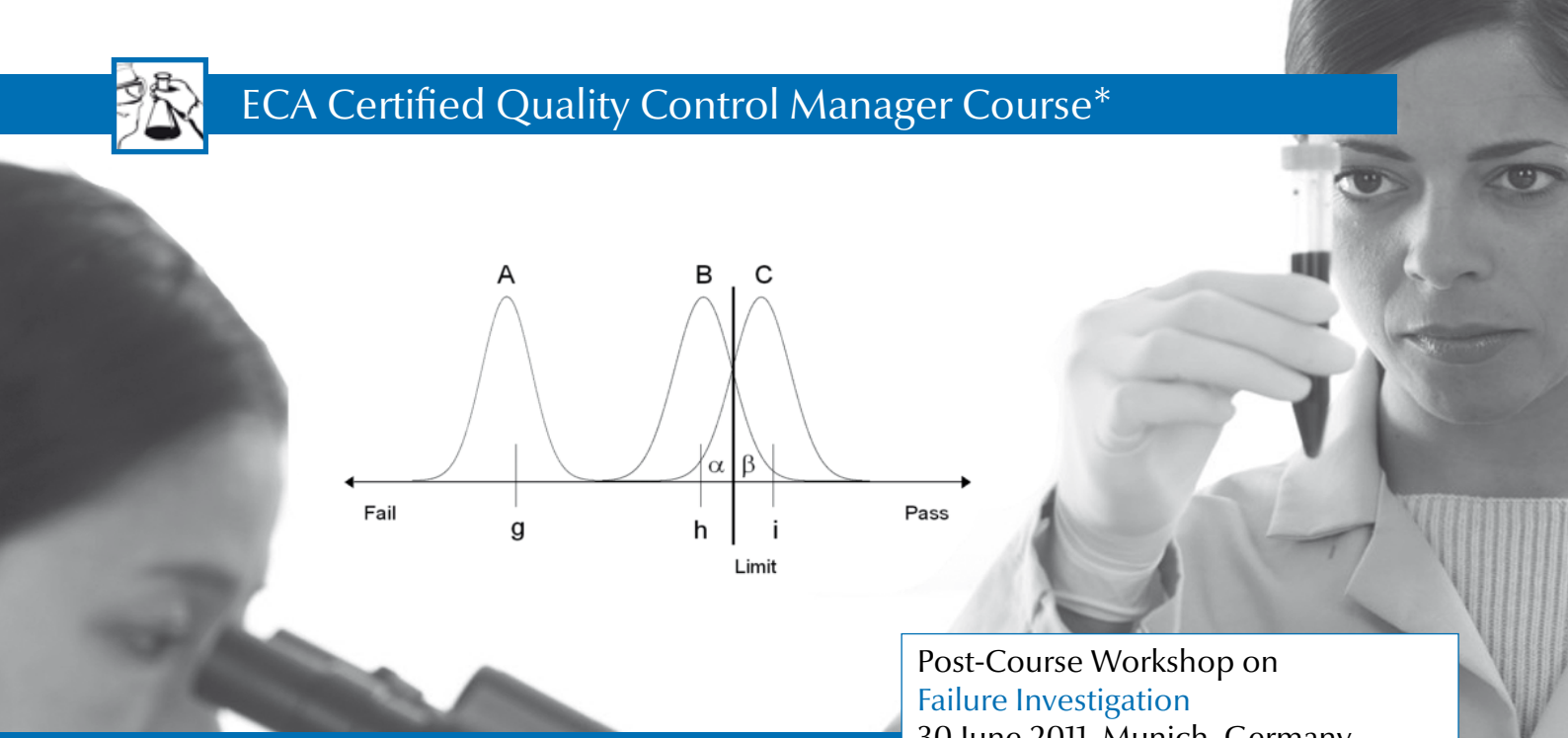
ECA Certified Quality Control Manager Course*



Post-Course Workshop on
Failure Investigation
30 June 2011, Munich, Germany

Out-of-Specification Results

Practical solutions on how to deal with OOS or atypical results in your laboratory

28 – 29 June 2011, Munich, Germany

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Dr Matthias Heuermann
LIGA.NRW, Münster, Germany

Dr Olaf Kunze
CSL Behring GmbH, Germany

Dr Bernd Renger
Bernd Renger Pharma Consulting

PROGRAMME:

- FDA's Final Guidance on Investigating OOS Test Results
- OOS Results in Analytical Laboratories
  - How to Identify and Investigate OOS Results
  - Reportable Value
  - Number of Retests
  - Strategies How to Avoid Them
  - Documentation
- Statistical Aspects
- OOS Results in R&D Laboratories
  - OOS SOP in R&D
  - OOS in Stability Testing
  - OOS in Clinical Trial Samples
- In Specification Results: Analytical Data Quality and Scientifically Sound Specifications
- OOS Results – What Does an European GMP Inspector Expect?

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

Out-of-Specification Results

28 – 29 June 2011, Munich, Germany

Learning Objectives

FDA's final Guidance for Industry titled **"Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production"** published in October 2006 addresses issues, such as:

- Responsibilities of the analyst and supervisor
- Retesting
- Resampling
- The appropriate and inappropriate use of averaging test results
- Statistical outlier tests

This OOS Guidance covers many points that are relevant to the investigations to be started in pharmaceutical laboratories once OOS results have occured.

The key elements of this final FDA OOS Guidance from October 2006 will be presented and discussed at this course.

Since the often cited Barr ruling (Wolin Judgement) of February 1993 pharmaceutical companies all around the world have implemented procedures and strategies on how to deal with results that do not comply with their predetermined specifications. Although 15 years have passed since that judgement, the investigation of OOS results is still a hot topic in FDA inspections. The incorrect handling and investigation of OOS results is a continuing source of 483 citations and Warning Letters.

In the everyday practice of analytical laboratories there are still uncertainties with regard to the GMP-compliant handling of OOS results and investigations.

This GMP Education Course will offer you practical solutions on how to deal with OOS or atypical results in your laboratory.

Key elements of this Education Course are **Workshops**. On both days workshops are offered to make this course as practice-oriented as possible. The instructors will provide workshop attendees with example problems to be solved, case studies and true industry examples.

Target Group

This course is intended for all levels of technical and managerial personnel dealing with out-of-specification results, including analytical laboratories, contract laboratories and employees in the Quality Assurance/Quality Control.

Moderator

Dr Christopher Burgess
Burgess Analytical Consultancy Ltd., Barnard Castle, UK

Programme

Introduction to the Investigation of OOS Test Results

- Barr case as starting point of the OOS regulations
- Restriction in scope of new guidance
- Positioning of the new guidance in the context of risk-based CGMPs and ICH Q10
- UPS General Chapter <1010> and FDA
- Key discussion points from the PDA OOS Expert Working Group

Dr Christopher Burgess, *Burgess Analytical Consultancy*

Evaluation of OOS Test Results in Quality Control Laboratories

- How to appropriately investigate the OOS problems
- Identification of OOS results
- Specifications
- Reportable value
- Isolation/invalidation of initial OOS results
- Number of retests
- Initial phase of laboratory investigation
- When should you inform QA and Production?
- Evaluation
- Strategies on how to avoid OOS Results in the Lab
  - Equipment qualification
  - Method validation – robustness testing
  - System suitability tests
  - Effective prevention strategies

Dr Olaf Kunze, *CSL Behring GmbH*

Documentation of OOS Results and Trend Analyses

- FDA expectations on OOS documentation
- Reporting of OOS results in quality and product review
- Documentation and raw data handling in case of abandoned tests, apparent errors or assignable causes
- Link of OOS investigations with deviation and CAPA system
  - Use of control charts
  - Trend analysis
- Retesting protocol and documentation
- Presenting OOS results in FDA inspections

Dr Bernd Renger, *Vetter Pharma-Fertigung GmbH*

FDA's "Guidance for Industry Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production"

- FDA's position on data integrity and data quality
- The draft OOS guidance of 1998
- Current issues as evidenced by Warning Letters, 483s and EIRs
- Final Guidance 2006; Scope & Applicability
- Key issues and differences from the 1998 draft

Dr Christopher Burgess, *Burgess Analytical Consultancy*

Statistical Aspects of Atypical or Aberrant Results

- Analytical processes and their capabilities
- Specifications and compliance
- Reportable value
- Atypical and aberrant results; USP General Chapter <1010>
- Outliers and their detection
- Confidence intervals in OOS investigations

Dr Christopher Burgess, *Burgess Analytical Consultancy*

OOS Results in R&D Laboratories

- The revised scope of the final OOS Guidance
- OOS SOP in R&D?
- OOE in scale-up activities
- OOE/OOS in validation and qualification
- OOE/OOT/OOS in stability
- OOS in clinical trial samples
- Variability and specifications

Dr Bernd Renger, *Vetter Pharma-Fertigung GmbH*

In Specification Results; Analytical Data Quality and Scientifically Sound Specifications

- In specification results and 'fitness for purpose'
- Process capability in the context of data quality management and the Quality System Approach
- Trend analysis and data quality
- Quality management of reportable results
- Migrating from fixed limits to risk-based scientifically sound specifications as required by 21CFR §160(b)

Dr Christopher Burgess, *Burgess Analytical Consultancy*

OOS Results – Expectations of a European GMP Inspector

- OOS results definition
- OOS results and drug legislation
- Expectations of the competent authority
- OOS SOP
- Frequently asked questions
- Surveillance of the release decision

Dr Matthias Heuermann, *LIGA.NRW*

Workshops

Practical workshops are an essential part of this GMP Education Course. Workshops will be offered on both course days.

Day 1
Workshop I
Typical examples of OOS results in the analytical laboratory will be presented and discussed in small workshop groups on the first day. The members of the workshop groups have to identify the OOS issues and to discuss and propose specific plans of action.

Day 2
Participants choose EITHER

Workshop II
Starting from the FDA final guidance participants will develop a flow chart that takes into consideration the various requirements of the guidance and describes responsibilities and the sequence of activities following an initial OOS result. Critical points will be discussed and specific issues will be addressed.

OR
Workshop III
Laboratory OOS results scenarios will be presented and evaluated in workshop groups.

Social Event

In the evening of the first course day, all participants are invited to a guided sight-seeing tour and a dinner in the city of Munich afterwards – free of charge!

Post-Course Workshop on
Failure Investigation
30 June 2011, Munich, Germany

Objectives

The outcome of a laboratory-based failure investigation requires often a QA authorised and QA led formal investigation extending into production and, where appropriate, the raw material and packaging material supply chain. The workshop is a continuation of the OOS GMP Education Course and takes a confirmed OOS result as its starting point. The purpose of the workshop is to allow **QC and QA professionals** to explore a tutor-led interactive case study. **Formal investigation requirements will be discussed and illustrated with real-life examples.** Attendees will have the opportunity of working within small teams facilitated by the tutors.

Participants will
- evaluate the case study
- assign likely root causes and
- present their conclusions

Key learning points will be captured during a feedback and discussion session. This will be preceded by presentations on the conduct and documentation of such investigations, process mapping and risk-based assessment methods designed to assist in establishing root cause of failures.

Programme

- Introduction, aims, and objectives
- Impact of ICH Guidelines Q 8 and Q 9 (Annex 20)
- FDA Guidance "Quality Systems Approach" (Sept. 2006) and ICH Guideline Q10 (step 4, June 2008)
- Failure investigation processes
- Risk assessment methodologies
  - Failure Mode Effect Analysis (FMEA)
  - Hazard Analysis Critical Control Points (HACCP)
  - etc.
- Process mapping and root cause analysis
- Corrective and Preventive Actions (CAPA) Overview
- Case study session
- Report back by teams and criticism
- Final discussion

Start of the Workshop: 09.00 h
End of the Workshop: approx. 16.00 h

Facilitators

Dr Christopher Burgess,
Burgess Analytical Consultancy, Barnard Castle, UK

Dr Bernd Renger,
Bernd Renger Pharma Consulting GmbH, Germany

Speakers

Dr Christopher Burgess
Burgess Analytical Consultancy Limited, Barnard Castle, UK

Chris Burgess is an elected member of the USP Council of Experts on General Chapters, 2010-2015 and member of the Qualified Person Association Advisory Board. During his time in industry he worked mainly for Glaxo (now GSK) in Quality Control, Quality Assurance and Analytical R&D positions. He has recently been appointed as Visiting Professor at the Strathclyde Institute of Pharmacy and Biomedical Sciences (SIPBS) within the University of Strathclyde's Faculty of Science.'

Dr Matthias Heuermann
LIGA.NRW, Münster, Germany

Since 2004 Dr. Heuermann is employed as head of the **O**fficial **M**edicines **C**ontrol **L**aboratory (OMCL), today within the Institute for Health and Work of the federal state Nordrhein-Westfalen (LIGA.NRW) in Münster. He studied pharmacy and gained his PhD thesis at the University of Münster, Germany. Since 1995 Dr Heuermann has been working as a GLP inspector, and he has been involved in GMP inspections, mainly focused on the QC laboratories and QA systems and has gained experiences from national and international GMP inspections.

Dr Olaf Kunze
CSL Behring GmbH, Marburg, Germany

Dr Kunze was employed with Henning Berlin and later with Engelhard Arzneimittel, where he worked first as head of the laboratory for analytical development and later as quality manager in charge of overall quality control. Since March 1998, Dr Kunze has been employed as head of analytical chemistry laboratories with Aventis Behring, now as Director Quality Control Chemistry with CSL Behring in Marburg, Germany.

Dr Bernd Renger
Bernd Renger Pharma Consulting GmbH, Germany

Dr Bernd Renger is a member of the ECA Advisory Board and Chairman of the European QP Association. Since 2011, he is running his own consultancy business. Before that he was Director of Quality Control at Vetter Pharma-Fertigung. He started his career at Hoechst AG as a research and development chemist. Since then, he has held several quality positions at Mundipharma, Altana Pharma and Baxter.

Organisation and Contact

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Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: 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 per e-mail at brendelberger@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Jessica Stürmer (Organisation Manager) at +49-62 21 / 84 44 43, or per e-mail at stuermer@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 200 € discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit: The GMP Guideline 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**

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

GMP Certification Programme

This course is recognised within the GMP Certification Programme Module „Quality Control Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- 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)

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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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)

+ 49 6221 84 44 34

Out-of-Specification Results, 28-29 June 2011, Munich, Germany

☐ Yes, I also want to participate in the **Post-Course Workshop on Failure Investigation**, 30 June 2011, Munich, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number, if applicable**

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

If the bill-to-address deviates from the specifications on the right, please fill out here:

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

D-69007 Heidelberg
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.
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)!

Date

GMP Education Course Out-of-Specification Results
Tuesday, 28 June 2011, 9.00 – 18.30 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 29 June 2011, 8.30 – 16.30 h

Post-Course Workshop on Failure Investigation
Thursday, 30 June 2011, 9.00 – 16.00 h
(Registration and coffee 8.30 – 9.00 h)

Venue

Holiday-Inn Munich City Centre
Hochstraße 3
81669 Munich, Germany
Phone + 49 / (0) 89 4803 0
Fax + 49 / (0) 89 4487170

Fees

Education Course only
ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590,- per delegate plus VAT
(does not include ECA membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT

Education Course and Post-Course Workshop
ECA Members € 1,990.- per delegate plus VAT
APIC Members € 2,090.- per delegate plus VAT
(does not include ECA membership)
Non-ECA Members € 2,190.- per delegate plus VAT
EU GMP Inspectorates € 1,095.- 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 all 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 when you have registered for the conference. Please use this form for your room reservation or be sure to mention "ECA" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 28 May 2011. 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.