ECA ACADEMY

SPEAKERS FROM AUTHORITY

DR USFEYA A. MUAZZAM
Bonn, Germany

DR CORINA NACHTSHEIM
Quality Assessor, Germany

INDUSTRY SPEAKERS

DR GISELA FONTAINE
Solvias AG, Switzerland

DR THOMAS HÄMMERLE
Baxter AG, Austria

DR GERD JILGE
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

DR SAMUEL POWELL
Pfizer, United Kingdom

DR HEIKE SCHMIDT-EISENLOHR
LPU Labor für Pharma- und Umweltanalytik GmbH, Germany

DR XAVER SCHRATT
LPU Labor für Pharma- und Umweltanalytik GmbH, Germany

DR LANCE SMALLSHAW
UCB Biopharma sprl, Belgium

DR ANDREW TEASDALE
Astrazeneca, United Kingdom

DR ANDREAS WOLF
AbbVie, Germany

IMPURITIES FORUM

16-18 June 2015, Prague, Czech Republic

PART I:

IDENTIFICATION AND DETERMINATION OF IMPURITIES

16 June 2015, Prague, Czech Republic

PART II:

ELEMENTAL IMPURITIES

17 June 2015, Prague, Czech Republic

PART III:

GENOTOXIC IMPURITIES

18 June 2015, Prague, Czech Republic

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

PART I: IDENTIFICATION AND DETERMINATION OF IMPURITIES

Objectives

Part I of the Impurities Forum will provide an opportunity to reinforce and expand your knowledge of the general area of impurities in chemical entities from initial development to the market with emphasis on

- Detection, profiling and control of impurities in drug substances, intermediates and drug products
- Practical aspects of method validation for impurities determination
- Analytical techniques used for detecting and qualifying impurities
- Extractables and Leachables as a source of impurities
- Impurities qualification in biotechnology products

This event is designed to provide a comprehensive review of impurities analysis and characterisation in drug substances and drug products and their recording and reporting.

Background

Setting specifications for impurities are one of the most critical topics in the development of new drug products. Impurities analysis in drug substances and drug products and their recording and reporting is quite often a challenge for the scientific experts in routine production and quality control. This challenge is even bigger when profiles of unknown impurities in complex matrices have to be established.

Target Audience

The conference addresses all personnel involved in development of drug substances and drug products from scientific staff to laboratory heads involved in R&D. The needs of Laboratory Managers, Supervisors and Analysts in pharmaceutical quality assurance and quality control departments will also be covered.

Programme

Impurities analysis in Drug Substances and Drug Products

- Impurity profiling in synthetic drug substances
- Qualification of impurities
- Degradation studies
- Identification of chiral impurities, polymorphic phases and new impurities
- Residual solvents
- Impurities in starting materials and intermediates
- Pharmacopoeial tests and acceptance criteria
- Drug product specifications and parametric release
- Inorganic impurities

Practical aspects of method validation for impurity determination

- Important ICH and FDA guidelines
- Quantitation of impurities
- How to define an impurity profile (stress tests)
- Reference substances
- Validation of methods at various development stages
- Statistical approaches to method validation (LOD & LOQ)

Analytical techniques for determination of impurities

- Purity analysis by HPLC, impurity profile
- Residual solvents by GC
- Inorganic impurities (heavy metals, sulphated ash)
- For chiral compounds in addition: enantiomeric purity and proof of the absolute configuration

Leachables and Extractables

- Why should Extractables & Leachables be assessed?
- Regulatory requirements EU and US
- Compendial requirements, industry standards and Consortia Landscape
- A laboratory perspective on E&L safety qualification
- Current industry situation and future perspectives

Impurity Qualification in Biotechnology Products

- Process related impurities: Host cell DNA and host cell protein
- Drug substance related impurities: Degradation products and ICH Guideline Q5C
- Assay validation: Critical aspects
- Process related impurities or contaminants: Endogenous retroviruses

PART II: ELEMENTAL IMPURITIES

Objectives

In Part II of the Impurities Forum the key principles of the new ICH Q3D Guideline will be highlighted. You will get to know the essential aspects and approaches of determining and controlling elemental impurities in drug products. You will learn

- which are the principles of the elemental impurities risk assessment process,
- how to implement risk-based strategies to control elemental impurities,
- which analytical methods are suitable to determine
- elemental impurities and what you have to consider when you apply them,
- what you need in your QC lab to be prepared for elemental impurities analytics.

Background

In November 2014 the **ICH Q3D Guideline for Elemental Impurities** was published as Step 4 document. This document outlines

- the evaluation of the toxicity data for potential elemental impurities
- the PDEs for each element of toxicological concern
- the development of controls designed to limit the inclusion of elemental impurities in drug products to levels at or below the PDE

In March 2015 USP announced a revision to General Notices section 5.60.30 Elemental Impurities in USP Drug Products and Dietary Supplements, establishing 1 January 2018 as the new date of applicability of General Chapters <232> Elemental Impurities-Limits and <2232> Elemental Contaminants in Dietary Supplements. The limits provided in GC <232> align with ICH Q3D Step 4. GCs <232> and <233> Elemental Impurities-Procedures will become official on 1 December 2015.

Also in March 2015 the European Pharmacopoeia decided to delete the reference to the test for heavy metals (2.4.8) from all individual monographs on substances for pharmaceutical use.

Target Audience

The conference addresses all personnel involved in development of drug substances and drug products from scientific staff to laboratory heads involved in R&D. The needs of Laboratory Managers, Supervisors and Analysts in pharmaceutical quality assurance and quality control departments will also be covered.

Programme

The new ICH Q3D Guidance on Elemental Impurities – authorities expectations

- Scope and applicability of the ICH Q3D guideline
- Similarities and differences with the EU-Metal Catalysts guideline
- What is the link with the EP and USP monographs?
- The classification system of heavy metals and metal catalysts in the proposed guideline, thresholds.
- Implications to the API industry – additional requirements – analytical work required – costs
- What do authorities expect?

Utilisation of Data as part of an Integrated EI Risk Assessment Process - Role of Industry Collaboration /FDA-IPEC Excipient Study Data

- An overview - Utilisation of Data as part of an Integrated EI Risk Assessment Process
- Practical Implementation Considerations
- Potential Sources of Elemental Impurities in the Finished Product
  - API
  - Equipment
  - Container-closure system
  - Excipients
- Data sharing - Elemental Impurities Pharma Consortium – current status – future aims
- Conclusions

Safety assessment of metallic impurities in oral dosage forms – limits and Permitted Daily Exposure (PDE)

- General principles of safety assessment
- How to determine PDEs
- Conversion between PDEs and concentration limits
- Justification for impurity levels higher than the PDE
- Case studies

Analytical methods to determine metallic impurities

- Principles and characteristics of the most common spectrometric techniques AAS, ICP-OES, ICP-MS
- Compound methods (sample preparation plus spectrometric detection and quantification)
- Special considerations for trace-elemental analysis
- Application-based approach for choice of methodology
- Analytical process (method development, validation strategy, routine testing)

QC lab infrastructure and equipment for metal impurities analytics

- Process-oriented laboratory design
- Basic components of a trace elemental laboratory
- Approaches for contamination control
- Handling of highly active pharmaceutical compounds in a trace elemental laboratory: operator protection versus product protection?
- Accessories for interference control in ICP-MS

Identification and assessment of potential elemental impurities in pharmaceutical excipients

- Potential sources of elemental impurities in pharmaceutical excipients
- Important aspects of excipients safety assessment
- Excipients supplier qualification
- Classification of elemental impurities: examples

An approach to risk assessing for elemental/metallic impurities

- ICHQ3D - what's expected
- An example of a Risk Tool Macro
- What information is required for Skip Testing – Ph.Eur./ICHQ3D expectations
- Regulatory filing – Where do I include information relating to a Risk Assessment

PART III: GENOTOXIC IMPURITIES

Objectives

Part III of the Impurities Forum will cover the key aspects of determining, analysing and assessing genotoxic impurities.

You will learn

- What authorities expect and how they assess genotoxic impurities
- How TTC levels of genotoxic impurities can be determined for different dosage forms
- Which methodologies can be applied to predict potential genotoxic impurities
- The key aspects to be considered when dealing with mutagenic impurities
- How to implement the requirements of ICH M7 from a quality and safety perspective

Background

Potential genotoxic impurities may arise from several sources. They may be generated as by-products in chemical synthesis or as degradants during storage. Therefore the determination of such impurities, their toxicological assessment and the establishment of acceptable limits is absolutely essential with respect to patient safety. Special guidance in terms of quality and safety risk management and assessment is provided by the EMA "Guideline on the Limits of Genotoxic Impurities" and the ICH M7 Draft Consensus Guideline on "Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk".

Target Audience

The conference addresses all personnel involved in development of drug substances and drug products from scientific staff to laboratory heads involved in R&D. The needs of Laboratory Managers, Supervisors and Analysts in pharmaceutical quality assurance and quality control departments will also be covered.

Programme

Genotoxic Impurities – requirements and authorities expectations
- General documents and Guidelines for the assessment of genotoxic impurities
- The assessor's approach: principles of toxicological assessment
- The TTC concept
- Structural alerts
- Limits and Permitted Daily Exposure
- The ALARP principle
- Applicability of the EU "Guideline on the Limits of Genotoxic Impurities"

Case studies for the assessment of potential genotoxic impurities
- Examples of low daily dose drug substances
- Impurities derived from alkylating agents (mesilate, besilate, tosilate, diisothionate); examples
- Potential genotoxic residual solvents
- Impurities derived from metal catalysts

ICH M7 Guideline – Mutagenic Impurities: overview of key aspects
- Applicability of the M7 Guideline
- General principles
- Considerations for marketed products

ICH M7 Guideline – practical implementation: a quality perspective
- Drug substance and drug product impurity assessment
- Hazard assessment elements
- Computational toxicology assessment
- Structure activity relationships
- Process related impurities
- Control strategy approaches

ICH M7 Guideline – practical implementation: a safety perspective
- Lifecycle management
- Considerations for clinical development
- In vivo relevance of in vitro mutagens
- Linear extrapolation from TD50; calculation examples

SPEAKERS

DR GISELA FONTAINE, *Solvias AG, Switzerland*
Gisela Fontaine studied Chemistry at the ETH Zürich where she also obtained her PhD in 2010 using (MC)-ICP-MS. Afterwards, she turned to elemental spectroscopy analysis of pharmaceuticals and food stuffs. She joined Solvias AG in 2013 as Senior Lab Manager for (Ultra) Trace Elemental Analysis. The analytical techniques covered by her team are ICP-MS, ICP-OES, ET-AAS as well as Polarography. Work is focused on development and validation of analytical methods for determination of trace elements as well as their routine analysis.

DR THOMAS HÄMMERLE, *Baxter AG, Austria*
Dr Hämmerle is currently heading the Department of Molecularbiological Control at the Baxter site in Orth/Danube Austria. His expertise relates to the fields of molecular biology, virology, biochemistry and cell biology. He is also a member of the EDQM Mycoplasma and CTP working parties, a member of the USP Residual DNA working party and co-chair of the PDA Mycoplasma Task Force Testing Subgroup.

DR GERD JILGE, *Boehringer Ingelheim Pharma GmbH & Co. KG, Germany*
In 1991 Dr Gerd Jilge came to Boehringer Ingelheim working in product development where he was responsible for method development and validation for the application of analytical procedures. In 2000 Dr Jilge took a position in Drug Regulatory Affairs of Boehringer Ingelheim GmbH with the focus on CMC documentation for the submission of new and registered drug products. Since July 2007 he is working in Quality Management on method development for new drug substances.

DR USFEYA A. MUAZZAM, *Bonn, Germany*
Dr. Usfeya A. Muazzam worked as Senior Assessor for Quality, Division: Quality, Department: Scientific Quality Assurance, Staff Unit: Strategy and Planning of BfArM. He left the agency in 2012. He is co-author of "Gute Regulatorische Praxis, Arzneimittelzulassung - Pharmazeutische Qualität", Wissenschaftliche Verlagsgesellschaft, Stuttgart, Germany and "Guide to Drug Regulatory Affairs", Editio Cantor Verlag, Aulendorf, Germany

DR CORINA NACHTSHEIM, *Quality assessor, Germany*
Dr Nachtsheim studied chemistry at the University of Cologne and received a Ph.D. (Dr. rer. nat.) in pharmaceutical chemistry at the University of Bonn. She is working as a quality assessor at the German Federal Institute for Drugs and Medical Devices since Jan. 2001. Since Nov. 2007, she is an external expert in the framework of the certification procedure of the EDQM in Strasbourg. She became a member of the chemical Technical Advisory Board (EDQM) in Nov. 2011 and is currently chairperson.

DR SAMUEL POWELL, *Pfizer, United Kingdom*
Dr Sam Powell graduated in medicinal and biological chemistry. He started his career at Invitrogen and joined Pfizer Discovery Biology in 2007. In 2008 he moved into pharmaceutical science as an analytical chemist and has held since then many positions within the organisation from vaccines and devices. He first started using ICP to assay gold particles from a needleless delivery device, moving this to assay gold and DNA in combination.

DR HEIKE SCHMIDT-EISENLOHR, *LPU Labor für Pharma- und Umweltanalytik GmbH, Germany*
Dr Heike Schmidt-Eisenlohr studied Biology at the Ludwig Maximilians University (LMU) of Munich. Currently she is Deputy Head of Department R & D at the LPU (formerly LAT). She is in charge of development of analytical methods, method validations and transfers, extractable and leachable studies and structure evaluation of unknown impurities via HPLC-MS.

DR XAVER SCHRATT, *LPU Labor für Pharma- und Umweltanalytik GmbH, Germany*
Dr Schratt studied Chemistry at the University of Bayreuth, where he specialized in HPLC and HPLC/MS. In 2005 he joined LPU (formerly LAT) and since 2006 he is head of department R & D 2. In charge of national and international pharmaceutical companies he manages all analytical aspects of projects from preclinical stage up to phase III and post market approval. As an expert for chromatography and mass spectrometry he mainly focuses on method development, validation and qualification of reference substances.

DR LANCE SMALLSHAW, *UCB Biopharma sprl, Belgium*
After completing nearly 30 years at Eli Lilly and Company based in various locations around the world specializing in both biopharmaceutical / chemical analytical development and QC (API/Parentals) testing Lance on-boarded at UCB Biopharma sprl. in Belgium in early 2011 and is a CChem and FRSC of the Royal Society of Chemistry. Following a publication in 2007 of a monograph on chapter 6 of the EU GMP Guide for the PQG and Chartered Quality Institute, he was recruited to the training team of the European Qualified Persons Association (EQPA) and in the past year was invited join the Advisory Foundation Board of the European Compliance Academy (ECA). He has been a member of the European CaSSS CMC Biopharm. Strategy Forum Committee for the past 8 years and is an Associate Director of CaSSS. In recent years Lance has co-published some guidances in Nature – Biotechnology on standards for international proteomics project.

DR ANDREW TEASDALE, *AstraZeneca, United Kingdom*
Andrew Teasdale PhD has over 20 years' experience in the pharmaceutical industry as an analytical chemist and within quality assurance and regulatory roles. He has led a number of industry expert groups; these include both safety and quality groups within Pharmaceutical Research and Manufacturers of America (PhRMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), Product Quality Research Institute (PQRI) and the Extractables and Leachables safety Information exchange (ELSIE) for which he is the chair of the materials working group. Dr Teasdale is also currently the chairman of the Joint Pharmaceutical Analytical Group (JPAG) in the UK.

DR ANDREAS WOLF, *AbbVie Deutschland GmbH+Co KG, Germany*
Dr Wolf joined Abbott in 2002 and held different positions in Quality Assurance and Quality Control. Currently he is Qualified Person and Quality Manager for release of bulk material and finished dosage forms at AbbVie Deutschland GmbH+Co KG (formerly Abbott Deutschland GmbH+Co KG) in Ludwigshafen, Germany.

Social Event

You are cordially invited to a guided sightseeing tour of Prague and dinner on 16 June 2015. These are a excellent opportunities to share your experiences with colleagues from other companies in a relaxed atmosphere.

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

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

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

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

Easy Registration

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Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Impurities Forum Part I: Identification and Determination of Impurities
16 June 2015, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)

Impurities Forum Part II: Elemental Impurities
17 June 2015, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)

Impurities Forum Part III: Genotoxic Impurities
18 June 2015, 09.00 – 16.00 h
(Registration and coffee 08.30 – 09.00 h)

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

Fees (per delegate + VAT)
Impurities Forum Part I
Non-ECA Members € 890.-
ECA Members € 690.-
APIC Members € 790.-
EU GMP Inspectorates € 445.-

Impurities Forum Part II
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Non-ECA Members € 1,990.-
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The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on each day and all refreshments. VAT is reclaimable.

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. 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.

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 Gerhard Becker (Operations Director) at +49(0)62 21 / 84 44 65, or per e-mail at becker@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Jessica Stürmer (Organisation Manager) at +49(0)62 21 / 84 44 43 or per e-mail at stuermer@concept-heidelberg.de.

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CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
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IMPURITIES FORUM, 16 - 18 June 2015, Prague, Czech Republic

- ☐ Part I: 16 June 2015
- ☐ Part II: 17 June 2015
- ☐ Part III: 18 June 2015
- ☐ Part I and II: 16-17 June 2015
- ☐ Part II and III: 17-18 June 2015
- ☐ Part I, II and III: 16-18 June 2015

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