Speakers

Annick Gervais
UCB Pharma, Belgium

Siegfried Giess
Paul Ehrlich Institut, Germany

Rainer Gnibl
EU-GMP Inspector, Bavarian Government, Germany

Holger Kavermann
Roche Diagnostics, Germany

Tim O'Mahony
Janssen Pharmaceutical, Ireland

Paul Stockbridge
Biopharm Consulting, UK

Highlights

- Authorities expectations on GMP-compliant production
- Key requirements of process validation in the EU and the US
- How to establish microbial control strategies in cell culture and down-stream processing
- Development of analytical test methods according to the new FDA guidance
- Requirements of the revised Annex 15 for cleaning and cleaning validation
- Key aspects of the European Biosimilar approach

ECA ACADEMY

A pre-conference session to the
18th APIC/CEFIC European Conference
on Active Pharmaceutical Ingredients

GMP-compliant Manufacture of Biotech APIs – an Update

3 November 2015,
Amsterdam, The Netherlands

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3 November 2015, Amsterdam, The Netherlands

Objectives

This pre-conference session **highlights the key aspects of GMP compliant manufacture of biotechnologically derived APIs. You will get to know the key requirements of the revised Annex 15**.

For example you will learn:
- what a GMP inspector expects from a GMP compliant manufacturing site
- how microbial control strategies can be implemented in cell culture and downstream processing
- which key points should be considered when developing analytical test procedures
- what the revised Annex 15 requires for cleaning procedures and their validation

Moreover you will get to know the key aspects of the European Biosimilar approach.
This pre-conference session ideally complements the following 18th 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

Regulatory expectations on GMP compliant manufacture of Biopharmaceuticals
- Obligations to authorities – import or registration
- Relevant guidelines for the Biotech industry
- GMP starting point
- How to achieve GMP-compliance?
- Overview of obligatory EU biotech-specific requirements
- Optional requirement to support
- Comments on special requirements and how to deal with them

Process Validation in the Manufacture of Biotech APIs
- Regulatory requirements in the EU and US
- The new EU/EMA approach on process validation
- Requirements of the revised Annex 15
- Key principles of the FDA Guidance on Process Validation
- Validation approaches and how to apply the principles of ICH Q8, Q9, Q10 and Q11
- Continuous process verification and life-cycle approach

Microbial Control Strategy for Cell Culture and Downstream Processing
- Applicable sampling regimes
- Sample sizes
- Methods and method qualification approaches
- Inhibitors, hold times and spiking sources
- Approach to specifications, action limits, alert limits

How to apply the Principles of the FDA Guidance on Method Validation to Biopharmaceuticals – Case Studies
- Method development overall strategy
- Method development for release and stability testing
- Robustness studies
- Typical non-compendial methods for release & stability of monoclonal antibodies
- Relative quantitative methods
- Control charts as continuous method performance verification

New Aspects of Cleaning Validation – how to implement the Requirements of the revised Annex 15

- 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

Quality Aspects of the European Biosimilar Approach

- European regulatory guidance
- Generics vs. biosimilars
- Biosimilar product and manufacturing process
- Comparability exercise

Speakers

Dr Annick Gervais, UCB Biopharma SA, Belgium
Dr Annick Gervais is Chemical engineer by education and Doctor from University Louis Pasteur (Strasbourg, France). She is currently Director of Physico-Chemical Method Development in Analytical Sciences for Biologicals in UCB Pharma (Braine L'Alleud, Belgium) dealing with development, validation, transfer of methods and process support from early phase to life cycle management for therapeutic proteins and monoclonal antibodies in the field of immunology. She is also representing UCB in European Biopharmaceutical Enterprises (EBE) biomanufacturing working group (part of EFPIA).

Dr Rainer Gnibl, GMP Inspector, District Government of Upper Bavaria, Germany
Dr. Gnibl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP-inspections worldwide. Before that, he was also working for the Bavarian Ministry of Environment and Health. Dr Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Dr Siegfried Giess, Paul Ehrlich Institute, Germany
Dr Giess works at the Paul-Ehrlich-Institut, the Federal Institute for Vaccines and Biomedicines in Germany. He is deputy head of the Department of Immunology and head of the Immunochemistry-Section. He is engaged in testing activities of the OMCL network and involved in the quality assessment of immunoglobulins, immunsera and monoclonal antibodies. Dr Giess is nominated expert of the CHMP at the European Medicines Agency (EMA) and is member of the Working Party Monoclonal Antibodies of the EP Commission and belongs to the USP Monoclonal Antibodies Expert Panel. Moreover he is member of the Heads of Medicines Agencies Working Group on Product Testing.

Dr Holger Kavermann, Roche Diagnostics, Germany
Dr Kavermann studied microbiology at the University of Göttingen and obtained his PhD in medical microbiology at the University of Munich. In 2003 he joined Roche Diagnostics GmbH, as Manager QC. He is responsible for the microbiological and cell biological analytics of QC- and In-Process-Control-samples in the production of biotechnological derived active pharmaceutical ingredients.

Dr Tim O'Mahony, Janssen Pharmaceutical, Ireland
Dr O'Mahony has worked for Janssen Pharmaceutical for the past 8 years as a process and laboratory microbiologist in Large Molecule API manufacturing and in sterile bulk API manufacturing. Prior to that he has variously worked as microbiology supervisor, laboratory manager, plant microbiologist and validation engineer, in solid oral pharmaceutical manufacturing, medical diagnostic kit manufacture and medical device manufacture respectively.

Dr Paul Stockbridge, Stockbridge Biopharm Consulting, United Kingdom
Dr Stockbridge spent 23 years with Eli Lilly, initially in fermentation development and then in quality assurance where he became a Q.P. and Q.A. Advisor for biotechnology projects for which he travelled globally. He then moved to a Head of Quality Operations role with Aventis Pharma before being appointed to the role of Corporate Quality Director for Cobra Biomanufacturing Plc. After over 7 years with Cobra he is now providing independent consulting and training services for the steriles, aseptic and biotechnology industries. Paul has a degree in biology, a PhD in fermentation, is an EU Qualified Person and is a Fellow of the U.K. Society of Biology.

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.api-conference.org

Date
Tuesday, 3 November 2015, 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)

Venue
Mövenpick Hotel Amsterdam City Centre
Piet Heinkade 11
1019 BR Amsterdam
The Netherlands
Phone: +31 (0)20 519 12 00
Fax: +31 (0)20 519 12 39

Fee
EUR 890.- per delegate plus VAT.

A special fee of 690,- Euro is granted to participants who also register for the 18th 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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P.O. Box 10 17 64
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 Amsterdam.
Note: there will be **no print-outs** available during the conference.

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☐ **Pre-Conference Session "GMP-compliant Manufacture of Biotech APIs – an Update"**
3 November 2015, Amsterdam, The Netherlands

☐ **I also register for the 18th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients**, 4-6 November 2015, Amsterdam, The Netherlands

I want to take part in
☐ **GMP Part** (4-5 November 2015)
☐ **Regulatory Affairs Part** (5-6 November 2015)
☐ **All three conference days** (4-6 November 2015)

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: Quality Agreements
☐	☐	Session 2: Post approval change management protocol
☐	☐	Session 3: GMP compliant manufacture of highly potent APIs
		Parallel Sessions II
☐	☐	Session 4: Q7 Q&A – how to implement
☐	☐	Session 5: Emerging Markets – current regulatory requirements
☐	☐	Session 6: Current regulatory issues and hurdles

☐ 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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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.

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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)!**

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