

SPEAKERS

PROF TUDOR ARVINTE

University of Geneva,
Switzerland

JONATHAN BARNESLEY

Merck Serono, Switzerland

DR FRANK BOETTGER

Vetter Pharma-Fertigung,
Germany

DR PATRICK GARIDEL

Boehringer Ingelheim,
Germany

DR BURKHART GÖDDE

Roche Diagnostics, Germany

DR HILTRUD HORN

Horn Pharmaceutical
Consulting, Germany

PROF WIM JISKOOT

Leiden University,
The Netherlands

SHERRY MARTIN-MOE

Genentech USA

DR JENS REGELIN

Merck Serono, Switzerland

DR ANDREAS ROTHMUND

Vetter Pharma-Fertigung,
Germany

DR TIM SERNO

Novartis Pharma, Switzerland

DR GÜNTER WAXENECKER

AGES PharmMed, Austria

DR JÖRG ZÜRCHER

Bayer Schering Pharma,
Germany

Including Site Visit at
Merck Serono, Aubonne

Bio Production Forum

Fill and Finish for Biopharmaceuticals

Drug Product Development
Process Development, Transfer and Launch Manufacturing
Marketed Product Compliance

Geneva, Switzerland, 15 – 17 June 2010

HIGHLIGHTS:

- Biopharma – the Road to Maturity
- High Throughput Formulation Screening
- From Formulation to final Product
- Assessment of Physical Stress during Fill & Finish Manufacturing of Biologics
- QbD Development
- Packaging of Biologics
- Current Regulatory Developments for Biopharmaceuticals and Considerations on Formulation
- Marketing Authorisation

Exclusive Media Partner:

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This conference is supported by

The University of Munich, Germany / Chair for Pharmaceutical Technology and Biopharmaceutics at the Department of Pharmacy-Center for Drug Research



The Center for Drug Research is dedicated to training in all areas of pharmaceutical technology for undergraduate and graduate students and to research in the field of parenteral dosage forms, colloidal systems and has a specific focus on protein drug formulations. The Center conducts research projects with a number of biotech drugs. Further research topics are drug delivery systems for topical delivery as well as systemic depot forms and targeting approaches using nano-scaled technologies. Process technologies in the area of freeze drying, spray drying, nanoparticle and liposome formulation etc. are applied and further developed.

ETH Zurich - A science and technology university with an outstanding research record



ETH Zurich is the study, research and work place of 20,000 people from 80 nations. About 370 professors in 16 departments teach mainly in the engineering sciences and architecture, system-oriented sciences, mathematics and natural sciences areas and carry out research that is highly valued worldwide.

As an internationally oriented institution of higher education and a nationally grounded one this forward-looking task is fulfilled in service to the Swiss nation.

Schweizerische Gesellschaft der Pharmazeutischen Wissenschaften (SGPhW) / Swiss Academy of Pharmaceutical Sciences (SAPhS)



The society promotes as a principal goal Pharmaceutical Sciences in Switzerland. For this purpose the society has assumed the function of an academy pursuing the following mission:

- Unifying and coaching the national and regional societies linked to the discipline of Pharmaceutical Sciences
- Promotion of national and international scientific contacts and of cooperations with other scientific societies and academies
- Public promotion of Pharmaceutical Sciences
- Promotion of the communication of eminent pharmaceutical findings and realizations in science, research, development, industry, health care and public society
- To award distinguished persons for their merits in Pharmaceutical Science

ECA grants cut-rate participations to Universities, Research Institutes, etc.

We encourage young scientists/students to apply for these grants! Please contact Mr Axel H Schroeder at schroeder@concept-heidelberg.de for details.

Cilag AG



Founded in 1936 in Schaffhausen, Switzerland, CILAG's creative and innovative approach has resulted in the continuous introduction of new products, processes and technologies. Today, the company is a worldwide strategic development, launch and production center of APIs (active pharmaceutical ingredients) and drug products within the Johnson & Johnson Pharmaceuticals Group, the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical and professional markets.

University of Leiden



Leiden University is the oldest university in the Netherlands. It was founded in February 1575, as a gift from William of Orange to the citizens of Leiden who had withstood a long siege by the Spaniards. In Leiden there are approximately 17,000 students and 4,000 staff members. The University consists of nine faculties, a School of Management and a School of Education. The University houses faculties of Archaeology, Arts, Creative and Performing Arts, Law, LUMC (Leiden University Medical Center), Mathematics and Natural Sciences, Philosophy, Social and Behavioural Sciences, and Theology.

Merck Serono



Merck Serono is the division for innovative prescription pharmaceuticals of Merck KGaA, Darmstadt, Germany, a global pharmaceutical and chemical company. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. In the United States and Canada, EMD Serono operates through separately incorporated affiliates.

Merck Serono has leading brands serving patients with cancer (Erbitux[®], cetuximab), multiple sclerosis (Rebif[®], interferon beta-1a), infertility (Gonal-f[®], follitropin alpha), endocrine and metabolic disorders (Saizen[®] and Seros-tim[®], somatropin), (Kuvan[®], sapropterin dihydrochloride) as well as cardiometabolic diseases (Glucophage[®], metformin), (Concor[®], bisoprolol), (Euthyrox[®], levothyroxine). Not all products are available in all markets.

With an annual R&D expenditure of around € 1bn, Merck Serono is committed to growing its business in specialist-focused therapeutic areas including neurodegenerative diseases, oncology, fertility and endocrinology, as well as new areas potentially arising out of research and development in autoimmune and inflammatory diseases.

For more information, please visit www.merckserono.com or www.merck.de

Objectives

Dear Colleagues,



On 15 – 17 June 2010, the 6th Bio Production Forum takes place in Geneva, Switzerland. It is an Event with tradition that was organised successfully in Schaffhausen, Switzerland the last five years. As an innovative event focussing on an innovative industry, we like to

change the venue towards Geneva, and are happy to provide the participants a new insight in the field of biopharmaceutical manufacturing by visiting the Merck Serono site, Aubonne.

Development and manufacturing of Biopharmaceuticals is a process chain with high value as well as high ethical values. For both reasons it is of utmost importance to manufacture drug products of highest available quality standards.

Therefore, ECA has dedicated this conference solely to these important steps in biopharmaceutical manufacture. We are all aware of the criticality of the late process stages. Only professional development well projected and managed transfer, and the use of state-of-the art technologies, ensures a safe market supply. Current developments in regulatory requirements will support the pharmaceutical industry in providing our customers with premium and safe medicines. In this event, we will initiate the discussion and help understanding and applying the new trends.

ECA is very honoured to be supported by the University of Munich, the Leiden University, the Swiss Society of Pharmaceutical Sciences, the ETH Zurich, Cilag AG and Merck Serono in hosting this event.

The involvement of all these organisations reflects the importance and actuality of the chosen topics.

It would be a great pleasure for me to welcome you in Vienna. It promises to be an outstanding experience.

Yours sincerely,



Daniel Scheidegger
Chairman of the ECA Advisory Board and
Managing Director of Genzyme

Target Group

- Vice Presidents, Directors, Heads of, Managing Directors and Managers responsible for:
- Manufacturing
- Quality
- Compliance
- Supply Chain
- Process Management
- Research and Development

Moderator

Christian Schröter, Merck
Axel Schroeder, CONCEPT HEIDELBERG

Scientific Advisory Board

Matej Janovjak, *Cilag, Johnson&Johnson*
Dr Christian Schröter, *Merck*
Prof Dr Gerhard Winter, *University of Munich*
Prof Dr Wim Jiskoot, *University Leiden*



Social Event in Geneva

On Tuesday, 15th June 2010, 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

Module 1 Drug Product Development

Key Note: Biopharma – the Road to Maturity

- A short history of biotech to date
- Challenges now facing our industry
- What the future could look like for Biopharma
- What do we need to do to survive?!

JONATHAN BARNESLEY, *Merck Serono*

Fluorescent Dyes for the Characterization of Aggregates

- Protein aggregation and its potential implications for product quality
- Orthogonal methods to characterize protein aggregates
- Fluorescent dyes to characterize protein aggregates
- Case studies: applications of fluorescent dyes

PROF WIM JISKOOT, *Leiden University*

High Throughput Formulation Screening

PROF TUDOR ARVINTE, *University of Geneva*

The Role of Cyclodextrins in Protein Aggregation

- Influence of formulation on system selection
- Inhibition of protein aggregation by cyclodextrins
- Cyclodextrins as formulation alternative to non-ionic surfactants
- Interaction between cyclodextrins and protein
- Interfacial behaviour of mixed protein-cyclodextrin solutions

DR TIM SERNO, *Novartis Pharma*

From QTPP to Control Strategy – Linking the QbD-Elements together

- Definition of QTPP drug substance COA's derived by risk analysis
- Linking to CPP's and trigger further process
- Characterization studies leading to design space and control strategy
- Multi disciplinary approach to put in practice

DR BURKHART GÖDDE, *Roche Diagnostics GmbH*

Module 2 Process Development, Transfer and Launch Manufacturing

From Formulation to final Product

- Influence of formulation on system selection
- Influence of application scheme on system selection
- Process- and component-options
- Consequences of system selection
- Potential add-ons - convenience, safety ...

DR ANDREAS ROTHMUND, *Vetter Pharma-Fertigung*

Drug Product QbD: The Integration of Formulation, Process Development and Process Validation with QbD

SHERRY MARTIN-MOE, *Genentech*

Advanced Packaging for Biologics

- Regulatory requirements
- Challenges of Biologics for Packaging
- Necessary characteristics of standard containers
- Functional Containers
- Container Materials
- Surface coatings

DR JÖRG ZÜRCHER, *Bayer Schering Pharma*

New Developments in Siliconisation and Silicone Layer Analytics

- Siliconisation – Why?
- Types and methods of siliconisation – Scope and limitations
- Analytical methods – scope and limitations
- Creation of specific siliconisation patterns
- Characteristics of silicone oil on glass surfaces
- Further applications

DR FRANK BOETTGER, *Vetter Pharma-Fertigung*

Programme (cont.)

Assessment of Physical Stress During Fill & Finish Manufacturing of Biologics

- Physical stresses encountered during the manufacturing process
- Physical stress and impact on stability
- Simulating physical stresses using accelerated stability studies
- Analytical assays to characterize product quality upon physical stress
- Improving physical and colloidal stability using a rational formulation design
- Reducing physical stress using an adequate process development strategy

DR PATRICK GARIDEL, *Boehringer Ingelheim*

Introduction to Aubonne Plant of Merck Serono

DR JENS REGELIN, *Site Director, Aubonne plant, Merck Serono*

Site Visit at Merck Serono, Aubonne

Merck Serono Aubonne (CH) is a fully integrated site including both Active Drug Substance (Biotech cell culture + purification), Fill & Finish and Packaging Production activities. Located close to Geneva, the facility is producing injectable recombinant drugs in the fields of Neurology, Infertility treatments, and Growth hormone mainly, covering both commercial products for WW global markets as well as clinical supplies and development activities, with over 300 employees. The site is FDA approved.



Expertise in mid-size perfusion and Fed-batch bioreactors, various purification technologies (large scale UF, packed bed chromatography, Immuno-affinity, Ion exchange, Size exclusion, RPHPLC, columns up to 1m diameter), protein formulations, liquid filling (ampoules, vials, syringes and cartridges), lyophilization, visual inspection and final packaging.

Site is well equipped with 5 independent cell culture suites (with over 25 bioreactors ranging from 40L to 350L scale), 4 purification suites, 3 filling lines, visual inspection and fully automated packaging lines.

Module 3 Marketed Product Compliance

Current Regulatory Developments for Biopharmaceuticals and Considerations on Formulation

- Biologics: Their Nature and Regulation
- Updates on relevant EMEA and ICH guidelines
- Immunogenicity of Biopharmaceuticals and Biosimilars
- Formulation aspects of Biosimilars

DR GÜNTER WAXENECKER, *AGES PharmMed, Austria*

Marketing Authorisation

DR HILTRUD HORN, *Horn Pharmaceutical Consulting*

Conference Exhibition

The European Compliance Academy offers you the opportunity to present your company, your products and services to your target group almost without any scattering losses. The costs for an exhibition space at this event are € 1,490. You will find details and a registration form on our website www.gmp-compliance.org. Just follow the link „Conferences“ on the homepage.



Speakers

Prof Tudor Arvinte, *University of Geneva, Switzerland*

Jonathan Barnsley, *Senior Vice President of Biotech Manufacturing & Process Development Merck Serono S.A., Switzerland*

Jonathan graduated with a First Class Honours Degree in Chemical Engineering and during the last 28 years he has acquired a broad range of experience in the pharmaceutical industry on an international level. Although principally orientated towards biotechnology his field of experience includes fine chemicals and fill/finish within both Development and Manufacturing environments. He had held senior positions in manufacturing and engineering in both large and start up companies, and he has currently Senior VP of Biotech Manufacturing & Process Development for one of the leading biotech company's in Europe.

Dr Frank Boettger, *Vetter Pharma-Fertigung, Ravensburg, Germany*

Dr Frank Böttger has studied Chemistry at the University of Kassel, Germany. He achieved his Ph. D. in Chemistry and Biochemistry for developing new polysaccharide derivatives suitable for the application as blood volume replacement fluids. His work was sponsored and awarded by B. Braun Melsungen AG. After his work at B. Braun Melsungen, he started as a member of the Process Implementation Team at Vetter-Pharma Fertigung GmbH Ravensburg in 2003. In 2004 he has built up Vetter's development laboratories and took over the responsibility of the group Process Development.

Dr Patrick Garidel, *Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany*

Dr. Burkhard Gödde, *Roche Diagnostics GmbH, Penzberg, Germany.*

After his study in chemistry, Burkardt Gödde worked at Eurofins Scientific, Switzerland. Since 2002 he is Manager Quality Assurance & Compliance at Roche and responsible for Qualification of technical equipment including validation of computer based systems. Since 2005 member of the Roche PAT working group and since 2008 establishing a QbD Team.

Dr Hiltrud Horn, *Horn Pharmaceutical Consulting, Germany*

Dr Horn is managing director of HORN PHARMACEUTICAL CONSULTING. From 1990 to 1997, she was employed by Hoffmann-La Roche in Quality Assurance. From 1997 to 1999, she dealt with medical writing in the 'International Drug Regulatory Affairs and Project Management' department of the same company. In 1999, she joined Knoll AG as head of the departments 'Regulatory Compliance and CMC Documentation' and 'Dossier Production and Compliance' for international drug registration. In 2002, she started at Cap Gemini Ernst & Young, where she was the responsible consultant for questions concerning biotechnology and life sciences.

Prof Wim Jiskoot, *Leiden University, The Netherlands*

Wim Jiskoot graduated as a pharmacist at Utrecht University, The Netherlands (1987). In 1991 he obtained his PhD degree at Utrecht University 1994 he became head of the Department of Bacterial Vaccine Development at the Dutch National Institute of Public Health and the Environment. In 1998 he became a staff member at the Department of Pharmaceutics of Utrecht University. In 2006 he became full professor at the Division of Drug Delivery Technology, Leiden/Amsterdam Center for Drug Research (LACDR), Leiden University.

Sherry Martin-Moe, *Ph.D., Genentech, USA*

Dr Jens Regelin, *Site Director, Aubonne plant, Merck Serono, Switzerland*

Dr Andreas Rothmund, *Qualified Person, Vetter Pharma-Fertigung, Ravensburg, Germany*

Dr Andreas Rothmund is Qualified Person at Vetter Pharma-Fertigung in Ravensburg, Germany, an independent contract manufacturer specialised in the aseptic production of pre-filled application systems. He joined Vetter in 1994, where he has held several positions, including Head of Production for one of Vetter's aseptic production units. Dr Rothmund holds a degree in organic chemistry from the University of Constance, Germany.

Dr Tim Serno, *Novartis Pharma, Switzerland*

Tim Serno has recently joined Novartis Pharma AG, Basel, Switzerland where he works in the field of formulation and process development of biopharmaceutical products. Prior to joining Novartis he worked as a project leader at Coriolis Pharma Service GmbH, Martinsried, Germany and completed a PhD at the University of Munich and the University of Colorado under the supervision of Prof Gerhard Winter and Prof John Carpenter.

Dr Günter Waxenecker, *AGES PharmMed, Austria*

Günter Waxenecker studied Food science and Biotechnology at the University of Agricultural Sciences in Vienna; Started in Research at Novartis Research Institute in Vienna, later in R&D for Igeneon and finally Intercell; Held various positions as Postdoc, Project Leader and Program Manager; Now working as Assessor (Expert Biologics) at AGES PharmMed (Austrian Competent Authority) involved in assessment of clinical trial applications and as EMEA expert assessing products submitted for marketing authorization under the EMEA centralized procedure. Additionally assessor for national and central (EMEA) Scientific Advice procedures.

Dr Jörg Zürcher, *Bayer Schering Pharma, Germany*

Jörg Zürcher is a pharmacist. He studied in Berlin and finished his studies with PhD-degree. Since July 1990 he is working for Schering AG, Berlin in the Pharmaceutical Development. His responsibility is the development of containers for Schering's new products as well as for the market product in the course of life-cycle management with focus on packaging of liquid dosage forms. In addition, he is responsible for the development of application systems like pre-filled syringes or unique, product-specific devices.

Conference language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
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For questions regarding content:

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

For questions regarding reservation, hotel, organisation etc.:

Ms Marion Weidemaier (Organisation Manager) at +49-6221/84 44 46, or per e-mail at weidemaier@concept-heidelberg.de.

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 Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide 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.

What Are the Benefits of ECA?

First benefit: During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit: The GMP Guideline Manager CD ROM with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.



How Do You Become Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. There are no obligations for the member! Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website <http://www.gmp-compliance.org>.

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 2 weeks after the event.

Easy Registration



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Internet:
www.bio-conference.org

Date

Tuesday, 15th June 2010, 09.30 - 17.30 h
(Registration and coffee 09.00 – 09.30 h)
Wednesday, 16th June 2010, 08.30 – 17.30 h
Thursday, 17th June 2010, 09.00 – 13.30 h

Venue

Mövenpick Hotel Geneva
Case Postale 556
Route de Pré-Bois 20
CH-1215 Genève 15
Tel +41 22 717 11 11
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Fees

Option I: Day 1 and Day 2

Non-ECA Members EUR 1,590.- per delegate plus VAT
ECA Members EUR 1,431.- per delegate plus VAT
APIC Members EUR 1,510.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates EUR 795.- per delegate plus VAT

Option II: Day 2 and Day 3

Non-ECA Members EUR 1,590.- per delegate plus VAT
ECA Members EUR 1,431.- per delegate plus VAT
APIC Members EUR 1,510.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates EUR 795.- per delegate plus VAT

Option III: Day 1 – Day 3

Non-ECA Members EUR 1,990.- per delegate plus VAT
ECA Members EUR 1,791.- per delegate plus VAT
APIC Members EUR 1,890.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates EUR 995.- 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.

ECA grants cut-rate participations to Universities, Research Institutes, etc.

We encourage young scientists/students to apply for these grants!
Please contact Mr Axel H Schroeder at
schroeder@concept-heidelberg.de for details.

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 or be sure to mention "VA 6441 ECA Event; Booking Reference 59.60.81" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 14 May 2010. Early reservation is recommended.

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

Reservation Form (Please complete in full)

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Bio Production Forum – Fill and Finish for Biopharmaceuticals

15 – 17 June 2010, Geneva, Switzerland

- Option I – Day 1 and 2
 Option II – Day 2 and 3
 Option III – Day 1 – 3
 Yes, I also would like to participate in the site visit
 Mr Ms

Title, first name, surname

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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 %

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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)!