmatically sound statistical principles to their day-to-day business as well as to meet future challenges.

A brief discussion of supporting software tools (e.g. Excel, Minitab, JMP) to facilitate the generation of statistical information in a consistent manner will be undertaken.

One of the main features of this course is the balance of presentations and more than four hours of practical exercise workshops which will allow participants to gain 'hands on' practical experience in applying the statistical methods described. By means of statistical simulation tools, the participants will gain intuitive understanding of the consequences of appropriate and inappropriate performance parameters, for example the relationship between precision and OOS results.

Background

Statistical calculations and tools are applied extensively in pharmaceutical analysis including

- Procedure development and validation
- Transfer of analytical procedures
- Setting or verification of specification limits
- Data evaluation, comparison and trending

Consequently, a thorough understanding of statistical fundamentals is essential in order to be able to select parameters and test methods that are 'fit for purpose'.

Target Audience

This Live Online Training is designed for analytical laboratory managers and their colleagues charged with the day to day management and evaluation of laboratory data throughout the lifecycle, i.e. in method development, validation, transfer, specification setting, batch release and stability, continuous performance verification and change control.

QA, manufacturing and regulatory affairs professionals will benefit from participation by gaining a clear understanding of the statistical fundamentals which are important to implement scientifically sound and pragmatic tools to conform to GMP and regulatory requirements for example Product Quality Review.

Programme

Analytical Procedure Lifecycle Management Overview

- Principles of APLM
- USP <1220>
- Risk based approach
- Target Measurement Uncertainty
- Decision rules

(Normal) Distribution of Data and its Parameters

- Data shape and its importance
- Characterisation of distributions (Location and Dispersion)
- Probability considerations; all measurements are subject to error
- Populations and samples
- Confidence intervals
- What is an outlier?
- Error of the error

Calculation and Evaluation of Precision Levels

- System precision, repeatability, intermediate precision, reproducibility
- ANOVA: Identification of relevant variance components from injection, measurement, sample preparation, intermediate conditions
- Total variability: precision of the reportable result and its optimisation
- Relationship between precision and probability of OOS results
- Practically relevant acceptance criteria for precision

WORKSHOP I

Understanding the Variability (Statistical Simulations)

- Scatter of results and risk of OOS
- Variability of standard deviations
- Number of data and reliability of calculated standard deviations

WORKSHOP II

Optimisation of Variability

- Statistically based format of the reportable result (single or average)
- Number of determinations for various levels

Trending of Data

- Why trend?
- Evaluation; do we expect a trend or not?
- Statistical Process Control principles
- Types of Control charts and their application
- Application to stability testing

WORKSHOP III

Control Charts & Trending
- Interactive workshop based on supplied real data sets for interpretation
- Use of Minitab for control charting
- Team working on evaluation and interpretation of trend data

Measurement Uncertainty without the Maths; Introduction to Monte Carlo Simulation

- Principles of Monte Carlo simulation
- Understanding variance contributions and how they combine
- Measurement uncertainty
- Application to analytical procedures
- Examples of unit and complete procedures using Companion by Minitab

Comparison of Data & Accuracy

- Significance (F- and t-test) and equivalence tests
- Statistical significance and practical relevance
- Differences caused by random variability: observed and true bias
- Applications in transfer and cross-validation

WORKSHOP IV

Comparison of Data (Statistical Simulations)
- Significance and equivalence tests: impact of number of data and series
- Differences between means and variability

Calibration Models, Linear and non-Linear

- What is a calibration model?
- What is the difference between linear and non-linear models?
- The principle of least squares and why it is important
- Applying the principles to linear and non-linear models

WORKSHOP V

Linearity (Statistical Simulations)
- Regression range and evaluation of the intercept
- Extrapolation effects

Performance Requirements for Impurity Procedures

- Concentration dependence of precision (Horwitz relation)
- Detection and Quantitation Limits

Summary Workshop & Discussion: Appropriate Choice of Tests/Calculations

- Practical objectives and data sets are provided
- The participants will discuss and define appropriate tests and parameters to be calculated
- The participants are given the calculation results and are asked to make an evaluation
- The defined tests and results are discussed in the audience

Speakers

Dr Christopher Burgess
Burgess Analytical Consultancy Ltd., UK

He is a Chartered Chemist and has more than 45 years' experience in the pharmaceutical industry initially with Glaxo in Analytical R&D, Quality Control and Quality Assurance followed by 25 years in international consultancy. He is a "Qualified Person" in the European Union. He was appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2025 and is a visiting professor at the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Extended board of European Compliance Academy Foundation. He was a member of the USP Expert Panel which developed General Chapter <1220> and is chairman of the JSC revising General Chapter <1058>.

Dr Joachim Ermer
Ermer Quality Consulting, Germany

He has 30 years of experience in pharmaceutical analytics including development products, global responsibilities as Director of Analytical Processes and Technology, Head of Quality Control, and Head of QC Lifecycle Management Frankfurt Chemistry at Sanofi. From 2010 till 2020, he was also responsible for the central reference standard group of Sanofi. He is member of the USP Expert Committee Measurement and Data Quality, and of the Chromatographic Separation Techniques Working Party of the European Pharmacopoeia. Since December 2020, he works as a consultant for topics of pharmaceutical analysis and Quality Control.

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Reservation Form (Please complete in full)

Practical Statistical Tools for Analytical Laboratories
Live Online Training on 07/08 October 2025

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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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training
Tuesday, 07 October 2025, 09.00 – 17.15 h
Wednesday, 08 October 2025, 09.00 – 17.15 h
All times mentioned are CEST.

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 events 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)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice.

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 21888.

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.

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

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