Lab Data Integrity

Meeting FDA & EU Concerns

Part 1: Establishing the Controls for Ensuring Laboratory Data Integrity, 13 - 14 April 2015, Barcelona, Spain

Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls, 14 - 15 April 2015, Barcelona, Spain

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Dr Bob McDowall
McDowall Consulting, UK

PROGRAMME:

- Laboratory Data & Results
  - EU and US GMP Requirements
  - FDA Guidance Documents
  - Inspection Findings: 483 and Warning Letters
- Dealing with Mistakes before they become Falsification or Fraud
- Principles of Data Generation
  - Integrity Issues
  - Security Issues
- Requirements for Raw Data Integrity for
  - Paper Records
  - Hybrid Systems
  - Electronic Systems incl. ELNs
- Audit of Analytical Records
- Data Transformation: How to Identify and Handle Transcription Errors
- Collation and Reporting of Results
- Archiving

ECA ACADEMY

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

Lab Data Integrity (Part 1 & Part 2)

13-15 April 2015, Barcelona, Spain

Objectives

These two new courses have the following objectives:

Course 1:
The learning objectives are firstly, understand the data integrity requirements of a GMP regulated laboratory in Pharmaceutical organisations and contract labs and secondly, how laboratory personnel can ensure compliance and be able to defend their positions. Records generated by three processes will be taken through the presentations and workshops: paper only with records maintained in a laboratory notebook or controlled sheets, hybrid system with signed paper records with underlying electronic records and an electronic system using electronic signatures.

Course 2:
The auditing course will develop the understanding of what is required for a data integrity audit of a laboratory computerized system and then develop the principles, based on workshops and discussions, of how to audit hybrid and electronic laboratory systems The scope of auditing a system for data integrity will be developed during the course along with a risk based prioritisation of the key areas to focus audit attention on. The attendees will audit one computerized system and then feedback the audit findings to the laboratory manager and business process owner.
Note that this course will focus only on hybrid and electronic systems and will not consider paper-based data integrity.

Background

Data Integrity is currently a major concern with both the FDA and European Regulatory Agencies. Several FDA warning letters and EU GMP inspections have highlighted major data integrity failures at companies globally. The regulatory concern has been responded by the FDA issuing Compliance Program Guide (CPG) 7346.832 that covers Pre-Approval Inspections. This document became effective in May 2012 after Agency inspectors received training in data integrity where they focus on computer systems and not the paper output. The CPG objective 3 covers the laboratory data integrity audit. Furthermore in August 2014, the FDA issued Level 2 guidance on their web site about the sharing of login credentials for computerized systems and the use of test injections for testing into compliance.

In Europe, the UK's MHRA in December 2013 gave notice to regulated users to begin conducting data integrity audits of their own systems and those of their suppliers from the beginning of 2014. Similar to the FDA, European Inspectors have also undergone training in data integrity. The UK has also gone further by writing to the major suppliers of chromatography data system software requesting copies of the application and documentation to that the MHRA can understand how they operate and how falsification could occur.
As the regulators are tightening their inspection approaches it is important that managers, supervisors and users in regulated GMP laboratories understand the issues around data integrity.

Course 1 focuses on three types of record that can be found in analytical laboratories working to GMP: paper, hybrid computerized system and electronic workflows with electronic signatures. Through presentations, workshops and discussions attendees are taken through the process from analysis to generation of results to understand data integrity issues.

Course 2 takes the principles from the earlier course and develops them to enable attendees to be able to conduct effective internal audits or self-inspections of either hybrid or electronic systems in compliance with EU GMP Chapter 9. This is achieved mainly via a series of interlinked workshops with a few presentations. This course will focus only on hybrid and electronic systems.

Target Audience

These courses will be of significant value to:

- Managers and scientists from Quality Control and Analytical Development Laboratories wanting to understand the data integrity and audit process
- Quality Assurance personnel
- Contract Research Organisation and Contract Manufacturing Organisation laboratory and QA personnel
- Auditors (internal and external) responsible for assessing laboratory quality and data integrity

Social Event

On Monday, 13 April 2015 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.

Programme Course 1:
Establishing the Controls for Ensuring Laboratory Data Integrity

13 - 14 April 2015, Barcelona, Spain

EU and FDA GMP Regulations Impacting Laboratory Data and Results

- EU GMP requirements
- FDA GMP requirements
- FDA Guidance documents OOS, Inspection of QC labs
- Inspection findings 483 and warning letters
- Defining data integrity, "complete data" and „raw data"

Principles for the Generation of Data

- Observational tests and instrument tests
- Training of staff
- Qualified analytical instruments and validated software
- Integrity issues
- Security issues

WORKSHOP I: Generation of Data

- What are the requirements for raw data integrity?
- Three scenarios covering
  - a paper system
  - a hybrid system
  - a client server electronic system

Recording of Data

- Paper based systems
- Hybrid systems with paper printouts and electronic records
- Stand alone systems containing only electronic records
- Networked systems containing only electronic records

WORKSHOP II: Recording of Data

- Audit of an analytical record
- Scenarios covering paper based record, a hybrid system and an electronic system

Transforming Data

- Converting laboratory data to information
- Identifying and handling errors on paper as well as electronic systems
- Calculations performed manually and by computer programs
- Issues with truncation and rounding of numbers
- Integrity and security issues of the records generated during transformation

WORKSHOP III: Data Transformation

- Using Excel correctly
- Data from printout transcription, rounding, truncation

Collation and Reporting Results

- Calculating the reportable value and comparison with the specification
- Paper processes versus electronic processes
- Linkage with out of specification investigations (OOS)

Key Learning Points and Final Discussion

End of Course 1 / Registration for Course 2

Programme Course 2:
Self Inspections and Audits to Confirm Effective Data Integrity Controls

14 - 15 April 2015, Barcelona, Spain

Introduction to Course 2 & Key Learning Points from Course 1

- Data integrity concerns of regulators:
- FDA warning letter and EU non-compliance concerns about data integrity
- FDA Compliance Program Guide 7346.832 for PAI
- MHRA requirement for self inspections to focus on data integrity
- Role of management in ensuring data integrity
- Key learning points from Course 1

WORKSHOP I: Identifying the Laboratory Controls to Audit for Electronic and Hybrid Systems

- Group work with facilitated discussion to take the data integrity cycle and establish the controls required at each stage
- This establishes what could be covered in a data integrity audit

WORKSHOP II: Risk Assessment and Prioritisation

- The data integrity cycle with the audit objectives developed in Workshop I will be applied to one of three systems (hybrid and electronic systems) to obtain a risk based approach to auditing

WORKSHOP III: FDA Key Laboratory Data Integrity Concerns

- Using some real FDA warning letters the teams will cross check that the output of Workshop II is congruent with the FDA concerns around laboratory
- Attendee validation of an updated audit list

Pulling it All Together

- Based on many years of the teaching team's laboratory experience, presentation of their top 10 non-compliances based on FDA and EU regulations and audit experience will be given
- There will be an opportunity to discuss and compare the output from Workshop III against this knowledge base and experience

WORKSHOP IV: Preparing for the Data Integrity Audit

- Based on the selected scenario the attendees will determine the preparation needed for a laboratory audit
- Feedback and discussion with the teaching team

WORKSHOP V: Observations and Findings During a Laboratory Audit and Planning the Closing Meeting

- Each teams will be provided with an audit of a laboratory with observations
- Teams will determine if there are any data integrity non-compliances with the regulations and laboratory procedures
- Teams will determine if any observations are findings (non-compliances) and grade the severity of each one
- Prepare for the closing meeting with the Head of the Laboratory and the business process owner of the systems

WORKSHOP VI: Feedback to the Auditees

- Teams will present the audit conclusions and the findings to the Head of the Laboratory and the business process owner of the systems
- Discussion with the auditees of the findings

Review of the Course and Key Learning Points

Speakers

Dr Christopher Burgess
Burgess Analytical Consultancy, Barnard Castle, UK
He is a Chartered Chemist and has more than 38 years experience in the pharmaceutical industry initially with Glaxo in Quality Assurance and Analytical R&D and then 20 years in international consultancy. He is a "Qualified Person" in the European Union and a member of the European QP Association advisory board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 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 Executive committee of European Compliance Academy. He is also a member of the USP Expert Panel on Validation and Verification entrusted to revise General Chapters <1224>, <1225> and <1226>.

Dr Bob McDowall
McDowall Consulting, Bromley, Kent, UK
Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry; Principal of McDowall Consulting, UK for over 20 years. He has been involved with the validation of computerised systems for over 25 years and is the author of a book on the validation of chromatography data systems. Bob is the writer of the Questions of Quality (LC-GC Europe) and Focus on Quality (Spectroscopy) columns and is a member of the Editorial Advisory Boards of several Journals.

Practical Statistical Tools for Analytical Laboratories

On 16-17 April 2015, i.e. on Thursday to Friday of the same week, there will be another ECA GMP Education Course in Barcelona about "Practical Statistical Tools for Analytical Laboratories".

This course will cover the following topics:

- (Normal) Distribution of Data and its Parameters
- Calculation and Evaluation of Precision Levels
- Trending of Data
- Design of Experiments (DoE) / Principles and the Investigation of Robustness
- Comparison of Data & Accuracy
- Calibration Models, Linear and non-Linear
- Performance Requirements for Impurity Procedures and Quantitation Limits

Speakers:
Dr Christopher Burgess,
Burgess Analytical Consultancy, UK
Dr Joachim Ermer, Sanofi, Germany

The courses "Lab Data Integrity", 13-15 April 2015, will be an ideal precursor to the Course "Practical Statistical Tools for Analytical Laboratories", 16-17 April 2015. Further information about this course can be received at www.gmp-compliance.org.

Participants who register simultaneously for both courses or all three courses will receive a 350€ discount (not valid for EU GMP Inspectorates).

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
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For questions regarding content:
Dr Günter Brendelberger (Operations Director) at +49-62 21 / 84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Susanne Ludwig (Organisation Manager) at +49-62 21 / 84 44 44, or per e-mail at ludwig@concept-heidelberg.de

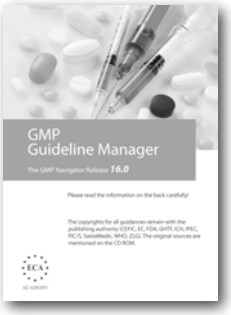
What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?



During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

Lufthansa is Mobility Partner for all ECA Events

Lufthansa Mobility Partner

As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

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☐ Lab Data Integrity (Part 1 AND Part 2)
13 – 15 April 2015, Barcelona, Spain
☐ Lab Data Integrity (Part 1 only), 13 – 14 April 2015, Barcelona, Spain
☐ Lab Data Integrity (Part 2 only), 14 – 15 April 2015, Barcelona, Spain
☐ Practical Statistical Tools for Analytical Laboratories, 16 – 17 April 2015, Barcelona, Spain

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **PO Number if applicable**

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

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)

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.

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GERMANY

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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Date Course 1: Establishing the Controls for Ensuring Laboratory Data Integrity

Monday, 13 April 2015, 09.00 h - 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Tuesday, 14 April 2015, 08.30 h - 12.30 h

Date Course 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

Tuesday, 14 April 2015, 13.30 h - 18.00 h
(Registration and coffee 13.00 h - 13.30 h)
Wednesday, 15 April 2015, 08.30 h – 16.00 h

Venue

Barceló Sants
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 490 60 45

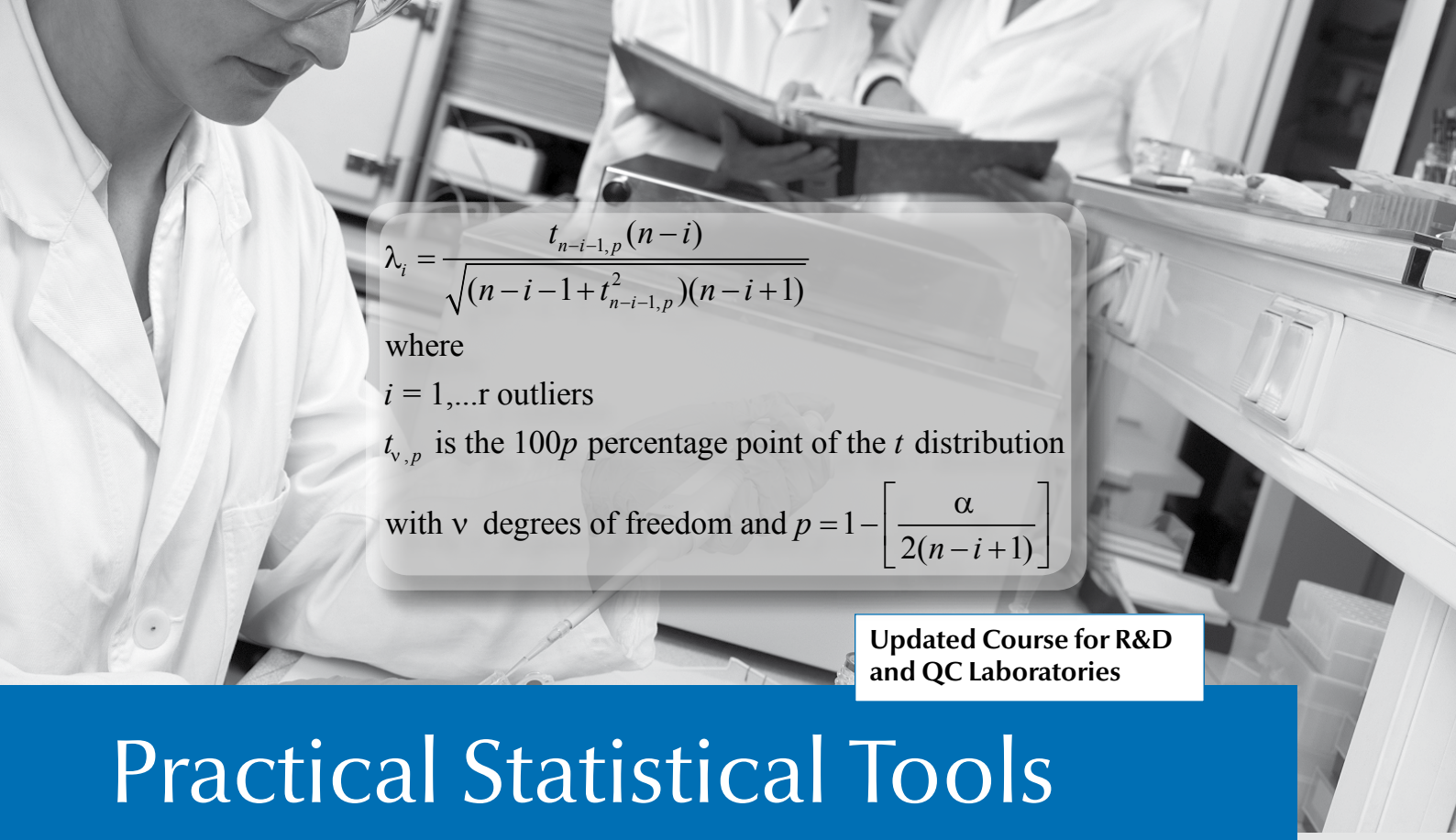
Fees (per delegate plus VAT)

Course 1: Establishing the Controls for Laboratory Data Integrity
ECA Members € 1,290
APIC Members € 1,390
Non-ECA Members € 1,490
EU GMP Inspectorates € 745
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.

Course 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls
ECA Members € 1,290
APIC Members € 1,390
Non-ECA Members € 1,490
EU GMP Inspectorates € 745
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch on the second day and all refreshments. VAT is reclaimable.

If you book <u>both courses</u> simultaneously, the fee for <u>each course</u> reduces as follows:
ECA Members € 1,090
APIC Members € 1,190
Non-ECA Members € 1,290
EU GMP Inspectorates € 645

If you register for the ECA Education Course "Practical Statistical Tools for Analytical Laboratories (16 to 17 April 2015) at the same time, you will receive a 350 € discount. This is not valid for EU GMP Inspectorates.



Updated Course for R&D and QC Laboratories

Practical Statistical Tools for Analytical Laboratories

Performance Evaluation and Monitoring for compliant Analytical Procedures and Processes

16 - 17 April 2015, Barcelona, Spain

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy

Dr Joachim Ermer
Sanofi, Germany

LEARNING OBJECTIVES:

- 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
  - perform Design of Experiments (DoE)
  - compare data and methods
  - establish reliable reporting/quantitation limits

ECA ACADEMY

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

16 - 17 April 2015, Barcelona, Spain

Objectives

Statistical calculations and tools are applied extensively in pharmaceutical analysis including:

- Method 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 (Draft) 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 USP Medicines Compendium, <10> "Assessing Validation Parameters for Reference and Acceptable Procedures".

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

(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

Design of Experiments (DoE) Principles and the Investigation of Robustness
- Why do we need Design of Experiments?
- Basics of DoE
- What is robustness?
- Worked example of DoE to the investigation of robustness

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

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, UK

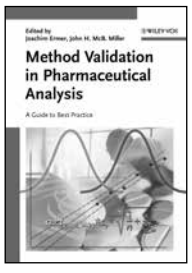
He is a Chartered Chemist and has more than 38 years experience in the pharmaceutical industry initially with Glaxo in Quality Assurance and Analytical R&D and then 20 years in international consultancy. He is a "Qualified Person" in the European Union and a member of the European QP Association advisory board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 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 Executive committee of European Compliance Academy. 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 Quality Control Services 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 20 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 Quality by Design working group.

Literature



Participants of this Course can purchase the new Edition of Dr Ermer's book "Method Validation in Pharmaceutical Analysis" (Wiley VCH, Weinheim 2014, ISBN: 978-3-527-33563-3) at a reduced price! You will receive the order form for this book at the course.

Lab Data Integrity

On 13 – 15 April 2015, i.e. on Monday to Wednesday of the same week, there will be another ECA GMP Education Course in Barcelona about **Lab Data Integrity.** This course will be divided in the following two parts:

Part I: Establishing the Controls for Ensuring Laboratory Data Integrity with the focus on paper / hybrid / e-records

and

Part II: Selfinspections and Audits to Confirm Effective Controls focussing on e-records

These courses will be an ideal precursor to the Education Course **Practical Statistical Tools for Analytical Laboratories** (16 - 17 April 2015). Further information about this course can be received at www.gmp-compliance.org.

Participants who register simultaneously for **both courses or all three courses will receive a 350€ discount** (not valid for EU GMP Inspectorates)

Social Event

On Thursday, 16 April 2015, 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.

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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Fax ++49-62 21/84 44 34
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For questions regarding content:
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at ++49-62 21 / 84 44 40 or at
brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Susanne Ludwig (Organisation Manager)
at ++49-62 21 / 84 44 44 or per e-mail at
ludwig@concept-heidelberg.de.

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

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This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

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On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Easy Registration

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69007 Heidelberg
Germany

Reservation Form:
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I would also like to register for the Education Course "Lab Data Integrity"

☐ Part I AND Part II (13-15 April 2015)
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- until 2 weeks prior to the conference 10 %,
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Date

Thursday, 16 April 2015,
09.00 - 18.00 h
(Registration and coffee
08.30 – 09.00 h)
Friday, 17 April 2015,
08.30 - 16.00 h

Venue

Barceló Sants
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 490 60 45

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.

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CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

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