ECA ACADEMY

A pre-conference session to the 17th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients

Speakers

Jürgen Groneberg
Sanofi, Germany

Franz Gruber
Baxter AG, Austria

Daniel Müller
GMP Inspectorate, Germany

Andreas Nechansky
Vela Laboratories, Austria

Ettore Ohage
Roche Diagnostics, Germany

Frank Ziemke-Kägeler
Roche Diagnostics, Germany

Highlights

- Cleaning validation and establishment of limits
- Applying Quality by Design (QbD) to Biotech Manufacturing
- How to determine, qualify and control impurities in biotech APIs
- Cold Chain Management and best practices in transport and logistics
- Stability testing of biotech APIs
- GMP-inspections of biopharmaceutical manufacturing sites

GMP and GDP Compliance for Biotech APIs

4 November 2014, Vienna, Austria

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4 November 2014, Vienna, Austria

Objectives

This pre-conference session **highlights the key aspects of GMP compliant manufacture of biotechnologically derived APIs**. You will also get to know the **key principles of transport and cold chain management of biotech APIs**. For example you will learn:

- what a GMP inspector expects from a GMP-compliant manufacturing site
- how to efficiently perform equipment cleaning and how to validate cleaning procedures
- what has to be considered before and during process validation with respect to the new FDA validation guidance
- how to qualify impurities
- which are the suitable approaches in order to assess and test API stability

This pre-conference session ideally complements the following 17th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients.

Target Audience

This pre-conference session is designed for all persons involved in the manufacture of biotechnologically derived APIs especially for persons from production, quality control, quality assurance and control, technical and regulatory affairs departments. We are also addressing interested parties from the pharmaceutical industry and GMP inspectorates.

Programme

cGMP compliance for Biopharmaceuticals – an inspector's view
- Biotech guidelines – overview
- Revised Annex 2
- Regulatory expectations on
  - quality management and personnel
  - premises and equipment
  - production
  - storage and transport
- Biopharmaceutical manufacturing
  - Common issues and examples of observations

Cleaning and cleaning validation in biotech manufacturing processes
- Identification of cleaning mechanisms and selection of cleaning agents
- Selection of analytical methods for the detection of residues
- Establishment of limits in fermentation and downstream processing
- Grouping strategies
- Final rinse versus swab testing

Process Validation and QbD Implementation for Biotech Manufacturing Processes
- Applying Quality by Design (QbD) to Biotech Manufacturing
  - Roadmap
  - Critical Quality Attributes (CQAs)
  - Critical Process Parameters (CPPs)
  - Design Space
  - Process Validation Approach
  - Post Approval Lifecycle Management
- Benefits of QbD
- Lessons Learned from Gazyva®/Obinutuzumab

Impurities Qualification in Biotech APIs

- 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

Cold Chain Management of temperature sensitive Biotech APIs - Best Practices in transport and logistics

- Regulatory/customer requirements
- Qualification/verification of transport processes
- Risk factors which cannot be controlled but must be taken into account
- How to deal with deviations

Stability assessment and testing of Biotech APIs

- Relevant guidelines
- Stability indicating profile; characteristics and strategy
- Analytical methods
- Storage conditions
- Points for assessment
- Impact of changes on stability

Speakers

Dr Jürgen Groneberg, Sanofi, Germany
Dr Groneberg is a molecular biologist by profession and has held various positions at Sanofi and its predecessor organizations. Since 2005 he is QA-Manager for various quality systems at the biotechnology site of Sanofi-Aventis in Frankfurt, Germany. In this role he oversees also the insulin transport activities to various external Sanofi drug manufacturing sites as well as to external customers worldwide.

Dr Franz Gruber, QC - Molecularbiological Control, Baxter AG, Vienna, Austria
Following basic training in Chemistry and Molecular Biology, Dr Gruber joined Immuno AG, which is now part of Baxter, and is working in the QC Department of Molecularbiological Control at the Baxter site in Orth/ Danube, Austria. His expertise and long-term experience relates to NAT applications such as qPCR based methods.

Dr Daniel Müller, GMP Inspectorate Local Government, Germany
Dr Müller started working in the pharmaceutical industry in 1998. Among other positions he served as a Qualified Person of large volume parenterals. In 2001 he joined a German inspectorate in Tübingen.

Dr Andreas Nechansky, Vela Laboratories, Austria
Andreas graduated in 1997 at the University of Vienna and did his postdoctorial work at the Novartis Research Institute in Vienna and The Scripps Research Institute in La Jolla, USA. He was of Head of Analytical Development at Igeneon/Aphton Biopharma. He is Founder/COO of Vela Laboratories and responsible for analytical operations. His experience covers the field of antibody/protein characterization, the underlying immunology and the regulatory requirements.

Dr Ettore Ohage, Roche Diagnostics, Germany
Dr Ohage is a chemist by profession and started his career in biotech development in 2000. He joined Roche Diagnostics at the Penzberg site in 2005. As senior manager QA & Compliance he is responsible for biotech APIs in clinical development and quality oversight of DSP operations for investigational APIs. Dr Ohage is also the QA representative in the development team for Obinutuzumab, the first monoclonal antibody with an FDA-approved design space.

Dr Frank Ziemke-Kägeler, Roche Diagnostics, Germany
Dr Ziemke-Kägeler is working since 1997 in Microbiological Quality Control with Roche Diagnostics in several positions. As Director Quality Control he is now responsible for environmental monitoring and cleaning validation for the Penzberg biotech facility.

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, 4 November 2014, 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)

Venue
Austria Trend Hotel Park Royal Palace Vienna
Schlossallee 8
1140 Vienna, Austria
Phone: +43 1 8911 0
Fax: +43 8911 9050

Fee
EUR 890.- per delegate plus VAT.

A special fee of 690,- Euro is granted to participants who also register for the 17th 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 link when you have registered for the event. Please use this link 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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D-69007 Heidelberg, Germany
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For questions regarding content:
Dr Gerhard Becker (Operations Director) at +49 (0) 6221/84 44 65, or at becker@concept-heidelberg.de

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 Vienna.
Note: there will be **no print-outs** available during the conference.

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

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69007 Heidelberg
Germany

☐ **Pre-Conference Session "GMP and GDP Compliance for Biotech APIs"**
4 November 2014, Vienna, Austria

☐ **I also register for the 17th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients**
5-7 November 2014, Vienna, Austria
I want to take part in
☐ **GMP Part** (5-6 November 2014)
☐ **Regulatory Affairs Part** (6-7 November 2014)
☐ **All three conference days** (5-7November 2014)

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

First choice	Second choice	
		Parallel Sessions I
☐	☐	Session 1: Current regulatory hurdles and opportunities – APIC's experiences
☐	☐	Session 2: Insoluble Matter and Particles in API manufacturing
☐	☐	Session 3: What with potential Genotoxic Impurities in APIs?
		Parallel Sessions II
☐	☐	Session 4: Process validation: A practical approach
☐	☐	Session 5: Biotech comparability studies
☐	☐	Session 6: API Changes - for better or for worse?

☐ 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

Phone / Fax

E-mail (please fill in)

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)!**