



EUROPEAN COMPLIANCE
ACADEMY

SPEAKERS

PROF SVEN FROKJAER

University of Copenhagen

DR ING CHRISTOF GROS

Cilag

DR FRANK HENNECKE

Cytos Biotechnology

DR AJAZ HUSSAIN

Philip Morris International
Global Services

MATEJ JANOVJAK

Johnson & Johnson

PROF WIM JISKOOT

University Leiden

PROF JEAN-CHRISTOPHE

LEROUX
ETH Zurich

DR PAUL MC KENZIE

Centocor

DR URS MEYER

University of Basle

DR RAINER MÜLLER

Roche Diagnostics

DR JUSTIN O. NEWAY

Aegis Analytical
Corporation

DR CHRISTIAN SCHRÖTER

Merck

DR MATHIEU STREEFLAND

The Netherlands Vaccine
Institute

PROF GERHARD WINTER

University of Munich



Image: Cilag

Bio Production Forum

From Development to Market Product Compliance

Schaffhausen, Switzerland
29 September – 1 October 2009

This conference is supported by:

ETH

Eidgenössische Technische Hochschule Zürich
Swiss Federal Institute of Technology Zurich

_____ **LMU**
Ludwig-
Maximilians-
Universität-
München _____



+ SAPHs
Swiss Academy of
Pharmaceutical Sciences



Universiteit Leiden

Objectives

Dear Colleagues,



This year, ECA's Bio Production Forum celebrates its 5th anniversary, and the success story goes on. Since 2005 the Bio Production Forum has developed as an important annual platform for industry, academia and regulatory bodies for exchanging the current developments in the final manufacturing steps for biopharmaceuticals. We are all aware of the criticality of the late process stages. Only the use of state-of-the-art technology ensures a safe market supply.

During the 2009 Conference we will concentrate on three key areas:

- Product & Process Development, Immuno Drugs, Genomic Medicines and Proteins
- Process Transfer & Launch Manufacturing
- Market Product Compliance

We are very happy that leading experts from science and industry accepted our invitation and will discuss with you the latest trends that have a major impact on our business.

Please use this unique opportunity to keep abreast of these changes.

We wish you a successful and interesting conference.

Yours sincerely,

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

Target Group

Vice Presidents, Directors, Heads of Production, Managing Directors and Managers responsible for:

- Manufacturing
- Quality
- Compliance
- Supply Chain
- Process Management
- Research and Development

Cilag AG grants free-of-charge participations to Universities, Research Institutes, etc. We encourage young scientists to apply for these grants! Please contact Mr Axel H Schroeder at schroeder@concept-heidelberg.de for details.

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*

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

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.

Programme
Module 1
Drug Product &
Process Development

Chairman:
PROF DR GERHARD WINTER

Reinventing Biologics Pharmaceutical Development and Marketed Product Support

- pH sensitive polymers incorporation in nanosized polyon complex micelles
- Development Challenge: Diverse and complex pipelines forward in record time vs. product quality and safety as well as cost of manufacturing.
- Centocors activities to meet these challenges
- Changes required for the processes, plants and people to ensure successful commercial products

DR PAUL MC KENZIE, Centocor

Drug Targeting Using pH-responsive Nano-particulate Systems

- pH sensitive polymers incorporation in nanosized polyon complex micelles
- increase the intracellular bioavailability of nucleic acids
- Possibility to ensure targeting of malignant cells and drug release inside off cells

PROF JEAN-CHRISTOPHE LEROUX, ETH Zurich

Formulation of Proteins – approaches and challenges

- Chemical modification
- Delivery systems, including micro- and nanoparticulates
- Protein stability/protein adsorption and aggregation

PROF SVEN FROKJAER, University Copenhagen

Progress at the Interface from protein downstreaming to final formulation

- Optimization of upconcentration
- Neglected excipient concentrations
- Surface effects in downstreaming
- Update on particle determination

PROF DR GERHARD WINTER, Ludwig Maximilian University, Munich

Protein aggregation: immunological concerns and analytical challenges

- What are protein aggregates
- Why are they troublesome
- How to avoid them
- How to measure them

PROF WIM JISKOOT, University Leiden

Product Development and Production of a New Class of Biologics

- Introduction: ImmunodrugsTM
- Investigational drug candidates
- Production & Analytics of ImmunodrugsTM
- Development of ImmunodrugsTM technology: case studies
- Successful management of collaborations

DR FRANK HENNECKE, Cytos Biotechnology

Genomic Medicine: Challenges and Opportunities

- Interindividual Genome Variation Explains Different Drug Response
- Personalized Medicine – Improve Clinical Outcome by Precise Diagnosis and optimizing Drug choice and dose
- Consideration of Individual's Environmental and Host actors

DR URS MEYER, University of Basle

Module 2
Process Transfer &
Launch Manufacturing

Chairman:
DR CHRISTIAN SCHRÖTER

Case Study: Transfer & Scale-Up to the 10.000L Scale of a Monoclonal Antibody Production Process

- Background of the manufacturing process to be transferred
- Responsibilities & deliverables during different stages of transfer
- Challenges and how they were overcome
- Key success factors & lessons learnt for future transfers

DR RAINER MUELLER, Roche

Programme (cont.)

Single use equipment during transfer of development products - a case study

- What are the issues transferring development products into production?
- How can single use equipment help?
- What are the issues with single use equipment?

DR CHRISTIAN SCHRÖTER, *Merck*

Reversing the 80/20 Rule: Satisfying the Requirements for On-demand Data Access, Aggregation, Analytics and Visibility in Process Development

- Quality by Design (QbD) starts in process development
- On-demand data access for collaboration
- Access to electronic and paper-based data
- Using on-line and off-line data together for analysis
- Automated batch genealogy for upstream / downstream correlations
- Leveling geographic and departmental barriers

DR JUSTIN O. NEWAY, *Aegis*

Biopharmaceutical Site Transfer: A perspective for process modernization - Risk and opportunities of a site-transfer of a large volume marketed pre-filled syringe

- Project Management perspective:
 - a) Enterprise Environmental Factors
 - b) Integration Management
- Introduction of Manufacturing Site, Process and Excipient Changes supported by historical product / process knowledge
- Production Start-up and Challenges during Product Launch

DR CHRISTOF GROS, *Cilag*

Site Visit at Cilag, Schaffhausen



Module 3 Market Product Compliance

PAT & Quality by Design for Biopharmaceuticals: Meeting the evolving regulatory system?

DR AJAZ HUSSAIN, *Philip Morris International Global Services*

Implementing PAT for biological processes

- Available PAT tools for bioreactor monitoring
- Challenges for the different biopharmaceutical product classes
- Challenges for the main biopharmaceutical platform organisms

DR MATHIEU STREEFLAND, *Netherland Vaccine Institute*

J&J Case study: Sterility assurance E2E

- Practical approach and experiences
- Model-based multivariate risk management

SPEAKER JOHNSON & JOHNSON

Case study: Strategic Product Life Cycle Management

- Complexity and performance of the Product life cycle process
- Key objectives of Product life cycle management
- Conceptual design and structure of the Model
- Operational concept, Managers user interface and demonstration of case studies

MATEIJ JANOVJAK, *Johnson & Johnson*

Social Events in Schaffhausen



At the end of the first conference day, you are cordially invited to the Conference Dinner.

Enjoy an evening of fine dining, fun and networking!

On the second evening, you are invited to a Reception/Cocktail at Economic Promotion of Schaffhausen with the possibility of a wine tasting with exquisite wines from the Schaffhausen area.

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 Sven Frokjaer, University of Copenhagen, Denmark

Professor Sven Frokjaer received his M.S. (Pharm.) in 1970 and his Ph.D. in physical chemistry in 1973 from the Danish University of Pharmaceutical Sciences. He spent nearly 20 years at Novo Nordisk. Since 1993 he has been Professor of pharmaceutics at the Department of Pharmaceutics, and he is Dean at the Faculty of Pharmaceutical Sciences at the University of Copenhagen. He is chairman of the board of the industrial oriented graduate research school “Drug Research Academy”.

Dr Ing Christof Gros, Cilag AG, Switzerland

Christof Gros joined Cilag in 2003, where he has held several positions including Head of Technical Services for the Parenteral Business Unit. In his current position he is responsible for the proper conduct of contract manufacturing operations at a major CMO and project lead with respect to product transfers and new product launches. Before, he was Head of Process Improvement & Assurance for plasma-derived proteins (Hemophilia and other bleeding disorders) at Baxter Bioscience, Vienna.

Dr Frank Hennecke, Cytos Biotechnology, Switzerland

Frank Hennecke is Executive Vice President, Product Development at Cytos Biotechnology, Schlieren (Switzerland). Frank obtained his Ph.D. in molecular biology at the University of Göttingen. He joined Cytos Biotechnology in 1998, where he built up the technical product development of Cytos' Immunodrugs™ and has been leading the product development and manufacturing department. During these 11 years, he gained broad experience in various fields of product development and manufacturing.

Dr Ajaz Hussain, Philip Morris International Inc., Washington D.C. USA

Ajaz Hussain currently serves as a Vice President Biological Systems, Research & Development. Before this he was Vice President and Global Head for Biopharmaceuticals Development at Sandoz, a Novartis Company. Prior to this appointment he served as the Deputy Director, Office of Pharmaceutical Science, CDER, FDA. He championed FDA's PAT, CGMP's for the 21st Century and the Critical Path Initiatives.

Matej Janovjak, Director of Technology Platforms Process Mgmt. & Methods, GPSG EMEA, Johnson&Johnson, Schaffhausen, Switzerland

Matej Janovjak has over 30 years of experience in mainly pharmaceutical engineering and industrial manufacturing as Engineering and Production manager as well as Member of Board of Directors. Today, he is responsible for deployment of new advanced methodology of science based process & product mapping to support harmonization and understanding of the technology performance and to enable a consistent implementation of the Quality by Design and Quality Risk Management along product life cycle.

Prof Wim Jiskoot, University Leiden, The Netherlands

Wim Jiskoot graduated as a pharmacist at Utrecht University, The Netherlands (1987). In 1991 he obtained his PhD degree at Utrecht University, in 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.

Prof Jean-Christophe Leroux, ETH Zurich, Switzerland

Dr Leroux received his B.Pharm. from the University of Montreal, followed by a Ph.D. in Pharmaceutical Sciences (1995) from the University of Geneva. From 1996 to 1997 he completed a postdoctoral training at the University of California, San Francisco and then joined the University of Montreal as an assistant professor. He was promoted to the ranks of associate professor in 2002 and full professor in 2007. Prof Leroux joined the Institute of Pharmaceutical Sciences at ETHZ as ordinary professor at the end of 2008.

Dr Paul McKenzie, Vice President, BIO Pharmaceutical Development and Marketed Product Support, Centocor R&D, Radnor, USA

Dr Urs Meyer, University of Basle, Switzerland

Urs A. Meyer is Professor of Pharmacology at the Biozentrum of the University of Basel and a Consultant Physician in the Department of Internal Medicine of the University of Basel Hospitals. Urs A Meyer has pursued a career in research and teaching in the field of Clinical Pharmacology and Molecular Medicine. His special interests are Pharmacogenomics and Personalized Medicine.

Dr Rainer Müller, Roche Diagnostics GmbH, Germany

Rainer Müller is currently Director Development Fermentation in Roche's Pharma Biotech Production & Development organization in Penzberg. Before joining Roche in 2005 he spent seven years at MediGene AG in Martinsried, Germany. After studying Biochemistry at the Eberhard-Karls-University of Tübingen he received his PhD in Cell Biology 1998 for work performed at the Max-Planck-Society in Tübingen.

Dr Justin O. Neway, Aegis Analytical Corporation, USA

Justin O. Neway currently serves as a Executive Vice President and Chief Science Officer for Aegis Analytical Corporation. For 15 years Dr Neway was with Wyeth Biosciences, Chiron Corporation, and Baxter Hemoglobin Therapeutics, where he held increasingly responsible positions from Technical Manager to Director of Process Sciences.

Dr Christian Schröter, Director of Liquid Manufacturing Merck KGaA, Darmstadt, Germany

Dr Schröter is currently Director of Liquid Manufacturing responsible for making, filling and packaging of sterile and non-sterile liquids. Before commercial manufacturing, he was working in various positions in pharmaceutical development.

Dr Mathieu Streefland, The Netherlands Vaccine Institute, Bilthoven, The Netherlands

Mathieu Streefland is currently employed as senior scientist for process development of bacterial vaccines at the Netherlands Vaccine Institute in Bilthoven, The Netherlands. In 2001 he received his MSc in Biopharmaceutical Sciences at Leiden University. He worked on the implementation of PAT/QbD for a bacterial cellular vaccine at the Netherlands Vaccine Institute. This research resulted in his thesis on this subject for which received his PhD degree in Bioprocess Engineering at Wageningen University in 2009. Currently he works to implement PAT/QbD principles in several vaccine manufacturing processes.

Prof Dr Gerhard Winter, LMU Munich, Department of Pharmacy, Germany

Since 1999 G. Winter is professor for Pharmaceutical Technology at the University of Munich, where he is currently working on protein stabilisation, parenteral dosage form technology, novel drying technologies, drug delivery systems and colloidal drug formulations. Before, he has spent 12 years in the biopharmaceutical industry.


Bus Shuttle Zurich Airport – Schaffhausen	There will be a bus shuttle free-of-charge available on Monday, 28 September 2009, and Tuesday, 29 September 2009, from Zurich Airport to Schaffhausen at 18.00 h and 20.00 h. On Wednesday, 30 September and Thursday, 1 October 2009, buses will transfer for Zurich Airport directly after the end of the conference day. Travelling time: approx. 1 h.
Bus Transfer Hotel – Conference Venue	Buses will pick up the delegates at the hotels on all three conference days.
Conference language	The official conference language will be English.
Organisation and Contact	<p>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</p> <p>For questions regarding content: Axel H Schroeder (Operations Director) at +49-6221/84 44 10, or per e-mail at schroeder@concept-heidelberg.de.</p> <p>For questions regarding reservation, hotel, organisation etc.: Ms Marion Grimm (Organisation Manager) at +49-6221/84 44 18, or per e-mail at grimm@concept-heidelberg.de.</p>
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	<p>This conference is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:</p> <ul style="list-style-type: none"> ■ Certified Quality Assurance Manager – Pharmaceutical Production (ECA) ■ Certified Quality Assurance Manager – API Production (ECA) ■ Certified Quality Control Manager (ECA) ■ Certified Pharmaceutical Engineering Manager (ECA) ■ Certified Computer Validation Manager (ECA) ■ Certified Regulatory Affairs Manager (ECA) ■ Certified Validation Manager (ECA) <p>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.</p>
What Is ECA?	<p>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.</p>
What Are the Benefits of ECA?	<p>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.</p> <p>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.</p>
How Do You Become Member of ECA?	<p>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.</p>



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, 29 September 2009
08.45 h Pick up at hotel
09.00 – 09.30 h Registration and coffee
09.30 – 17.30 h Lectures

Wednesday, 30 September 2009
08.00 h Pick up at hotel
08.15 h – 08.30h Registration and coffee
08.30 h – approx. 17.30 h Lectures and Site Visit

Thursday, 1 October 2009
08.00 h Pick up at hotel
08.30 h – 13.30 h lectures
Following bus transfer to hotel, railway station and airport.

Venue

Klostergut Paradies
Stiftung der Georg Fischer AG
8252 Schlatt TG / Switzerland
Phone +41 52 631 27 27, Fax +41 52 631 27 50
paradies@georgfischer.com, www.klostergutparadies.ch

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.

Accommodation

CONCEPT has reserved a limited number of rooms in Schaffhausen. Reservation should be made directly with Schaffhausen Tourismus Herrenacker 15, Postfach CH-8201 Schaffhausen, Switzerland Phone +41 52 632 40 20, Fax +41 52 632 40 30 not later than 21 August 2009. 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 ECA/CONCEPT to receive the specially negotiated rate for the duration of your stay. 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)

 +49 6221 84 44 34

Bio Production Forum – From Development to Market Product Compliance

29 September – 1 October 2009, Schaffhausen, 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

Company

Department

Important: Please indicate your company's VAT ID Number

Please indicate the Purchase Order Number, if applicable

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E-Mail (Please fill in)

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

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)!