ECA Academy
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GMP Certification Programme
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Speakers

Dr Christopher Burgess
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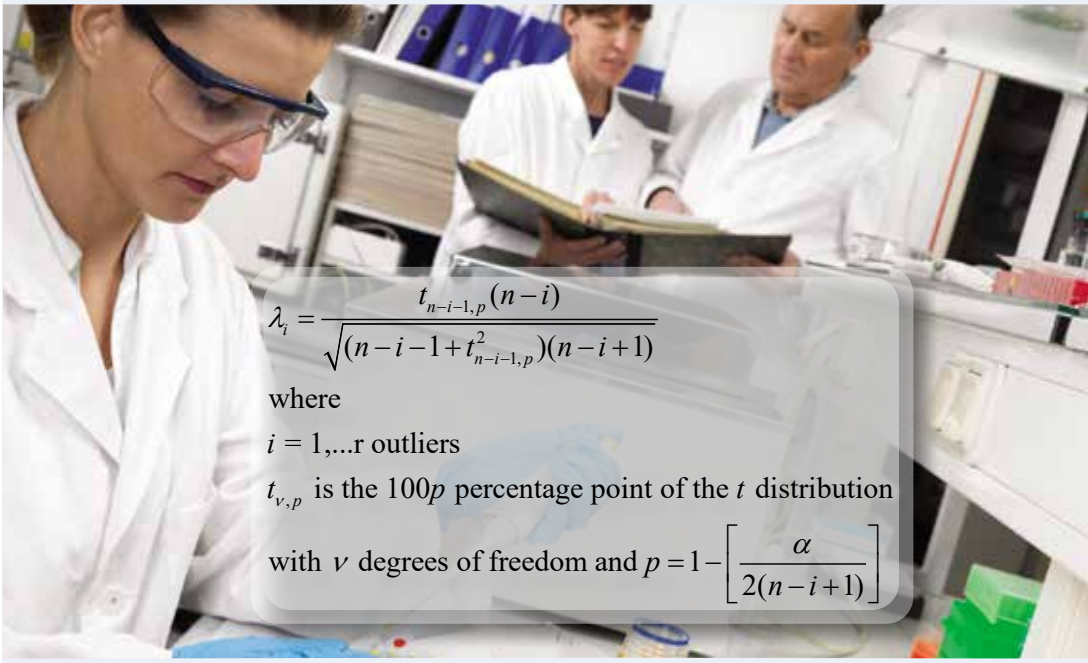
Practical Statistical Tools for Analytical Laboratories

01/02 October 2024 | Barcelona, Spain



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

Includes a free Pre-Course Webinar
"Statistical Simulations for Enhanced Understanding of Analytical Performance"

Objectives

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. The new ICH guidelines Q2 Validation of Analytical Procedures (Revision 2) and Q14 Analytical Procedure Development request the use of "appropriate statistical methods" to evaluate calibration functions, precision, and accuracy, for example by regression analysis, confidence, prediction, and tolerance intervals. 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 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 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.

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.

Moderator

Dr Christopher Burgess, Burgess Analytical Consultancy Ltd., UK

Programme

This course includes an optional free pre-course **webinar "Statistical Simulations for Enhanced Understanding of Analytical Performance" on Monday, 09 September 2024 from 14.00 – 16.00 CEST**. The participants will receive an Excel file with simulation worksheets, which will be explained in the webinar and which can be used later for own applications. If you are unable to attend the live webinar, we will provide you with a recording upon request.

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

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.

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
01/02 October 2024 | Barcelona, Spaain

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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If you cannot attend the conference you have two options:
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- Cancellation until 2 weeks prior to the conference 50 %
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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.

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Date
Tuesday, 01 October 2024, 09.00 - 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 02 October 2024, 08.30 - 16.00 h

Venue
Barceló Sants Hotel
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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 and includes participation in the pre-course webinar, 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.

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.

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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