Speakers:

Dr Christopher Burgess
Chairman of the Analytical Quality Control Working Group

Stephen Young
Head of Analytical Science Inspection, Enforcement and Standards Division, MHRA, UK

Dr Peter Rauenbuehler
Roche, USA

Dr Bernd Renger
Member of the Analytical Quality Control Working Group

Dr Lance Smallshaw
UCB Biopharma sprl, Belgium

Dr Bianca Teodorescu
UCB Biopharma sprl, Belgium

Every participant will receive the Draft Version of ECA's SOP on OOE and OOT Results!

ECA ACADEMY

International Conference

OOT Forum 2014

SOP Out of Expectation (OOE) and Out of Trend (OOT) Results

Compiled by ECA's Analytical Quality Control Working Group

Prague, Czech Republic, 22 - 23 October 2014

Highlights

- Methods and Approaches for Detecting
  - Out of Expectation (OOE) Data
  - Out of Trend (OOT) Data, where no Trend is Expected
  - Out of Trend (OOT) Data, where a Trend is Expected, e.g. for Stability Testing
- Become Part of the Peer Review Group to have a direct impact on the contents of this new document:
  All participants will have the opportunity to provide input to the contents of this guidance document during the interactive 'critique of the proposals' sessions for each of these topics.

Objective

The **ECA Working Group on Analytical Quality Control** was set up in 2010 in order to generate a harmonised SOP on managing analytical deviations within the laboratory including OOS, OOE and OOT results.

The result was a framework **SOP Version 1 which was launched at the OOS Forum in 2012** as a basis for broader discussion. In the meantime Version 2 of this ECA OOS SOP is available for all ECA members. At the same time it was decided that the handling of OOT results should be addressed in a separate **OOT SOP**, since there is a lack of knowledge in the industry and a lack of guidance for trend analysis from the regulators. In the EU there have been recent updates to Chapter 6 and Chapter 1 of the EU GMP for trend requirements.

The aim of ECA's QC Working Group is to address these issues by developing a new guideline - OOT SOP - aimed at QC and other quality groups to encourage the application of a consistent and scientifically sound approaches to trend analysis as part of a QMS for assuring data integrity. There are three planned components:

1. methods and approaches for detecting out of expectation (OOE) data within an analytical sequence which could be based on process capability of analytical procedures
2. methods and approaches to detecting out of trend (OOT) data between analytical sequences where no trend is expected. This could be a variety Statistical Process Control approaches and
3. methods and approaches to detecting out of trend (OOT) data between analytical sequences where a trend is expected as is the case for Stability Testing.

At this ECA OOT Forum in Prague we want to discuss and explore these methods and approaches some of which will be simple and others more complex. Furthermore it is our desire to position the regulatory needs and inspection expectations to put all the technical aspects in context.

Participants will have the opportunity to provide input to the contents of the guidance document during the interactive 'critique of the proposals' sessions for each of the topics.

The ECA QC Working Group's goal is to have a basic global framework for OOT within R&D, production and QC laboratories acceptable to the authorities which individual companies may adapt to fit their particular Quality Management System.

Target Group

This conference is intended for all levels of technical and managerial personnel dealing with out-of-trend results, including R&D, production, analytical laboratories, contract laboratories, microbiological laboratories and employees in the Quality Assurance/Quality Control.

Forum Moderator

Dr Christopher Burgess,
Burgess Analytical Consultancy, UK,
Chairman of the Analytical QC Working Group

Social Event

In the evening of the first course day, all participants are invited to a guided sight-seeing tour of Prague and a dinner in the city of Prague afterwards. This is an excellent opportunity to share your own views and experiences with colleagues from other companies in a relaxed and casual atmosphere

INTRODUCTION / REGULATORY SESSION

Introduction to ECA's Analytical QC Working Group and the OOT Process
- Aims & Objectives
- Lessons learned from the OOS SOP process
- Structure of the OOT process
- Technical aspects of OOT
- Outline of OOT Forum; aims & objectives

Dr Christopher Burgess, UK, Chairman of the Analytical QC Working Group

Regulatory Importance of Trend Analysis under the EU GMPs
- Inspectors expectations
- Trending within/across techniques
- Challenges for trending non-routine tests

Stephen Young, MHRA, UK

SESSION 2 — OUT OF EXPECTATION RESULTS (OOE)

Position Talk: Out of Expectation Results (OOE) and Recommended Methods of Detection with Examples
- Single Out of Expectation Results – how to detect?
- Stable processes – unstable processes - does SPC apply?
- Nested Out of Expectation Results
- What level of investigation is necessary and appropriate?

Dr Bernd Renger, Bernd Renger Consulting, Germany
Member of the Analytical QC Working Group

SESSION 3 — TRENDING FOR PROCESS CONTROL OF VARIABLES (OOT 1)

Position Talk: Trending for Process Control of Variables (OOT 1)
Types of Control Charts that can be applied for Continuous Data Monitoring for manufactured batches and for analytical test control samples
- Turning data into information
- Types of run rules for Control Charts
- Periodic Review of Control Charts
- Out of Control, when should a CAPA be raised

Dr Lance Smallshaw, UCB Biopharma sprl, Belgium

Basics of SPC for Variables
- Statistical Basis of the Charts
- Setting the control limits
- Process Capability
- What if data are not normally distributed?

Dr Bianca Teodorescu, UCB Biopharma sprl, Belgium

SPC for Variables – Recommended Methods with Examples
Speaker to be named

SESSION 4 — TRENDING FOR PROCESS CONTROL OF ATTRIBUTES (OOT 2)

Position Talk: Trending for Process Control of Attributes (OOT 2)
- Basic differences between attributes and variables
- Distributional requirements
- Control charts for attributes
- Applications for attribute data

Dr Christopher Burgess, UK, Chairman of the Analytical QC Working Group

Trending for Process Control of Attributes (OOT 2) – Recommended Methods with Examples
Speaker to be named

SESSION 5 — TRENDING FOR STABILITY DATA (OOT 3)

Position Talk: Trending for Stability Data (and Differences from SPC)

- Generation and maintenance of trend limits for stability test results
  - Calculated from existing historical stability data
- Simplified linear regression approach
  - Focus on stability indicating assays
  - Minimum data requirements
- More sophisticated random coefficients statistical model for analyzing more complex stability data sets
  - Calculating the 99% prediction interval
- Periodic review of trend limits
  - Reassessment of trend limits

Dr Peter Rauenbuehler, Roche, USA

Trending for Stability Data - Recommended Methods with Examples
N.N. OR
Dr Peter Rauenbuehler, Roche, USA

SESSION 6 — PULLING IT ALL TOGETHER / NEXT STEPS

Summary of the OOT Forum / Next Steps

- Review of Forum activities
- Challenges remaining
- Capturing the outputs
- Process of developing the OOT SOP

Dr Christopher Burgess, Chairman of the Analytical QC Working Group, UK

Dr Christopher Burgess, Burgess Analytical Consultancy Limited, UK - Chairman of the Analytical QC Working Group
Dr Burgess 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 In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Executive committee of European Compliance Academy.

Stephen Young, Head of Analytical Science Inspection, Enforcement and Standards Division, MHRA, UK
Stephen Young worked for ten years in the UK Pharmaceutical Industry, in various roles including analytical development, product stability and manufacturing technical support. He joined the Inspection, Enforcement and Standards division of MHRA in 2003 and currently provides leadership to the Agencies physico-chemical laboratories, which include the Pharmacopoeia and Regulatory Laboratory functions.

Dr Peter Rauenbuehler, Roche, USA
Peter Rauenbuehler, Ph.D., is a Senior Principal Technical Advisor, within Global Quality Systems & Processes at Genentech focused on laboratory policies.

Dr Bernd Renger, Bernd Renger Consulting, Germany
Member of the Analytical QC Working Group
Dr Bernd Renger started at Hoechst AG. Since then, he has held several quality management positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna and Vetter Pharma-Fertigung. He is a member of the European Compliance Academy (ECA) Advisory Board and Immediate Past Chair of the European QP Association.

Dr Lance Smallshaw, UCB Biopharma sprl, Belgium
Lance Smallshaw is Global Director of Analytical Strategy for NBEs at UCB Biopharma sprl in Belgium. Before that he was Senior Scientist at Eli Lilly and Company, having nearly 30 years experience in Analytical Development and QC Laboratories. He is one of the original conception members of the UK Pharmaceutical Analytical Science Group (Pasg) Biopharm. Working Group and currently is their honorary secretary..

Dr Bianca Teodorescu, UCB Biopharma sprl, Belgium
Bianca Teodorescu is Principal Statistician CMC Development in the Technical Operations department at UCB Biopharma sprl in charge of the non-clinical statistical team supporting the development department for biological and chemical entities (analytical, process, pharma), as well as the QC and manufacturing department.

Organisation / Contact

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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:
Mr Ronny Strohwald (Organisation Manager) at +49 (0) 62 21 / 84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

Special Offer with Lufthansa – Discounted Travel for OOT Forum 2014 Attendees

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 that you may have to enable pop-ups on this site – otherwise the booking platform window will not open.

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. The ECA Academy has entrusted CONCEPT HEIDELBERG with the organisation of its events.

ECA Education Course
Reduced Sampling/Reduced Testing
20-21 October 2014, Prague, Czech Republic

Directly before the OOT Forum on 20-21 October 2014 - , there will be the ECA Education Course Reduced Sampling/Reduced Testing with these topics:

- Regulatory Requirements for Sampling Procedures
- Design and Qualification of Sampling Areas for Incoming Goods Products
- Supplier Qualification: an important Prerequisite for Reduced Sampling and Reduced Testing
- How to Deal with Divergent Compendial Method Requirements (EP, USP, JP)
- Case Study I: How to Define Inspection Procedures for Packaging Materials (Primary and Secondary) in the Incoming Goods Control
- Case Study II: How to Define and Optimise Sampling and Testing Procedures for APIs and Excipients in the Incoming Goods Control
- Sampling and Documentation to make the Supplier liable for Defect Products

Further details will be discussed in a parallel session with 3 workshops.

Further information about this course 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).

Date
Wednesday, 22 October 2014, 09.00 – 18.30 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 23 October 2014, 08.30-16.00 h

Venue
Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone + 420 261 191 111
Fax + 420 261 225 011

Conference Fees (per delegate plus VAT)
ECA Members EUR 1,590
APIC Members EUR 1,690
Non-ECA Members EUR 1,790
EU GMP Inspectorates EUR 895

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.

Would you like to safe money?
If you register for the ECA Education Course "Reduced Sampling/Reduced Testing" from 20-21 October 2014 at the same time, you will receive a 350 EUR discount. This is not valid for EU GMP Inspectorates.

Conference Language

The official conference language will be English.

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 to info@concept-heidelberg.de by fax to +49 6221 / 84 44 34 .
Or you register online at www.gmp-compliance.org

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☐ **OOT Forum 2014**
22 - 23 October 2014, Prague, Czech Republic

☐ Yes, I also want to participate in the ECA Education Course **Reduced Sampling/ Reduced Testing on 20-21 October 2014**, Prague, Czech Republic

☐ Mr ☐ Ms

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Company Department

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

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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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

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. You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed) (As of January 2012)

Reduced Sampling / Reduced Testing

cGMP compliant Sampling and Testing of Starting and Packaging Materials – how to Meet EU and FDA Requirements and safe Costs in QA/QC

20-21 October 2014, Prague, Czech Republic

SPEAKERS:

Emerich Grassinger
Haupt Pharma Wülfing GmbH, Germany

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

Dr Gerald Kindermann
F. Hoffmann-La Roche, Switzerland

Dr Michael Möhlen
Valneva Austria GmbH, Austria

Dr Bernd Renger
Bernd Renger Consulting, Germany

Dr Martin Wesch
Wesch & Buchenroth, Law Office, Germany

LEARNING GOALS:

- Regulatory Requirements for Sampling
- Design and Qualification of Sampling Areas
- Supplier Qualification as an Important Prerequisite for Reduced Sampling / Reduced Testing:
  - Supplier Audits
  - Quality Agreements
  - Specifications / Monographs / Supplier CoA
- How to Define and Optimise Sampling and Testing Procedures for
  - APIs
  - Excipients
  - Primary Packaging Materials
  - Secondary Packaging Materials
- Options for Reduced Sampling
- Options for Reduced Testing
- How to Deal with Multicompendial Testing?

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

Reduced Sampling / Reduced Testing

20-21 October 2014, Prague, Czech Republic

Objectives

The aim of this course is to demonstrate the process of the qualification of starting materials (APIs and excipients) and packaging materials (primary and secondary) and to define the prerequisites for implementing a system for reduced sampling and reduced testing for these products. This system has to be in compliance with the actual GMP requirements in Europe and in the US, though. Case Studies will show how to define and optimise sampling and testing procedures and you will discuss further details in a parallel session with 3 workshops.

Background

Testing active pharmaceutical ingredients, excipients and packaging materials is one of the main tasks of the quality control units in the pharmaceutical industry. It must be ensured that the necessary tests are conducted on the incoming goods and that the materials are released only after their quality was judged as satisfactory.

According to the revised draft chapter 5 – Production – of the EU GMP Guide from January 2013, the selection, qualification, approval and maintenance of suppliers has to be documented and the level of control has to be proportionate to the potential risks posed by the individual materials. Manufacturers of medicinal products are responsible for testing the starting and packaging materials as described in the marketing authorisation dossier. However, it is explicitly accepted to utilise partial or full test analysis results for a material from an approved manufacturer, if the following requirements are fulfilled:

a) A formal agreement including the transport conditions to ensure the maintenance of the quality characteristics of the starting materials

b) Regularly performed audits at the production sites

c) A certificate of analysis signed by a designated person with appropriate qualifications and experience

d) Significant experience in dealing with the starting material manufacturer ("history of compliance")

e) Full analyses that are performed regularly by the medicinal product manufacturer to compare the results with the supplier's certificate of analysis.

It is the aim of this GMP Education Course to show how these requirements can be put into practice.

Other focus areas of this course are the regulatory requirements for sampling, the design and qualification of sampling areas and the handling of varying specifications in the different pharmacopoeias for identical APIs and excipients used for finished drug products dedicated for the markets in Europe, in the US, and in Japan.

Must different tests be conducted according to EP, USP, and JP, respectively?

The course programme will be completed by a lawyer's presentation about the legal and contractual liability of suppliers for defect products

Target Audience

This GMP Education Course is directed at all those employees from quality control units in the pharmaceutical industry (including heads of quality control and laboratory managers) who are competent or responsible for sampling, testing and release of starting materials (APIs and excipients) and packaging materials (primary and secondary). This course is also of interest to personnel from quality assurance and to those employees from API, excipient or packaging material suppliers who want to inform themselves about the requirements of the pharmaceutical industry on the testing of these materials.

Programme

Regulatory Requirements for Sampling Procedures

- API and finished goods sampling
- Regulatory requirements
  - EU GMP Part 1, Chapters 4, 5, 6
  - EU GMP Part 2, Chapter 7
  - EU GMP Annex 8
  - EU GMP Annex 19
- Other regulations
  - US / FDA Requirements
  - WHO - PIC/S - ISO (former Military Standard)
- Supplier qualification and audits
  - Reduced testing

Design and Qualification of Sampling Areas for Incoming Goods Products

- Sampling area for raw materials, APIs and excipients
- Layout and design of premises and equipment
- "Cleanroom"-like classification?
- What are the appropriate environmental requirements for sampling areas?
- How to qualify and maintain sampling areas?
- Is a change of pallets/removal of cart boxes required?
- Are expectations increasing? - Lessons learned during inspections

Supplier Qualification: an important Prerequisite for Reduced Sampling and Reduced Testing

- Prerequisites
- Qualification of packaging materials
- Qualification of APIs and excipients
- Supplier qualification / Supplier audits
- Quality Agreements
- Specifications / Pharmacopoeial monographs / Supplier CoA
- Complaint Handling

Sampling and Documentation to make the Supplier liable for Defect Products

- Legal and Contractual Liability
- Definition of a Product Defect
- Express Warranty
- Admissible Evidence
- Insurability

Case Study I: How to Define Inspection Procedures for Packaging Materials (Primary and Secondary) in the Incoming Goods Control

- Sampling Plans for printed packaging materials, glass containers, plastic containers, etc.
- AQL (Acceptable Quality Level)
- Tests required according to Ph.Eur. / USP
- Options for reduced sampling
- Options for reduced testing
- Skip lot testing

Case Study II: How to Define and Optimise Sampling and Testing Procedures for APIs and Excipients in the Incoming Goods Control

- Sampling Plans for APIs / excipients
- Verification of pharmacopoeial procedures
- Options for reduced sampling
- Options for reduced testing
- Use of / NIR / Raman for an efficient control

Parallel Sessions: Working on specific Tasks

1. Strategies/Prerequisites for Reduced Testing / Reduced Sampling

The aim of this workshop is to evaluate in small discussion groups how the opportunities and requirements of EU GMP Annex 8 and 21 CFR Part 211 should be implemented in QA / QC.
Moderator: Dr Bernd Renger

2. Reduced Testing / Reduced Sampling for APIs / Excipients

Participants will discuss in small groups scenarios of different materials / suppliers / qualification status / etc. and their impact on the sampling and testing plans with regard to reduced sampling and reduced testing for APIs and excipients.
Moderator: Emerich Grassinger

3. Reduced Testing / Reduced Sampling for Primary and Secondary Packaging Materials

Participants will discuss in small groups scenarios of different materials / suppliers / qualification status / etc. and their impact on the sampling and testing plans with regard to reduced sampling and reduced testing for packaging.
Moderator: Dr Gerald Kindermann

You will be able to attend 2 of these parallel sessions. Please choose the ones you would like to attend when you register for this Course.

How to Deal with Divergent Compendial Method Requirements

- ICH QB4 and the Pharmacopoeial Discussion Group
- Divergent and conflicting pharmacopoeial requirements
- CDER's MAPP 5310.7 "Acceptability of Standards from Alternative Compendia"
- How to proceed in case of missing harmonization?
- How to proof equivalence?

Speakers

Emerich Grassinger
Haupt Pharma Wülfing GmbH, Germany
Emerich Grassinger works since 1995 in various positions for the pharmaceutical industry. 2002-2010 he headed several labs within Boehringer Ingelheim and was there also responsible for the Raw Material laboratory in which the testing and release of the APIs and Excipients was carried out. He led several improvement projects throughout the supply chain involving the raw material releasing process. 2010 he joined Haupt Pharma Wuelfing, where he is responsible for Quality Control, including the raw material laboratory and the sampling of incoming goods.

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 North Rhine-Westphalia. He studied pharmacy and gained his PhD thesis at the University of Münster, Germany. Since 1995 Dr Heuermann is involved in national and international GMP inspections with a focus on QC laboratories and QA systems.

Dr Gerald Kindermann
F. Hoffmann-La Roche, Basel, Switzerland
Dr Gerald Kindermann is Product Quality Manager at the Global Quality Group at Roche working on quality systems. Before that he was Group Leader Quality Control and Quality Manager for the Supply Center.

Dr Michael Möhlen
Valneva Austria GmbH, Vienna, Austria
Dr Möhlen is the Head of Technical Operations at Valneva Austria GmbH in Vienna and responsible for industrialisation of Vaccine candidates. This includes oversight as well to Quality Control and Clinical Serology. Until 2009 Dr Möhlen held various management positions in the Quality Control arena with Chiron and later Novartis Vaccines, including responsibility for raw material sampling and testing.

Dr Bernd Renger
Bernd Renger Consulting, Germany
Dr Bernd Renger is a member of the European Compliance Academy (ECA) Advisory Board and Immediate Past Chair 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 1977 at Hoechst AG as a research and development chemist. Since then, he has held several quality management positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna.

Dr Martin Wesch
Wesch & Buchenroth, Law Office, Germany
Dr Martin Wesch is a lawyer specialised in medical and industrial law and working for the Stuttgart-based firm of lawyers Wesch & Buchenroth, which he founded in 2001. Since April 2002, he has been teaching industrial law at the University of Stuttgart. He is author of several publications, both in journals and books, to legal demands on quality assurance in manufacturing pharmaceuticals. In 2007 he received the Wallhaeusser Prize for publications in that field from Concept Heidelberg.

Social Event

On 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.

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, 20 October 2014, 09.00 - 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Tuesday, 21 October 2014, 08.30 - 15.30 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague, Czech Republic
Phone + 420 261 191 111
Fax + 420 261 225 011

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
The course 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 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

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
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Günter Brendelberger (Operations Director) at phone +49-62 21 / 84 44 40, or by e-mail at brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager) at phone +49-62 21 / 84 44 46, or by e-mail at weidemaier@concept-heidelberg.de.

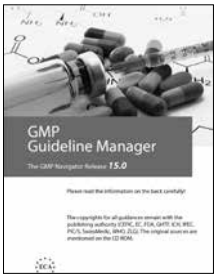
What are The ECA Foundation and the ECA Academy?

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.

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

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CONCEPT HEIDELBERG
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Reduced Sampling / Reduced Testing
20-21 October 2014, Prague, Czech Republic

☐ Mr ☐ Ms

+ 49 6221 84 44 34

Please choose TWO parallel sessions:
☐ Strategies/Prerequisites for Reduced Testing /Reduced Sampling
☐ Reduced Testing / Reduced Sampling for APIs / Excipients
☐ Reduced Testing / Reduced Sampling for Primary and Secondary Packaging Materials

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)

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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)