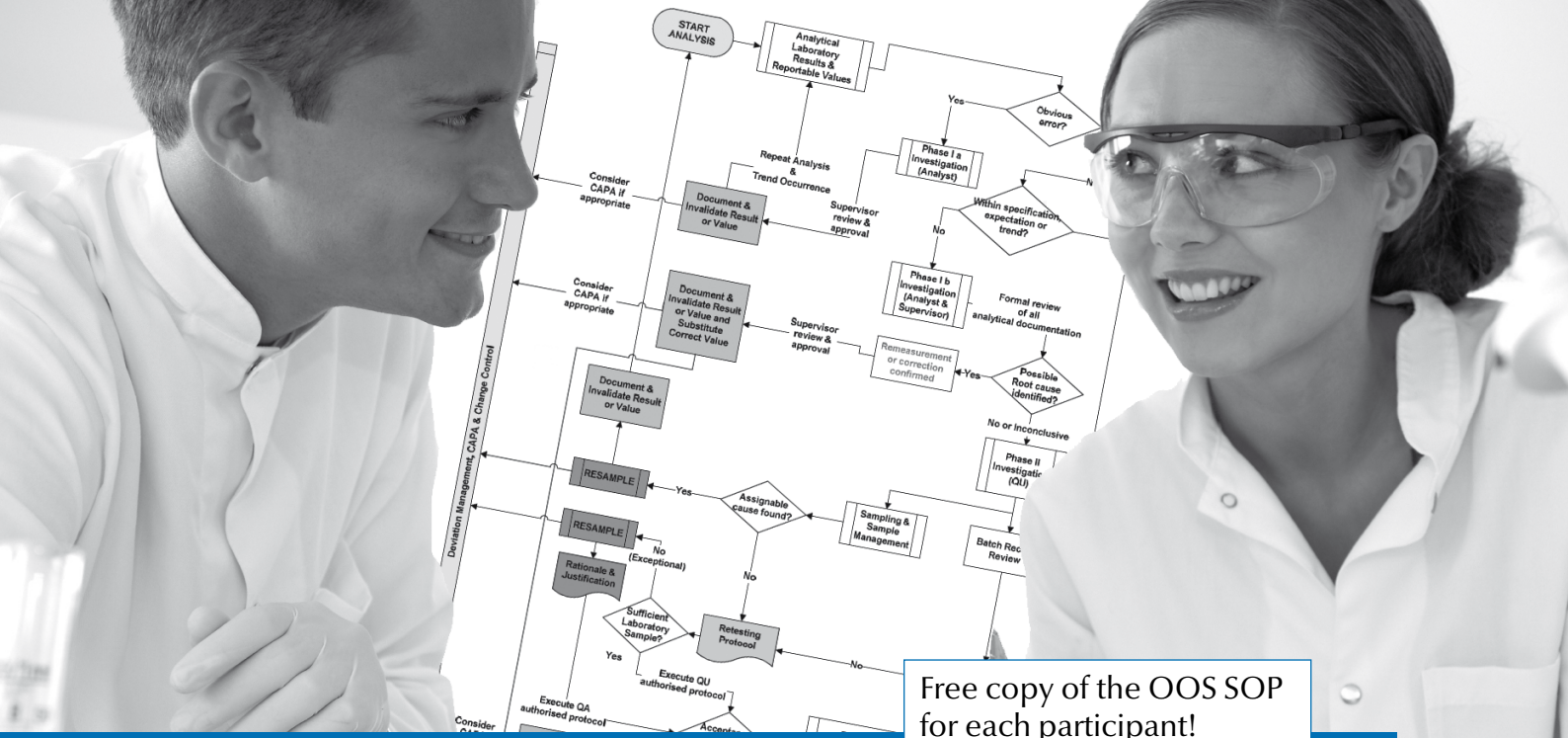

Free copy of the OOS SOP for each participant!

OOS Training Course

Learn all about the OOS SOP Version 2 developed by ECA to comply with FDA and EU standards

9 – 10 April 2013, Copenhagen, Denmark

SPEAKERS:

Dr Christopher Burgess
Chairman of the ECA Analytical Quality Control Working Group, UK

Dr Matthias Heuermann
European GMP Inspector, NRW Centre for Health (LZG.NRW), Germany

Dr Olaf Kunze
CSL Behring GmbH, Germany

Dr Bernd Renger
European QP Association, Germany

PROGRAMME:

- OOS: US /FDA Regulatory Expectations
- Requirements and Expectations of a European GMP Inspector
- Presentation and Discussion of ECA's Analytical Quality Control Working Group OOS SOP (Version 02)
- Statistical Approaches – How Many Retest Samples are Needed?
- Strategies How to Avoid OOS Results
- OOS Results in R&D Laboratories
  - OOS SOP in R&D
  - OOS in Stability Testing
  - OOS in Clinical Trial Samples
- Out of Trend Results (OOT) – Identification, Investigation and Evaluation
- OOS for Discrete Parameters / AQLs
- OOS in Biologics and Microbiological Labs

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

OOS Training Course

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Objectives

FDA's final Guidance for Industry titled "Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production" was published in 2006. It covers the points that are relevant to the investigations in pharmaceutical laboratories once OOS results have occurred. Unfortunately, the inappropriate handling and investigation of OOS results is still a continuing source of 483 citations and Warning Letters and the investigation of OOS results is still a hot topic in FDA inspections.

A separate European OOS guidance was not considered necessary by most competent authorities as they found the FDA Guidance generally acceptable. However there were problems with individual companies QA departments how to interpret the FDA guideline. Therefore the MHRA published a response in UK in 2010 to problems of interpretation that they had seen in order to issue Guidance.

The **ECA Working Group on Analytical Quality Control** was set up in 2010 in attempt to generate a harmonised SOP on managing analytical deviations within the laboratory including OOS, OOE and OOT results. More than 100 ECA members were registered as OOS Review Team Members and approx. 80 members provided their feedback, first to the general OOS Flowchart and second to the draft OOS SOP. The result was a framework **SOP Version 1 which was launched at the OOS Forum in Prague on 19 – 20 June 2012.**

The purpose of the OOS Forum was to discuss that document and other inputs as well as consider debate these alternative approaches in order to provide a broader basis of discussion which resulted in version 2 of this document.
Version 02 of the ECA OOS SOP was finally approved in August 2013.

ECA's ultimate goal is to have one basic global framework for handling OOS results within QC laboratories acceptable to the authorities which individual companies may adapt to fit their particular Quality Management System.

It was decided at the OOS Forum that this SOP should focus on OOS results only, while OOE and OOT results would be addressed in a future SOP. This is one of the next tasks for ECA's QC Working Group.

It is the intend of this course to present ECA's final OOS SOP in detail and to address practical case studies how to deal with OOS results in analytical laboratories today.

Target Group

This conference is intended for all levels of technical staff and managers dealing with out-of-specification results, including analytical laboratories, contract laboratories, and Quality Assurance/Quality Control.

Programme

OOS: US / FDA and EU Regulatory Expectations

- Background to the FDA Final Guidance 2006
- Long standing FDA Principles
- Key points from the Final Guidance
  - Scope
  - Investigation Processes
  - Roles and Responsibilities
  - Analysis and reporting of results
  - Outlier testing
  - Cautions

Dr Christopher Burgess

OOS Results - Expectations of a European GMP Inspector

- The OOS SOP
- Definition of in-spec- and out-spec-Results
- OOS Investigation phases
- Batch disposition
- Surveillance of the release decision
- ECA OOS SOP versus MHRA approach
- Practical examples from inspections

Dr Matthias Heuermann

Strategies not to generate OOS Results

- Analytical Validation & Variability
- Specifications and Limits
- SST and RSD of SD
- Trending and Process Capability
- The concept of Analytical Uncertainty
- Decision points during testing

Dr Bernd Renger

Workshops

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

WORKSHOP I:
ECA Analytical Quality Control Working Group OOS SOP (Version 02)
Participants will discuss the background, scope and limitations, the process and the key elements and the process flow of Version 02 of ECA's OOS SOP.
Moderator: Dr Christopher Burgess

Statistical Appendices in ECA's OOS SOP

- Inconclusive laboratory investigations
- FDA approach to outlier 'isolation' by retesting
- How many retest samples are needed?
- Traditional confidence interval approach
- Strengths and weaknesses
- Robust methodology

Dr Christopher Burgess

OOS Results in R&D Laboratories
- Drug development &analytical life cycle
- Aberrant analytical data in R&D
- OOE results in preclinical development & investigation medicinal products
- OOE in bioassay samples
- OOE and OOT results in stability studies

Dr Bernd Renger

Out of Trend Results
- Time dependent parameter
- Trending tools
- Identification of trends
- Investigation and evaluation of trends.

Dr Olaf Kunze

OOS for Discrete Parameters
- Basic differences between attributes and variables
- Distributional requirements
- AQLs and OOS Resampling and retesting for attributes
- Control charts for attributes
- Applications for attribute data

Dr Christopher Burgess

OOS in Biologics
- Biological Assays
- Intermediates
- Real time equipment or system adjustments
- OOE
- Stability OOS
- OOS results in microbiological labs

Dr Olaf Kunze

WORKSHOP II
Laboratory OOS Results Scenarios
Typical examples of OOS results in the analytical laboratory will be presented and discussed in small workshop groups on the second day. The members of the workshop groups have to identify the OOS issues and to discuss and propose specific plans of action.
Moderator: Dr Bernd Renger

Moderator

Dr Christopher Burgess
Chairman of the Analytical QC Group, UK

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 Copenhagen afterwards!

Speakers

Dr Christopher Burgess
Burgess Analytical Consultancy Limited, UK
Dr Burgess is a Chartered Chemist and has more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" 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

Dr Matthias Heuermann
NRW Centre for Health (LZG.NRW), Münster, Germany
Since 2004 Dr. Heuermann is employed as head of the Official Medicines Control Laboratory (OMCL), today within the NRW Centre for Health of the federal state Nordrhein-Westfalen 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 held several positions in the quality organisation at CSL Behring Marburg Germany. He is now employed as a qualified person and head of quality control support.

Dr Bernd Renger
European QP Association, 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 VP 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 management positions at Mundipharma, Altana Pharma and Baxter.

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

OOS Training Course
9 – 10 April 2013, Copenhagen, Denmark

☐ 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

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E-Mail (please fill in)

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

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Fax +49 (0) 62 21/84 44 34

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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.
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)

Date

Tuesday, 9 April 2013, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 10 April 2013, 08.30-16.00 h

Venue

Radisson BLU Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S
Denmark
Phone +45 33 96 50 00
Fax +45 33 96 55 55

Fees

ECA Members EUR 1,490.- per delegate plus VAT
APIC Members EUR 1,590.- per delegate plus VAT (does not include ECA Membership)
Non-ECA Members EUR 1,690.- per delegate plus VAT
EU GMP Inspectorates EUR 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 all two 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. 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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
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.:
Ms Jessica Stürmer (Organisation Manager) at +49-62 21 / 84 44 43, or per e-mail at stuermer@concept-heidelberg.de.

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