Bio Production Forum 2014

Image: IDT

Vaccines and Biologics

GMP Compliance from Development to Manufacturing

7 - 8 October 2014,
Dessau-Roßlau (near Leipzig), Germany

HIGHLIGHTS:

- Regulatory Requirements, Inspection and Findings
- Process Development and Validation
- QbD – a successful Approach
- Microbiological Safety of Biopharmaceuticals
- Development – From Lab to Patient

Special Site Visit of IDTs New Manufacturing Site for Viral Vaccines

SPEAKERS FROM AUTHORITIES

DR ANNIE RIETVELD
Dutch Health Care Inspectorate, The Netherlands

DR GÜNTER WAXENECKER
AGES Austrian Medicines and Medical Devices Agency, Austria

DR MICHA NÜBLING
Paul Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines

SPEAKERS FROM INDUSTRY:

DR SVEN DEUTSCHMANN
Roche Diagnostics, Germany

DR HILTRUD HORN
Horn Pharmaceutical Consulting, Germany

DR JOCHEN PROBST
IDT GmbH, Germany

JOHN A. BENNAN
ComplianceNet Consulting, USA

DR ANDREAS NEUBERT
IDT, Germany

DR PAUL STOCKBRIDGE
Stockbridge Biopharm Consulting, United Kingdom

DR FRANK ZETTL
Roche Diagnostics, Germany

ECA ACADEMY

This conferences is recognised for the ECA GMP Certification Programme „Certified Biotec Manager". Please find details at www.gmp-certification.eu

Bio Production Forum 2014

Vaccines and Biologics

7 - 8 October 2014, Dessau-Roßlau (near Leipzig), Germany

Objectives

During this two day conference, you will become acquainted with examples and strategies to develop, transfer and manufacture Vaccines and Biologics. Experts from authorities and industry will give you an insight view in their experience with optimising development processes, regulatory requirements and possible pitfalls.
The site visit at IDT's new manufacturing site will close the gap between theoretical background and practical implementation.
Additionally you will get information about the current developments on microbiological safety for biopharmaceutical products.

Background

The way from product development to manufacturing of Biopharmaceuticals, Biosimilars and Biologics is complex, time-consuming and risky. The product development business is expected to provide long-term revenues, which could be significant for blockbusters on the market, even for Biopharmaceuticals. Even Especially the pharmaceutical industry's strategy to retreat operationally from this market segment should encourage small and mid-sized biopharmaceutical companies to look for convincing and profitable product candidates. Furthermore, this development provides contract manufacturers with good prospects for developing and manufacturing biological products.

The time aspect should not be underestimated - 8-12 years from the beginning to product launch is a general rule.

Target Audience

Responsible Authorities and associates of biopharmaceutical companies and vaccine manufacturers who are involved in

- Product development
- Process development
- Scale-up and Manufacturing of Biologics
- Analytical Contract Laboratories

Moderators

Axel H. Schroeder, Concept Heidelberg
Dr Andreas Neubert, IDT

Social Event

On 7 October 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.

Programme

European GMP Inspections, Common Findings and Pitfalls, Annex 2 Requirements

- Points of interest in Annex 2
- Common observations

DR ANNIE RIETVELD, *Dutch Health Care Inspectorate*

Changing Regulatory Expectations for Process Validation: Impact on Contract Manufacturing

- Understanding the new FDA and EMA Guidances
- Sharing and managing process knowledge and understanding
- Specific challenges for contract manufacturers and sponsors
- Avoiding common pitfalls and misconceptions

JOHN A. BENNAN, *ComplianceNet Consulting*

Current Regulatory Developments and Considerations on Formulation of Biologics

- Regulatory science of biologics
- Guidance and Monographs
- Wanted and unwanted immunogenicity
- Formulation changes in the course of development and in the life cycle

DR GÜNTER WAXENECKER, *AGES – Austrian Medicines and Medical Devices Agency*

Industrial Experiences esp. New Annex 2 GMP and PIC/S

- Challenges facing the implementation of GMP quality
- Required thought processes
- Ways of approaching the subject

DR PAUL STOCKBRIDGE, *UK*

Process Development and Validation

- Challenges between European and US FDA regulations

DR ANDREAS NEUBERT, *IDT*

QbD Submission – The Roche Approach

- Development and implementation of a design space for a new therapeutic Antibody – a case study

DR FRANK ZETTL, *Roche*

A Newly Constructed Production Plant for Vaccines – An Introduction to the Site Visit

- Purpose and capabilities: Filling and freeze drying of live viral vaccines
- Layouts: A virtual tour
- Compliance: Implementation of GMP requirements for the manufacturing of biologicals for human use

DR JOCHEN PROBST, *IDT*

Mycoplasma and Virus Testing – State of the Art, New Standards and Pharmacopoeial Outlook

- Features of testing technologies
- Harmonisation of test systems by international standards
- Specifications defined by regulatory documents

DR MICHA NÜBLING, *Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines*

Rapid Microbiological Method for Use in Biomanufacturing

- Method Description
- Potential Application
- Pros & Cons

DR SVEN M. DEUTSCHMANN, *Roche*

Development of Biotech Products: From Lab to Patient

- Key aspects for EU and US
- GMP and regulatory challenges
- QBD
- Strategies for success
- Practical examples

DR HILTRUD HORN, *HORN Pharmaceutical Consulting*

SITE VISIT AT IDT BIOLOGIKA

On the second day, we are pleased to invite you to a site visit at IDT manufacturing site in Dessau.

Image: IDT

You will see their new multipurpose site for high- speed filling and large scale freeze-drying of human vaccines (liquid and lyophilized). It is equipped to handle and respond to the complex quality and safety demands of current and future live vaccines and immunotherapeutic medicines.

Key Capabilities:

- **Live Vaccines**: Biosafety Level (BSL) to level 2
- **Presentations**: Liquid and freeze-dried
- **Live recombinant** and **non-recombinant** products
- **Fully automated loading**/unloading freeze-dryer
- **Vial Formats**: 2ml to 10ml
- **Filling Speed**: 24,000 vials/hour (2ml vials)
- **Vial Production**: 20-100 million vials/year (freeze-dried and liquid respectively)
- **Scalability for 2nd line**: Option to use technology of choice in isolation conditions.
- **100% vial control**

IDT Biologika GmbH is an innovative, privately-held company with over 90 years of experience in researching, developing, manufacturing and marketing of biologics. The company focuses on three core areas – animal health, human vaccines, and pharmaceuticals.

The company has experience in technically sophisticated projects, such as innovative biopharmaceuticals and lyophilized compounds, in EMEA- and FDA-inspected facilities, most of which have been built within the last five years. IDT Biologika is a member of the Klocke Group. With more than 1300 employees at six locations worldwide the Klocke Group has been offering its customers a complete range of services for contract manufacture and contract packaging, from development, production and filling through to the development of customised packaging methods and packing for more than 40 years.

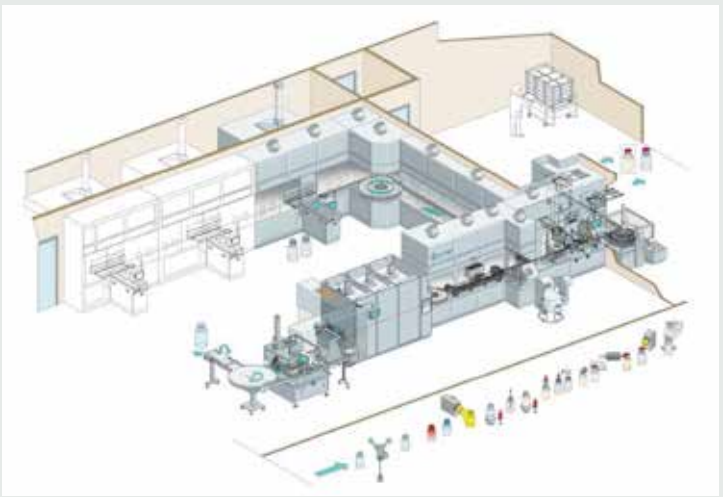

Image: IDT

Speakers

John A. Bennan,
ComplianceNet Consulting LLC, Golden, USA
John has over 28 years of extensive practical experience in GMP compliance for the manufacture of primarily biologics and biopharmaceuticals. An analytical chemist by degree from Northern Arizona University with an MBA from the University of Colorado gained while working in a management position. He was the former head of Quality Assurance at Synergen (later Amgen) where he gained hands-on experience in implementation of quality systems, qualification of facility/equipment, and development/validation of processes and at two multi-product clinical facilities as well as the large-scale LakeCentre market manufacturing facility. After leaving Amgen, Mr. Bennan founded ComplianceNet and has been consulting and training in GMP compliance worldwide for over 19 years specializing in compliance auditing, quality system implementation/remediation as well as process validation with emphasis in biologics/biopharmaceuticals.

Dr Sven M. Deutschmann,
Roche Diagnostics GmbH, Germany
Sven is Director of the Microbiology QC Department in the Pharma Division at Roche Diagnostics GmbH. He is member of the German Pharmacopoeia Commission, the Microbiology Committee and the Working Party "Pyrogentests" of the German Pharmacopoeia Commissions as well as member in the Working Parties "Monocyte Activation Test", "Bacterial Endotoxins", "Mycoplasmas" and "Alternative Methods for the Control of Microbiological Quality" of the European Pharmacopoeia Commissions. In 2009 he was appointed as commissioner of the Central Commission for Biological Safety, a brains trust of the Federal Office of Consumer Protection and Food Safety. In addition, he is member of the PDA "Mycoplasma Task Force" and chairman of the advisory board of the ECA "Rapid Microbiological Methods Working Group".

Dr Hiltrud Horn,
Horn Pharmaceutical Consulting, Germany
Dr Hiltrud Horn is managing director of Horn Pharmaceutical Consulting providing consulting services for the pharmaceutical and biotech industry in EU and US. From 1990 to 1997, she worked at Hoffmann-La Roche, Basel in QC/QA. From 1997 to 1999, she was responsible for medical writing and project management in the "International Regulatory Affairs" department of the same company. In 1999, she joined Knoll AG as Head of "Regulatory Compliance and CMC Documentation" and later "Dossier Production and Compliance" for International Regulatory Affairs. In 2002, she was working as consultant at Cap Gemini Ernst & Young (biotechnology and life sciences) prior to starting her own business.

Dr Andreas Neubert,
IDT Biologika, Germany
Andreas Neubert has more than 25 years experience in vaccine development and manufacturing. He worked about 10 years on R&D projects for viral vaccines. He is Vice President for Vaccines within IDT Biologika, and responsible for the production of vaccines for human and veterinary use. Andreas Neubert was invited to study Veterinary Medicine at the Veterinary Academy in Moscow, Russia, and received his doctorate in veterinary virology from the University Leipzig, Germany, in 1991. He is appointed guest lecturer at University Halle/Saale for cGMP in Pharmaceutical Biotechnology.

Dr Micha Nübling,
Head of Section Molecular Virology, Paul-Ehrlich-Institut, Germany
Micha studied biology in Freiburg with specialization on virology. In the 90's he joined the Division of Virology at PEI and became responsible for the assessments of virological IVDs (focus on nucleic acid amplification tests). He was involved in regulations on virus testing of blood and plasma in Germany and Europe, His work includes the cooperation with the European Medicines Agency in the assessment of epidemiological data included in the Plasma Master File.

Speakers

Dr Jochen Probst,
IDT Biologika GmbH, Dessau-Rosslau, Germany
Jochen Probst studied Biology at the University of Tübingen. After completing his PhD in 2005 he joined the biotech company CureVac GmbH in Tübingen where he held different positions in preclinical research and development as well as in vaccine manufacturing. He was substantially involved in achieving regulatory approval for first in man clinical trials of an entirely new vaccine technology based on messenger RNA in Europe and the US. In 2012 he joined IDT Biologika GmbH in Dessau-Rosslau. As Senior Compliance Manager Quality Unit Vaccines he is heading the quality assurance of the vaccine manufacturing business of the company.

Dr Annie Rietveld,
Coordinating/Specialised Senior Inspector, Dutch Health Care Inspectorate, The Netherlands
Annie Rietveld holds a PhD in biochemistry and has been working in Biotech companies in production and quality assurance. She also acted as QP for release of biotech products for the market and for clinical studies. Since 2001 she joined the Dutch health care inspectorate in different positions. Focus now is GMP inspections of manufacturers of ATMP's

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.

Dr Günter Waxenecker,
MDRA, Austria
Department Biologicals, Preclinical, Statistics & Veterinary Medicinal Products (BPSV), Institute Assessment & Analysis , BASG - Federal Office for Safety in Health Care, AGES - Austrian Agency for Health and Food Safety Günter Waxenecker is biotechnologist and started in Research at Sandoz, later Novartis Research Institute in Vienna and worked as Project Leader and Program Manager in R&D for Igeneon, Pelias and Intercell. He holds a Master degree in drug regulatory affairs and is also lecturer in technical colleges. Since 2007 he is working as Expert biologics for the Austrian Federal Office for Safety in Health Care, is involved in the evaluation of clinical trial applications, scientific advices, marketing authorisation applications and life-cycle processes. He is member of the CHMP Safety Working Party, representative to the EMA Pandemic task force, participates in the work of the CHMP biologics WP and is drafting group member for different CHMP guidance documents.

Dr Frank Zettl,
Director Development Recovery & DSP, Roche Diagnostics GmbH, Germany
Frank Zettl studied Chemistry at the Ludwig-Maximilians University in Munich. In 2006 he joined Roche. He has experience in QbD, Downstream Processing, Process Validation, and methods for chromatography, filtration and UF/DF. Today he holds the position of Director.

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

- Validation Manager (ECA)
- QA Manager (ECA)
- API (Production) Manager (ECA)
- Quality Control Manager (ECA)
- Pharmaceutical Engineering/Production Manager (ECA)
- Computer Validation Manager (ECA)
- Regulatory Affairs Manager (ECA)
- Microbiological Laboratory Manager (ECA)
- Sterile Production Manager (ECA)
- Pharmaceutical Development Manager (ECA)
- Biotech Manager (ECA)

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.

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.

Special offer with Lufthansa – discounted travel for Bio Production Forum attendees

Lufthansa
Official Airline

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!

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.bio-conference.org

Date
Tuesday, 7 October 2014, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 8 October 2014, 8.30 – 17.00 h

Venue
Radisson Blu Fürst Leopold Hotel
Friedensplatz
06844 Dessau, Germany
Phone +49(0)340 25 15 0
Fax +49(0)340 25 15 146

Bus Shuttle Berlin Tegel Airport and Airport Leipzig-Halle to Conference Hotel
There will be a bus shuttle free-of-charge from Airport Berlin Tegel and Airport Leipzig–Halle to Radisson Blu Fürst Leopold Hotel on Monday, 6 October at 19.00 h.

On 8 October at appr. 17.30 h a free-of-charge bus will take you to Airport Berlin Tegel (transfer time approx. 90 minutes) or Leipzig Airport (transfer time approx. 60 minutes). You will receive a booking form for the shuttle service with your conference confirmation.

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

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.bio-conference.org.

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 room rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference language
The official conference language will be English.

Organisation and Contact
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Axel H Schroeder (Operations Director) at +49(0)6221/84 44 10, or per e-mail at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Jessica Stürmer (Organisation Manager) at +49(0)6221/84 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
Germany

Reservation Form (Please complete in full)

+49 6221 84 44 34

Vaccines and Biologics – Bio Production Forum 2014
7-8 October 2014, Dessau-Roßlau (near Leipzig), Germany

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General terms and conditions
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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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)

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