A pre-conference session to the 16th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients

ECA European Compliance Academy

ICH Q3D Guideline for Elemental Impurities

What you need to know about controlling elemental impurities

5 November 2013, Madrid, Spain

Objectives

This pre-conference session highlights the key principles of the new ICH Q3D Guideline. 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.

This pre-conference session ideally complements the following 16th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients.

Target Audience

This pre-conference session is designed for all scientists, and persons involved in R&D departments. Furthermore, the session will be of interest to Laboratory Managers, Supervisors and Analysts in pharmaceutical quality control departments and to personnel from quality assurance and regulatory affairs.

Programme

The new ICH Q3D Guideline for elemetal impurities and its implications to the pharmaceutical and API industry

- Scope and content of the Guideline
- Principles of safety assessment and toxicity data for potential elemental impurities
- Principles of risk assessment
  - Converting between concentration limits and permitted daily exposure
  - How routes of administration can be considered
- Control approaches of elemental impurities

How to implement strategies to control elemetal impurities: risk-based approaches

- How and where to start?
- In-house testing versus outsourced testing
- Supplier strategies
- Selection of best risk based approaches
- Generic versus specific tests
- Managing transition of requirements
- Opportunities from ICH Q3D

Analytical methods to determine elemetal 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

QC lab infrastructure and equipment for elemetal 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

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

Speakers

Melissa Figgins, Sandoz Inc., USA
Melissa Figgins is QC Director at largest Sandoz US solid oral dosage manufacturing site. She is Vice Chair of GPhA USP Stakeholder Working Group, member of IGPA Science Committee and IGPA ICH Interested Party Representative of Q4D EWG and Q3D EWG.

Dr Oliver Grosche, Novartis Pharma AG, Switzerland
Oliver Grosche is analytical expert by training and had been leading the implementation strategy on elemental impurities at Novartis Pharma Global Technical Operations, Basel, Switzerland.

Dr Eberhard Koenig, Novartis Pharma AG, Switzerland
Eberhard Koenig is analytical expert in inorganic analytics. He is currently building up the Novartis center of expertise for elemental impurities testing at Novartis Pharmaceutical Operations, Stein, Switzerland.

Lance Smallshaw, UCB Pharma S.A., Belgium
Lance Smallshaw is Global Director of Analytical Strategy for NBEs at UCB in Belgium. He has more than 25 years experience in Analytical Development and QC Laboratories.

Easy Registration

Reservation Form:
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P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.api-conference.org

Date
Tuesday, 5 November 2013, 10.00 – 18.00 h
(Registration and coffee 09.30 – 10.00 h)

Venue
Melia Castilla Hotel and Convention Center
Capitán Haya, 43
28020 Madrid, Spain
Phone: +34 (0)91 567 50 77
Fax: +34 (0)91 567 50 66

Fee
EUR 890.- per delegate plus VAT.
A special fee of 690,- Euro is granted to participants who also register for the 16th APIC/CEFIC European Conference on APIs.
The conference fee is payable in advance after receipt of invoice and includes lunch 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.api-conference.org.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted CONCEPT HEIDELBERG with the organisation of this event.
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For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager) at + 49 (0)6221/84 44 18, or at grimm@concept-heidelberg.de

Important Information!
You will receive a USB memo stick when you register in Madrid.
Note: there will be **no print-outs** available during the conference.

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☐ **Pre-Conference Session "ICH Q3D Guideline for Elemental Impurities"**
5 November 2013, Madrid, Spain

☐ **I also register for the 16th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients**
6-8 November 2013, Madrid, Spain
I want to take part in
☐ **GMP Part** (6-7 November 2013)
☐ **Regulatory Affairs Part** (7-8 November 2013)
☐ **All three conference days** (6-8 November 2013)

Please choose 2 out of 6 parallel sessions (one choice in Session I and one in Session II)

First choice	Second choice (in case your first choice is fully booked)		
		Parallel Sessions I	
☐	☐	Session 1:	Current regulatory hurdles and opportunities – APIC's experiences
☐	☐	Session 2:	The new EU GDP Draft Guide and the APIC 'How to do' Guide on GDP for APIs
☐	☐	Session 3:	Application of process analytical technology in the API industry
		Parallel Sessions II	
☐	☐	Session 4:	Improvement of the ASMF Guideline: Industry point of view
☐	☐	Session 5:	Drug substance preparation
☐	☐	Session 6:	Continuous processing from fumehood to factory – how can it be done

☐ Mr ☐ Ms Title _____

First name, surname

Company ☐ APIC Member ☐ ECA Member ☐ Inspectorate

Department

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

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City Zip Code Country

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General Terms of Business
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 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 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)!**