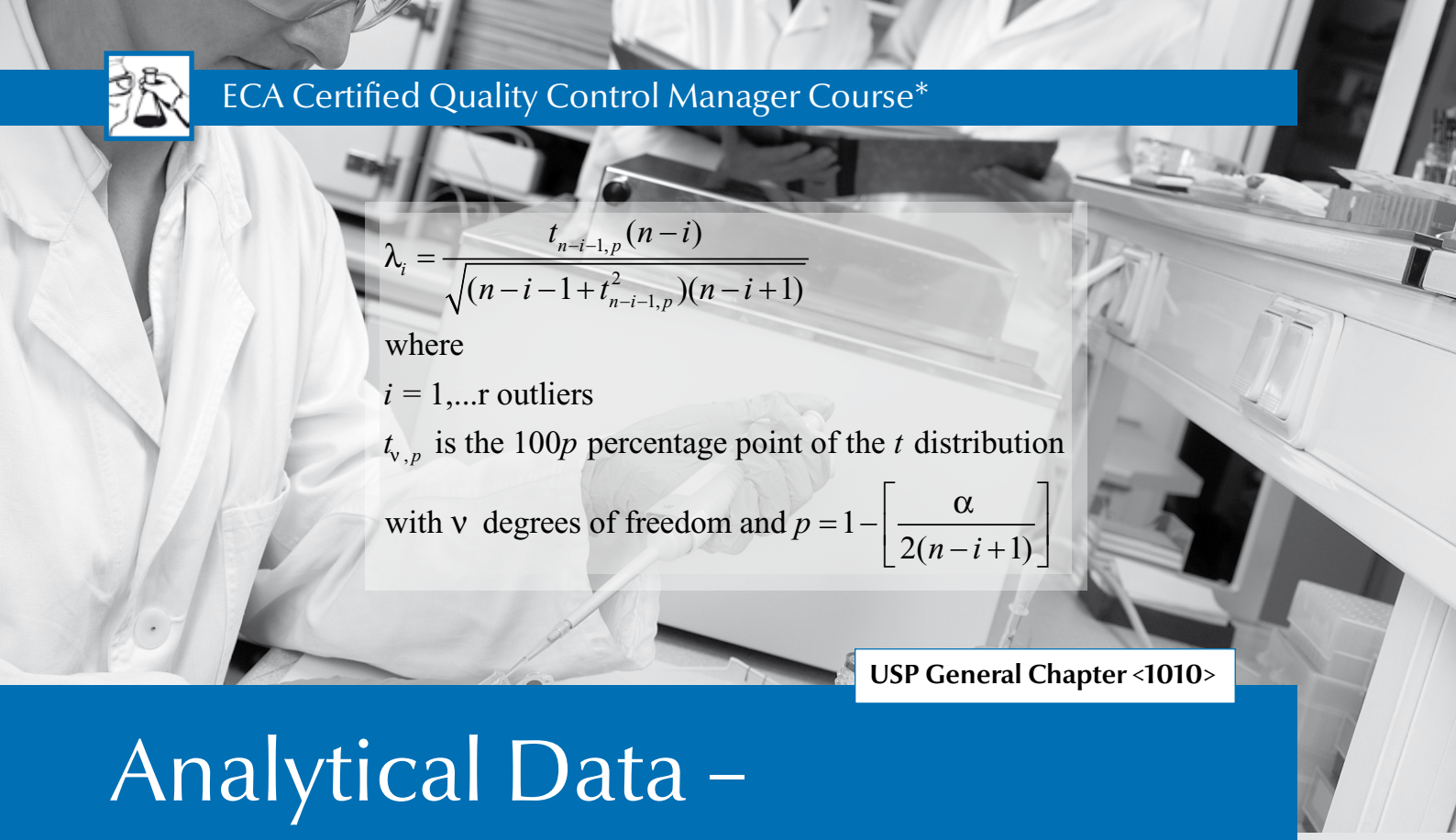
ECA Certified Quality Control Manager Course*



USP General Chapter <1010>

Analytical Data – Interpretation and Treatment

A Practical Introduction to the Requirements of USP General Chapter <1010> on Statistical Approaches for Evaluating Data

8 - 9 November 2010, Amsterdam, The Netherlands

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy

Dr Joachim Ermer
Sanofi-Aventis

LEARNING OBJECTIVES:

- Recommendations of USP Chapter <1010>
- Variability of Data
  - Standard deviation, mean and averaging
  - ANOVA
  - Optimisation of precision
  - Control charts: Shewhart and CuSum
  - Out-of-Specification Results
- How to Compare Analytical Methods
- Approaches for Detection and Quantitation Limits
- Product Quality Review
  - How to assess trends

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Analytical Data – Interpretation and Treatment

8 - 9 November 2010, Amsterdam, The Netherlands

Objectives

This course will cover the following topics from UPS <1010>:

- The background and usage of the general chapter
- Good laboratory practices for the recording and reporting of data
- Measurement principles and variation
- Outlying results
- Comparison of analytical methods

It will also provide the participants with recommendations, tools and examples to apply statistical principles scientifically and pragmatically sound in their day-to-day business. This includes, for example, questions from areas as OOS investigations, calibration models, trend analysis (a hot topic due to recent FDA, EU and PIC/S requirements), detection and quantitation limit.

One of the main features of this workshop is the **inclusion of exercises** which will allow participants to gain 'hands on' practical experience in applying the statistical methods described to real data sets. The objective is to ensure that participants using only pen and paper aided by a pocket calculator can become confident in the use of such methods. For this reason, the course is **limited to 30 participants** so that individual attention and support can be given.
Note: Attendees should bring a ruler and a pocket calculator (or a notebook with Excel®) for the workshops in order to fully benefit from the course.

Background

One of the key conclusions of the Barr Ruling (Wolin Judgement) was that statistical procedures such as outlier testing must not be used for chemical analysis data because they were not specified in the United States Pharmacopoeia (USP). As a consequence the USP has prepared a General Information Chapter <1010>, which became official in 2005. This chapter provides information regarding acceptable practices for the analysis and consistent interpretation of data obtained from chemical and other analyses. **Basic statistical approaches for evaluating data are described**, and the treatment of outliers and comparison of analytical methods are included.
The aim of this two day course is to provide a practical guide to the implementation of <1010> as part of best laboratory practices for the analysis and evaluation of analytical data.

Target Group

This user-friendly course is designed for analytical laboratory managers and their colleagues charged with the day to day management and evaluation of laboratory data in an FDA regulated environment. In addition, **QA and regulatory affairs professionals will benefit from participation** by gaining a clear understanding of the latest USP requirements.

Programme

Session 1: Overview and Background

Introduction to General Chapter <1010>

- Why was it written?
- The role of <1010> in the context of the USP
- Prerequisite laboratory practices and principles
- Sampling considerations
- Use of reference standards
- System performance verification
- Method validation and verification (General Chapters <1225> & <1226>)
- Record keeping

Dr Christopher Burgess, Burgess Analytical Consultancy

Session 2: Variability of Data

Measurement Principles and Variation

- Sources and types of error
- Normal distribution of analytical data
- Standard deviation, mean, and averaging
- Introduction to confidence intervals
- Precision studies and ANOVA

Dr Joachim Ermer, Sanofi-Aventis

Exercise 1: ANOVA for Intermediate Precision

Exercise 2: Optimisation of Precision

Control Charting

- Process capability and control charting
- Shewhart Charts
- CuSum Charts

Dr Christopher Burgess, Burgess Analytical Consultancy

Exercise 3: Control Charts

Outlying Results

- Requirements in FDA's new Guidance for Industry on Investigating Out-of-Specification Results
- Atypical or aberrant results
  - OOS – Out of Specification
  - OOE – Out of Expectation
  - OOT – Out of Trend
- Statistical outlier tests
  - Z scores
  - ESD (Grubbs Test)
  - Dixon's Q
  - Hampel's rule

Dr Christopher Burgess, Burgess Analytical Consultancy

Exercise 4: Outlier Testing

Session 3: Comparison of Results

Comparison of Analytical Methods

- Accuracy and precision
- The role of t and F test
- Assumptions and limitations
- Equivalence testing, largest acceptable difference between two methods
- Sample size determination

Dr Joachim Ermer, Sanofi-Aventis

Exercise 5: Comparing Results

Session 4: Guidance Omissions from <1010>

Calibration Models

- Common types of calibration model
- How good is my calibration model?
- Confidence of prediction from calibration models

Dr Christopher Burgess, Burgess Analytical Consultancy

Exercise 6: Product Quality Review / Trend Analysis

Trend Analysis

Trend Analyses are required in:

- FDA's Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations: "Analyze Data for Trends – Quality systems call for continually monitoring trends and improving systems
- EU GMP Guide Chapter 6: "6.9 For some kinds of data (e.g. analytical test results, yields, environmental controls, ...) it is recommended that records be kept in a manner permitting trend evaluation.
- PIC/S Aide-Memoire Inspection of Pharmaceutical Quality Control Laboratories: "Trending – Do you assess trends? How and by whom are trends evaluated? SOP exists?"

Detection and Quantitation Limits

- Requirements in pharmaceutical impurity determination
- Distribution of blank and analyte measurement data
- DL/QL approaches and their comparison

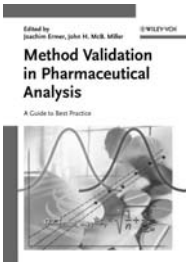
Dr Joachim Ermer, Sanofi-Aventis

Exercise 7: Detection and Quantitation Limits

Feedback from a former participant:
„The course was really a good combination of the issues under <1010>. Lecturers were real professionals in this area. ...
The advice given and lessons learned have already proven useful in our company."
Mr Miko Alanko, Schering Oy, Finland

Literature

Participants of this Course can purchase Dr Ermer's book „Method Validation in Pharmaceutical Analysis" (Wiley VCH, Weinheim 2005, ISBN: 3-527-31255-2) at a 15% reduced price! You will receive the order form for this book at the course.



Speakers

Dr Christopher Burgess

Burgess Analytical Consultancy, UK

Chartered Chemist with more than 30 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R & D. He is a "Qualified Person" and a qualified ISO 17 025 Guide assessor and was member of the PDA (USA) ‚OOS Task Force'.

Dr Joachim Ermer

Sanofi-Aventis Deutschland GmbH, Germany

Head of Quality Control Chemistry, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany. Deputy Head of the Working Group Quality Control / Pharmaceutical Analytics, German Pharmaceutical Society.

Moderator

Dr Christopher Burgess, *Burgess Analytical Consultancy, UK*

Social Event

On the evening of the first course day all participants and speakers are invited to dinner in the restaurant of the Mövenpick hotel in Amsterdam.

ECA Education Course
FDA Compliance in Analytical Laboratories
10-12 November 2010

On 10 –12 November 2010, i.e. from Wednesday to Friday of the same week, there will be another ECA GMP Education Course in Amsterdam about FDA Compliance in Analytical Laboratories. The objective of this course is to give the participants comprehensive insight into the key laboratory compliance issues for laboratories in an FDA-regulated environment.

Topics that will be covered are:

- Regulatory Requirements and FDA Inspections
- Documentation in the Pharmaceutical Quality Control
- Sampling in Compliance with FDA Requirements
- Qualification of Analytical Instruments in the QC
- Calibration for FDA Inspected Analytical Laboratories
- Reference Standards and Reagents for FDA-inspected Laboratories
- Validation of Analytical Procedures
- Stability Testing
- Out of Specification Results
- Practical Computer Validation in Analytical Laboratories
- Transfer of Analytical Procedures
- Validation of Excel Spreadsheets
- Training Case Study

In addition, Workshops are offered about:

- Method Validation
- Out of Specification Results
- Validation of Excel-Spreadsheets
- Method Transfer

Speakers:
Dr Wilfried Arz, Sanofi-Aventis ,Germany
Dr Manfred Fischer, SkyePharma AG, Switzerland
Dr Christopher Burgess, Burgess Analytical Consultancy, UK
Jürgen Martin, Nycomed, Germany
Dr Joachim Ermer, Sanofi-Aventis, Germany
Dr Bob McDowall, McDowall Consulting, UK

The course on USP Monograph <1010> Analytical Data – Interpretation and Treatment (8 - 9 November 2010) is an ideal precursor to the Education Course FDA-Compliance in Analytical Laboratories (10 -12 November 2010). Further information about the course FDA-Compliance in Analytical Laboratories can be received at www.gmp-compliance.org.

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

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

Date

Monday, 8 November 2010, 09.00 h - 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Tuesday, 9 November 2010, 08.30 h - 16.30 h

Venue

Mövenpick Hotel Amsterdam City Centre
Piet Heinkade 11
1019 BR Amsterdam
The Netherlands
Phone + 31 20 519 12 00
Fax + 31 20 519 12 49

Fees

Non-ECA Members € 1,690.- per delegate plus VAT
ECA Members € 1,521.- per delegate plus VAT
APIC Members € 1,605.- per delegate plus VAT
(does not include ECA membership)
EU GMP Inspectorates € 845.- per delegate plus VAT
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.

If you register for the ECA Education Course "FDA Compliance in Analytical Laboratories" from 10-12 November 2010 at the same time, you will receive a 350 € discount. This is 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 or be sure to mention "Concept Heidelberg" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 27 September 2010. 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

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany,
Phone ++49-62 21/84 44-0, Fax ++49-62 21/84 44 84
info@concept-heidelberg.de, www.concept-heidelberg.de

For questions regarding content:
Dr Günter Brendelberger (Operations Director)
at ++49-62 21 / 84 44 40 or at
brendelberger@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager)
at ++49-62 21 / 84 44 46 or per e-mail at
weidemaier@concept-heidelberg.de.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.
The ECA will provide 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.

What Are the Benefits of ECA?
First benefit:
During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guidelines Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG.

More information about ECA can be obtained on the Website **http://www.gmp-compliance.org**

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme for the module „Certified Quality Control Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following qualification levels:

- 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

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

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34 

Analytical Data – Interpretation and Treatment
8 - 9 November 2010, Amsterdam, The Netherlands

☐ I would also like to register for the Education Course
FDA Compliance in Analytical Laboratories, 10-12 November 2010, Amsterdam, The Netherlands

☐ 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)

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.
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)!