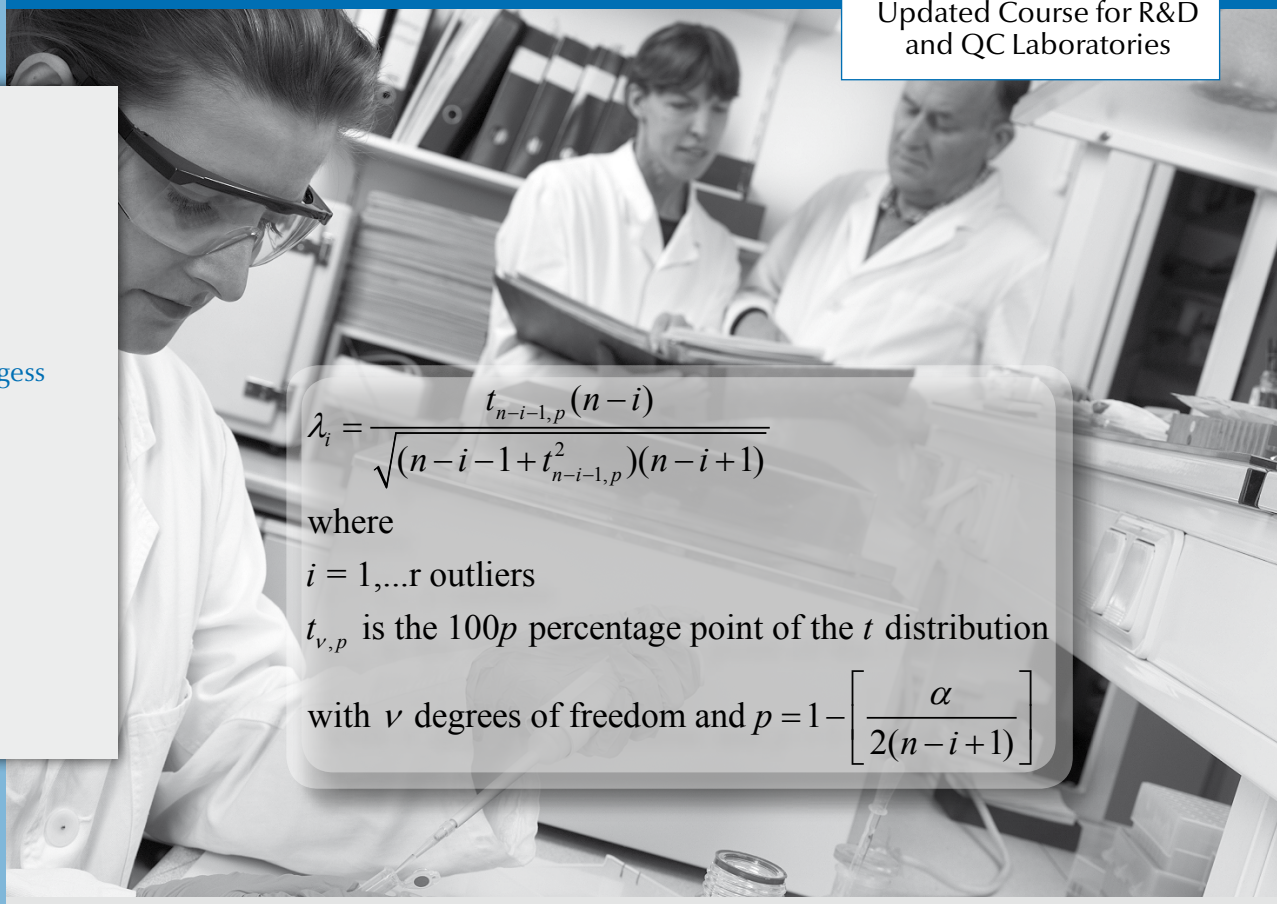
20 YEARS ECA Academy Your GMP/GDP Information Source

Practical Statistical Tools for Analytical Laboratories

Performance Evaluation and Monitoring for compliant Analytical Procedures and Processes

Updated Course for R&D and QC Laboratories



SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy Ltd., UK

Dr Joachim Ermer
Sanofi, Germany

10 – 11 April 2019, Heidelberg, Germany

LEARNING GOALS:

- 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
  - apply statistical tools for analytical lifecycle management

This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager“. Please find details at www.gmp-certification.eu

Practical Statistical Tools for Analytical Laboratories

10 – 11 April 2019, Heidelberg, Germany

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. 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 new 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.

Moderator

Dr Christopher Burgess,
Burgess Analytical Consultancy Ltd., UK

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

Speakers

DR CHRISTOPHER BURGESS
Burgess Analytical Consultancy Ltd., UK
He is a Chartered Chemist and has more than 44 years experience in the pharmaceutical industry initially with Glaxo in Quality Assurance and Analytical R&D and then 24 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
Sanofi, Frankfurt, Germany
Head of QC Lifecycle Management Chemistry, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany, and Global Reference Standards Coordinator of Sanofi. He studied biochemistry at University of Halle and has more than 25 years experience in pharmaceutical analytics including development products, global responsibilities as Director of Analytical Processes and Technology, and Head of Quality Control. He is member of the USP Expert Panel on Validation and Verification and of the EFPIA support team for the update/establishment of ICH Q2/Q14.

Easy Registration

Reservation Form:
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date

Wednesday,10 April 2019, 09.00 - 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 11 April 2019, , 08.30 - 16.00 h

Venue

Hotel Chester Heidelberg
SRH Hotel Handels- und Betriebs GmbH
Bonhoefferstraße 10
69123 Heidelberg, Germany
Phone -49(0)6221 9983 700
Email reservations@chester-heidelberg.de

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845

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 event. 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

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Dr Günter Brendelberger (Operations Director)
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brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc., please contact:

Mr Rouwen Schopka (Organisation Manager)
at +49-62 21/84 44 13, or per e-mail at
schopka@concept-heidelberg.de.

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.

Heidelberg – Optimal Accessibility via Frankfurt

As one of the most beautiful cities in Europe, Heidelberg is at first sight an interesting venue – but is it also easily accessible? The answer is: Yes! The connection to Frankfurt Airport is convenient and fast. Next to London, Frankfurt Airport offers the most frequent air connections in Europe. It takes only about 45 minutes to get from Frankfurt to Heidelberg.

TLS: http://www.tls-heidelberg.de

Lufthansa Bus:
http://www.transcontinental-group.com/en/frankfurt-airport-shuttles

PMJ: http://www.pmj-fahrservice.de

Train: You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg.
http://www.bahn.de

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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.

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10 – 11 April 2019, Heidelberg, Germany

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