ECA
European Compliance Academy

Images: IDT Biologika

**Special Site Visit on the Occasion of IDT's 90th Anniversary**

# Vaccines and Biologics

## Development, Scale Up and Manufacturing

**Dessau-Roßlau (near Leipzig), Germany**
**22 – 23 November 2011**

**AUTHORITY SPEAKERS:**

**DR STEFFEN GROSS**
Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biologics, Germany

**DR DANIEL MÜLLER**
GMP Inspectorate Tübingen Germany

**INDUSTRY SPEAKERS:**

**DR SVEN DEUTSCHMANN**
Roche Diagnostics, Germany

**DR KARLHEINZ ENSSLE**
CSL Behring, Germany

**DR MARKUS FIDO**
Vela Laboratory, Austria

**DR ANDREAS NEUBERT**
IDT, Germany

**ALAIN PRALONG**
Pharma-Consulting ENABLE, Switzerland

**PETER LASHLEY**
Sanofi Pasteur, Canada

90 Years IDT

IDT

**HIGHLIGHTS:**

- Regulatory Requirements
- Inspection and Findings
- Challenges in Development of Biologics
- Disposable Manufacturing Processes
- Optimising of Development Processes

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

# Vaccines and Biologics

Dessau (near Leipzig), Germany, 22-23 November 2011

## Objectives

During this two day conference, you will become acquainted with examples and strategies for developing, transferring and manufacturing 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 manufacturing site will close the gap between theoretical background and practical implementation.

## 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. Especially the pharmaceutical industry's strategy to retreat operationally from this market segment should encourage small and mid-sized bio-pharmaceutical 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 under-estimated – 8-12 years from the beginning to product launch is a general rule.

What are the possibilities to speed up and optimise the process of development to manufacturing? Do modern methods in analysis and microbiology provide the chance to save time and costs? Further, are QbD and Process Validation benefits or constraints?

This conference will help to find answers.

## 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 Biologika*

## Conference Folder

You cannot take part in this event? Just order the documentation at the price of € 180.- + VAT + postage and packing. You can use the registration form for this purpose. Please note: In order to ensure that the documentation is complete, the conference folder will not be available until two weeks after the event.

## Programme

**Process Development for Biologicals – Major Challenges, Tools and Solutions**
- Process development approaches
- Variability of biological manufacturing processes
- Process understanding – the major goal to meet future cGMP regulations

**DR ANDREAS NEUBERT,** *IDT Biologika*

**Development of Disposable Manufacturing Processes**
- History of Development
- How disposable technology changes the manufacturing
- Setup in USP and DSP
- Impact of disposable technology on timelines, CAPEX and COGS – Crucell's experience
- Remaining challenges in USP and DSP for disposable technology

**ALAIN PRALONG,** *Pharma-Consutling ENABLE*

**Inspections and Authorisation for Manufacturing of Biologicals – Trends and Future (Regulatory View)**
- Cmc Challenges Encountered During Life Cycle Management
- Considerations for design of control strategy and regulatory perspectives
- Process Improvements under the "QbD" Paradigm
- Regulatory perspectives on 'Post-approval change management protocols
- Minor Process Changes Leading to Major Product Changes

**DR STEFFEN GROSS,** *Paul-Ehrlich-Institut*

**Evolution of Product Development during Clinical Trial Phases – Industry Perspective**
- Requirements for preclinical process development activities
- Process validation
- Scale-up for commercial production

**PETER LASHLEY,** *Sanofi Pasteur*

**90 years IDT Biologika Introduction Site Visit**
- 90 years of development and manufacturing of biologicals in Dessau
- IDT Biologika today
- Future targets

**DR ANDREAS NEUBERT,** *IDT Biologika*

**Process Validation – how does that match with Product and Process Development**
- Risk assessment and small scale studies as a prerequisite for range finding and process validation
- Process validation at full scale and small scale
- Development of equipment cleaning process

**DR KARLHEINZ ENSSLE,** *CSL Behring*

**Inspection – GMP at manufacturing sites of biologics**
- Important Regulatory Documents
- Update Annex 2
- Hot topics during Inspections
- Examples of observations

**DR DANIEL MÜLLER,** *GMP Inspectorate Tübingen*

**How to characterize a complex Molecule – Proteins and Vaccines? Analytics between Method Development and Validation**
- Analytical methods for Biologics and Biosimilars
- Challenges during analysis of proteins
- Method parameters, specifications and acceptance criteria
- Stability studies and product release

**DR MARKUS FIDO,** *Vela Laboratory*

**May Rapid Microbiological Methods Speed up Process Development and Process Validation**
- Applications for Alternative Microbiological Methods
- Applications for Alternative Molecular-based Methods

**DR SVEN DEUTSCHMANN,** *Roche Diagnostics*

## Programme (cont.)

**Site Visit at IDT Biologika**
On the second day, we are pleased to invite you to a site vist at the IDT Manufacturing site in Dessau.

Image: IDT Biologika

IDT Biologika GmbH is an innovative, privately-held company with 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: For **veterinary markets**, IDT Biologika manufactures and markets a comprehensive range of high-quality vaccines and other products for animal health. For **vaccines**, IDT Biologika offers development services and manufacturing facilities for clinical phase I to III as well as commercial supplies for leading edge viral and bacterial human vaccines, addressing health issues such as tuberculosis, AIDS, malaria and pox. For **pharmaceutical markets**, IDT Biologika specializes in the development and manufacture of sterile liquid drugs, providing fully-integrated services ranging from formulation development and clinical manufacturing through to large-scale production, packaging and quality control.

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. The Group also has extensive experience in contract manufacturing of solid dosage forms and cytostatics.

## Social Event

On 22 November 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.

## Speakers

**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".

**Speakers (cont.)**

**DR KARLHEINZ ENSSLE,** *CSL Behring GmbH, Marburg, Germany*
Dr Karlheinz Enssle is responsible for e.g. validation of development products with recombinant proteins at CSL Behring in Marburg, Germany. He studied Biology and Chemistry (doctoral thesis in Immunology and Virology). After eight years in research of former Behringwerke AG (e.g. development of recombinant products) he worked as a head of quality control labs and as qualified person with Chiron Behring before joining process evaluation and validation of Aventis Behring (now CSL Behring).

**DR MARKUS FIDO,** *Vela, Austria*
Markus Fido is CEO and Founder of Vela Laboratories, were he is responsible for Finance & Controlling Regulatory Affairs & Quality Operations. Before that he was Head Quality Control at Igeneon / Aphton Biopharma AG where he was in charge for all QC aspects of pre-clinical and clinical projects such as stability studies, specifications, method validation, and product release. Prior he was working as a Group Leader of Immunology and Product Development at Biomin GmbH, Head Biochemical Control at Baxter AG and Head Quality Operations at Octapharma GmbH. His focus is GMP/GCP concerns during the development of Biopharmaceuticals, Biosimilars and Biologics. He holds a Ph.D. in biochemistry and molecular microbiology from the Technical University in Graz (Austria).

**DR STEFFEN GROSS,**
*Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biologics, Germany*
From1990-1995, Friedrich-Schiller- University Jena, Germany, study in Biology . 1995-1998, Max Planck Research Unit Molecular Cell Biology Jena, Germany, Pursuing a Ph.D. degree (1998), "The PDGF-receptor directed protein tyrosine phosphatases in cell signaling pathways". 1998-2001 Institute of Cellular Signaling, University Nijmegen, The Netherlands, postdoctoral position, "Characterization of IA-2/IA-2 two phosphatase-like proteins identified as major auto antigens in diabetes mellitus", during this time several month working visit at the NIH, Bethesda, Maryland, USA. 2001-2005 Institute for Biochemistry II, University of Frankfurt, Germany, Research group leader: "Regulation of the NO receptor soluble guanylyl cyclase by tyrosine phosphorylation". Since 2005 - present, Paul-Ehrlich Institute, Deputy Head Section Monoclonal and Polyclonal Antibodies, Laboratory Head and Scientific Assessor (Quality, Pre-clinic).

**PETER LASHLEY,**
*Director Executive Support, BioProcess R&D, Sanofi Pasteur, Toronto, Canada*
Peter has a Masters of Business Administration degree from McMaster University and a B.Sc. in Microbiology from the University of Toronto. Peter has been with sanofi pasteur for more than 25 years starting as a technician and progressing through positions with greater responsibility through, Quality Control, Manufacturing, Sales and Operations Planning and finally, Research and Development. Today he is Director Executive Support, BioProcess R&D.

**DR DANIEL MÜLLER,** *GMP Inspectorate Local Government, Tübingen, Germany*
Daniel Müller studied Pharmacy at the University of Wuerzburg, followed by doctorate. He 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 at Tübingen. Since that time he has been working as a GMP Inspector with focus on biotechnological active ingredients and sterile drug products.

**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.

**ALAIN PRALONG,** *Pharma-Consulting ENABLE GmbH, Switzerland*
Alain Pralong obtained his doctorate in molecular and cellular biology at the University of Berne in 2000. His research into apoptosis was conducted jointly between the University and Novartis, where all laboratory-based investigations were carried out. From 2000 to 2004 he worked on manufacturing Adenovaccine clinical trial material at Schering-Plough. Following a move to Roche in 2004, he managed their transfer of Avastin process manufacturing from Genentech. From 2007 to 2008, he worked at Merck-Serono in the manufacturing of hormones used in treatment of infertility. Since 2008, Alain has been Vice President at Crucell where he led the Global Process Development Department working on various monoclonal antibodies and vaccines until the take over of Crucell by Johnson & Johnson in 2011. Alain works now as consultant for Pharma-Consulting ENABLE GmbH.

## 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.gmp-compliance.org**

### Date
22 November 2011, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)
23 November 2011, 08.30 – 17.00 h

### Venue
Radisson Blu Fürst Leopold Hotel
Friedensplatz
06844 Dessau–Roßlau (near Leipzig)
Phone 0340 25 15 0; Fax 0340 25 15 177

### Bus Shuttle Berlin Tegel Airport and Airport Leizig-Halle to Conference Hotel
There will be a free of charge bus shuttle from the Airports Berlin Tegel and Leipzig–Halle to Radisson Blu Fürst Leopold Hotel on Monday, 21 November 2011 at 19.00 h.
On 23 November a free of charge bus shuttle will take you to the Airports Berlin Tegel (transfer time approx. 90 minutes) and Leipzig (transfer time approx. 60 minutes) after the end of the conference at approx. 17.30 h.

For booking the shuttle service please use the order form which you will receive with the confirmation for your registration by e-mail.

### Conference fees
ECA Members EUR 1.490,- per delegate plus VAT
APIC Members EUR 1.590,- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members EUR 1.690,- per delegate plus VAT
EU GMP Inspectorates EUR 845,- per delegate plus VAT
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.

### 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 conference. Please use this form for your room reservation or be sure to mention "VA 1419414 ECA Event" to receive the specially negotiated room rate (86 EUR for a Single, 112 EUR for a Double – both incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 24 October 2011. Early reservation is recommended.

### Conference Language
The official conference language will be English.

### Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
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**For questions regarding content:**
Axel H. Schroeder (Operations Director) at +49-62 21/84 44 10 or per e-mail at schroeder@concept-heidelberg.de.
**For questions regarding reservation, hotel, organisation etc.:**
Jessica Stürmer (Organisation Manager) at +49-62 21/84 44 43 or per e-mail at stuermer@concept-heidelberg.de.

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Reservation Form (Please complete in full)

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### Vaccines and Biologics
Dessau (near Leipzig), Germany, 22-23 November 2011

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- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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