ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

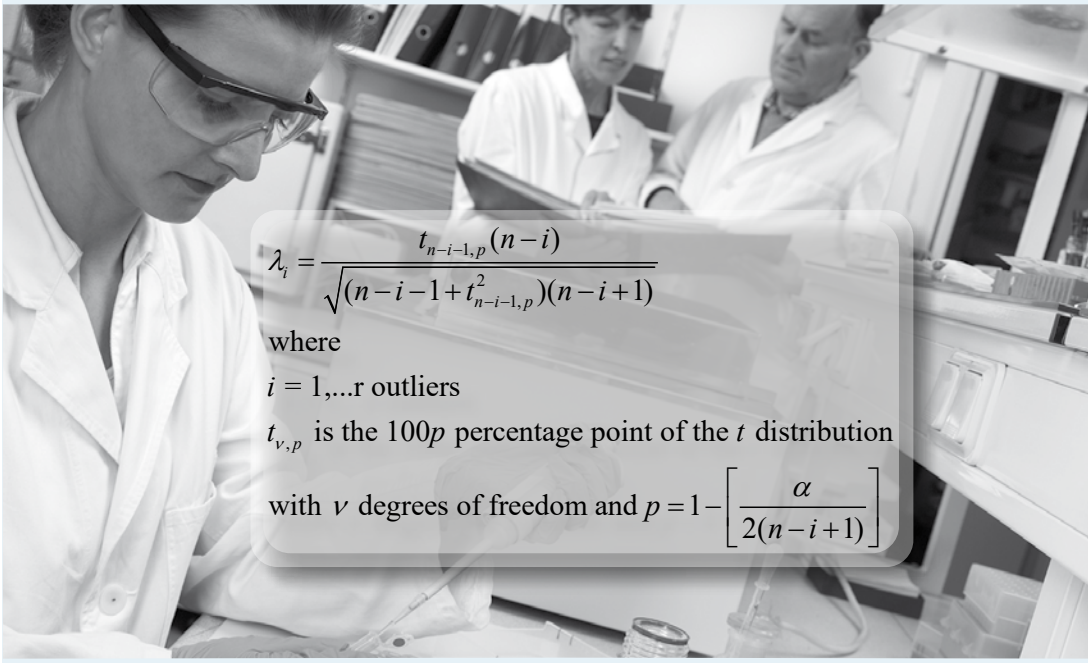
## Speakers

Dr Christopher Burgess
Burgess Analytical Consultancy Ltd., UK

Dr Joachim Ermer
Sanofi, Frankfurt, Germany

# Practical Statistical Tools for Analytical Laboratories

## 01/02 December 2021 | Berlin, Germany




*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

Updated Course for R&D and QC Laboratories

# Objective

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

The ICH Q10 Guideline "Pharmaceutical Quality System", the FDA Guidances on Process Validation and Methods Validation require monitoring of "process performance and product quality" and "Trend analysis on method performance" throughout the product lifecycle. Hence the appropriate use of statistical trending and evaluation tools has become mandatory.

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'.

**Do you speak statistics?**
In addition, such an understanding facilitates the communication with other technical and regulatory functions applying statistical tools in order to ensure an overall consistent approach.

# Background

The course 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 described above.

The relevance of such statistical tools is also increasingly recognised by the Compendia, as reflected, for example, in the USP General Information Chapter <1010> "Interpretation and treatment of analytical data" and the recently introduced <1033> "Biological assay validation" together with the proposed General Chapter <1220> on Analytical Procedure Lifecycle.

Statistical tools are needed, for example, to evaluate:

- Distribution of data and its parameters
- How to detect outliers and trends?
- How to establish the total variability of the method?
- How to identify method parameters that must be controlled?
- Method performance and specification limits
  - Which accuracy and precision is needed to achieve an acceptable risk of OOS results?
  - Scientifically based justification and optimisation of the reportable result (single or average?)
  - What are the requirements for impurity methods?
- Comparison of methods and data
- What are the requirements for calibration models?
- How to optimise the number of calibration replicates on a scientific basis?

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 five 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.

For this reason, the course is limited to 30 participants so that individual attention and support can be given. **In order to fully benefit from the workshops, attendees should preferably bring a notebook with Excel® 2007 or later.**

# Target Audience

This best practice oriented course 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 (USP & ICH initiatives)

- Principles of APLM
- Proposed 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

## WORKSHOP I

**Understanding the Variability (Statistical Simulations)**

- Range of expected data
- Variability of standard deviations
- Number of data and reliability of calculated standard deviations

## 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
- Optimisation of single-point calibration
- Relationship between precision and probability of OOS results
- Practically relevant acceptance criteria for precision

## WORKSHOP II

**Optimisation of Variability**

- Statistically based format of the reportable result (single or average)
- Number of determinations for various levels
- Probability of results outside established limits

## 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

## Monte Carlo simulation of Analytical Procedures

- 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: influence 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

## WORKSHOP VI

**Quantitation Limit**

- Basics to consider for calculation from linearity
- How to determine appropriately from precision

### 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

# Moderator

Dr Christopher Burgess, Burgess Analytical Consultancy Ltd., UK

# 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.

# Speakers

Dr Christopher Burgess
Burgess Analytical Consultancy Ltd., UK

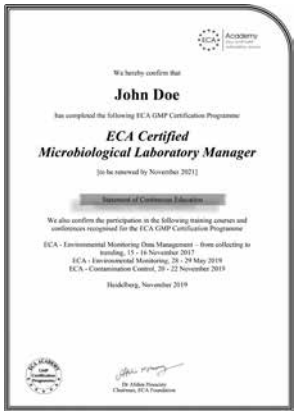
He is a Chartered Chemist and has more than 45 years experience in the pharmaceutical industry initially with Glaxo in Quality Assurance and Analytical R&D and then 25 years in international consultancy. He is a "Qualified Person" in the European Union. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2020 and is a visiting professor of 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 is also a member of the USP Expert Panel on Validation and Verification entrusted to revise General Chapters <1224>, <1225> and <1226>.

Dr Joachim Ermer
Ermer Quality Consulting

HHe 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 in Frankfurt. He is member of the USP Expert Committee Measurement and Data Quality, of the Chromatographic Separation Techniques Working Party of the European Pharmacopoeia, and of the EFPIA support team for the update/establishment of ICH Q2/Q14.

# GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.


We hereby confirm that

**John Doe**

has completed the following ECA GMP Certification Programme

***ECA Certified***
***Microbiological Laboratory Manager***

[to be renewed by November 2021]

Statement of Continuous Education

We also confirm the participation in the following training courses and conferences recognised for the ECA GMP Certification Programme

ECA - Environmental Monitoring Data Management – from collecting to trending, 15 - 16 November 2017
ECA - Environmental Monitoring, 28 - 29 May 2019
ECA - Contamination Control, 20 - 22 November 2019

Heidelberg, November 2019

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GERMANY

Reservation Form (Please complete in full)

Practical Statistical Tools for Analytical Laboratories, 01/02 December 2021, Heidelberg, Germany

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 2 weeks prior to the conference 10 %,
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**Important**: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
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 January 2012).
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, 01 December 2021, 09.00 - 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 02 December 2021, 08.30 - 16.00 h

## Venue
Steigenberger Airport Hotel Berlin
Willy-Brandt-Platz 3
12529 Berlin Schönefeld
Phone: +49 (0)30 246 497 - 0
Email: berlin-airport@steigenberger.de

## Fees (per delegate, plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895

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 in the conference hotel. You will receive a room reservation form/POG when you have registered for the conference. Reservation should be made directly with the hotel.
Early reservation is recommended.

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

## 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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