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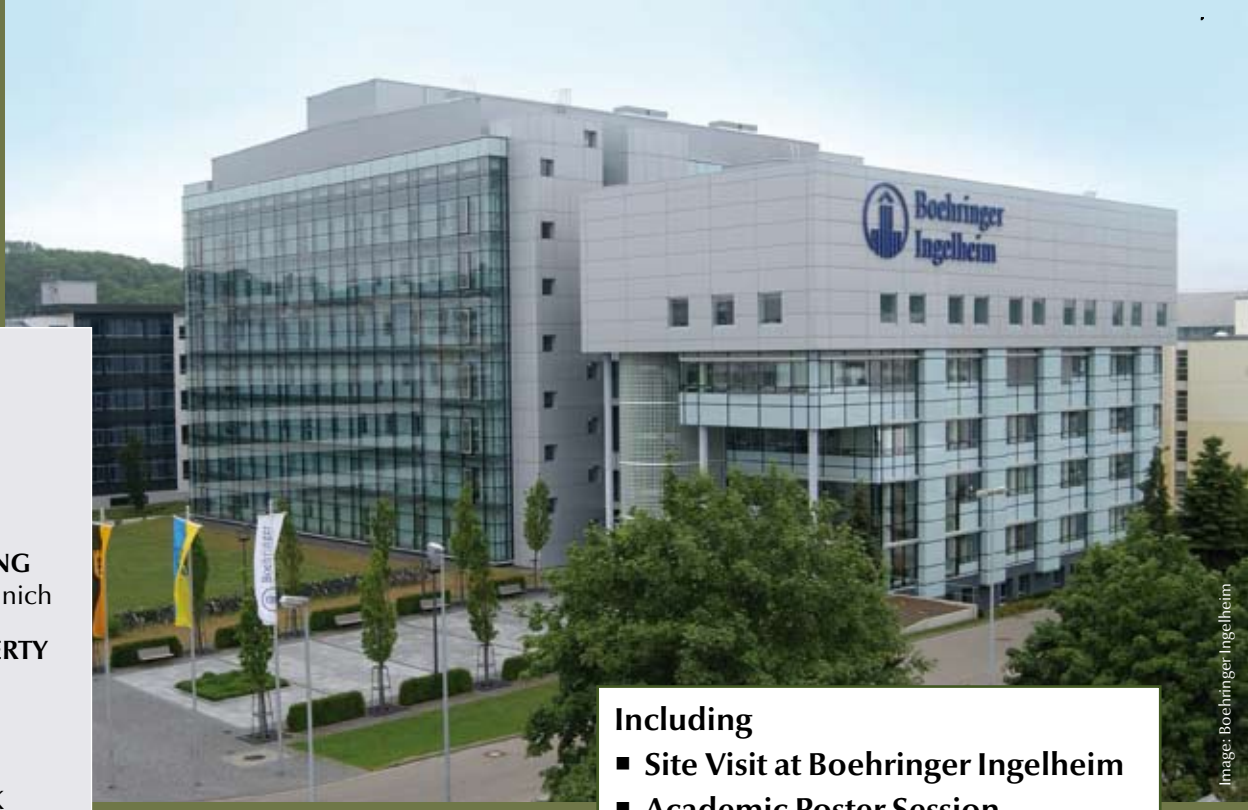


Image: Boehringer Ingelheim

**Including**
- **Site Visit at Boehringer Ingelheim**
- **Academic Poster Session**

# Bio Production Forum

## Bridging the world of academic and industrial Bio Pharmacy

**Ulm (near Stuttgart), Germany, 8 – 10 June 2011**

### HIGHLIGHTS:

- Recent progress in development of Biopharmaceuticals
- Protein Formulation
- Quality by Design of Monoclonal Antibodies – Regulatory and Industrial Experiences
- GMP Aspects for Development of Biopharmaceuticals
- Fill and Finish – Requirements on HVAC and Rooms
- Visual Inspections

### SPEAKERS

**BORKE VAN BELLE**
Cilag AG, Switzerland

**ALEXANDER BEPPERLING**
Technical University Munich

**DR MICHELE DOUGHERTY**
FDA, USA

**GORDON FARQUHARSON**
Critical Systems Ltd., UK

**SAMUEL FOX**
Beckman Coulter United

**DR FRIEDRICH HAEFELE**
Boehringer Ingelheim, Germany

**DR HILTRUD HORN**
Horn Pharmaceutical Consulting, Germany

**DR INGO PRESSER**
Boehringer Ingelheim, Germany

**DR THEODORE RANDOLPH**
University of Colorado, USA

**DR VICTOR VINCI**
Eli Lilly, USA

**DR JOHN WANG**
Genentech, USA

**PROF ROLF WERNER**
Boehringer Ingelheim, Germany

**DAVY DE WILDE**
Sartorius, Germany

**PROF DR GERHARD WINTER**
Ludwig Maximilians University Munich, Germany/Coriolis Pharma

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European Biotechnology News

This conference is supported by:

LMU Ludwig-Maximilians-Universität München
ETH Eidgenössische Technische Hochschule Zürich Swiss Federal Institute of Technology Zurich
Universiteit Leiden
SAPhS Swiss Academy of Pharmaceutical Sciences
SGRW
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PHAST quality standards

## 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 nanoscaled 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.

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

**Boehringer Ingelheim**

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 142 affiliates in 50 countries and more than 41,500 employees. Since it was founded in 1885, the family-owned company has been committed for 125 years to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.
Today, Boehringer Ingelheim is one of the world's leading companies for contract development and manufacture of biopharmaceuticals. All types of services from mammalian cell line or microbial strain development to final drug production can be delivered within a one-stop-shop concept. Boehringer Ingelheim delivers services for pre-clinical development up to global market supply with a strong commitment to its customers at its manufacturing facilities for mammalian cell culture and microbial fermentation. Boehringer Ingelheim has brought 17 molecules to market and has many years of experience in multiple molecule classes such as monoclonal antibodies, recombinant proteins, interferons, enzymes, fusion molecules and plasmid DNA. Furthermore, high-titer platform technologies for new antibody mimetic formats such as scaffold proteins and antibody fragments are available for the manufacture of customer products.
To find further details please visit wwww.biopharma-cmo.com.

**PHAST GmbH**

PHAST GmbH is an international analytical service provider, performing development and validation of analytical methods, stability testing and storage according ICH, quality control for release for both small molecules and large molecules. According to cGMP (FDA audited) PHAST GmbH takes over the responsibility for manufacturing including import, quality control and for market release by its QPs.
Since 2002 the highly motivated analytical team of PHAST GmbH is continuously growing. Based on the accumulative experience of our 150 employees, our mission is to be your partner during the overall life cycle of your drug product starting from formulation development towards clinical trial supply until life cycle management both for small molecules as well as large molecules.

## Objectives

Dear Colleagues,

During the last years the Bio Production Forum became a fixed component in the calendar of many scientists and industrial representatives and emerged to one of the most important events in the field of biopharmaceutical manufacturing.

To continuously improve the forum and to get closer to our goal to bring together academic sciences and industrial R&D and commercial manufacturing, we added the possibility for young academics and researchers to present their work to academic and industrial scientists and managers in a poster session.

I'm very pleased that Boehringer Ingelheim give us the chance to highlight our conference programme with a site visit at their site in Biberach. Therefore, we moved with the conference from Switzerland to Germany, but everyone will remember the roots of the Bio Production Forum in Schaffhausen and the favourite efforts of the Swiss supporting organisations to realise the first five Bio Production Forums.

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 development and manufacturing of biopharmaceuticals.

Please use this unique opportunity to keep abreast of these developments.
We wish you a successful and interesting conference.

Yours sincerely,

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

## Target Audience

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

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

## Moderators

**Prof Gerhard Winter,** *University of Munich*
**Dr Christian Schröter,** *Merck*
**Dr Friedrich Haefele,**

## Scientific Advisory Board

**Prof Dr Wim Jiskoot,** *Leiden Univerity*
**Matej Janovjak,** *Dipl. Ing. ETH, Insystea*
**Dr Christian Schröter,** *Merck*
**Prof Dr Gerhard Winter,** *University of Munich*

## Poster Session

**CILAG** and **Boehringer Ingelheim** grant free-of-charge participations to young scientists from Universities, Research Institutes, etc. to present at the poster session and attend to the conference. We encourage young scientists to apply for these grants!
Please contact Axel H. Schroeder at schroeder@concept-heidelberg.de for details.

**Programme**

**Day 1**
**Chaired by**
**Prof Dr Gerhard Winter**

**Key Note**
**„Biopharmaceutical Manufacturing: Trends & Discovery of Long-Term Viable Manufacturing Solutions"**
**PROF ROLF WERNER,** *Boehringer Ingelheim*

**Aggregation mechanisms/high pressure treatment to disaggregate proteins**
- Complications of analysis of protein kinetics and thermodynamics by typical irreversibility of protein aggregation
- Possibilities of High Pressure treatment to form protein aggregates reversibly
- Effects for understanding both - protein aggregation and reversing it in industrial applications

**DR THEODORE RANDOLPH,** *University of Colorado*

**Poster Presentations**

**Recent progress in formulation development for biologics**
- Critical assessment of methods for particle counting/characterization
- Fluorescence enhanced analysis of protein aggregation
- Modern stability prediction methods
- Miniaturized stress testing
- Miniaturized freeze-drying

**PROF DR GERHARD WINTER,** *LMU Munich/Coriolis Pharma*

**New trends in Quality control of monoclonal Antibodies with Capillary Electrophoresis**
**SAMUEL FOX,** ***Beckman Coulter United***

**QbD case study for a monoclonal antibody**
- Monoclonal antibody development from molecule design through validation
- Risk assessment tools
- Mammalian cell culture and protein purification – Use of prior platform knowledge and experimental design
- CQAs and control strategy
- Design space and life cycle management of the process and product

**DR VICTOR VINCI,** *Eli Lilly*

**QbD for Monoclonal Antibodies – Regulatory Considerations**
- Application of QbD concepts to monoclonal antibodies: Preliminary thoughts from FDA's pilot program
- Manufacturing Process Development: Concepts under consideration for ICH Q11

**DR MICHELE DOUGHERTY,** *FDA*

**Day 2**
**Chaired by**
**Dr Friedrich Haefele**

**Protein formulation and stability "what can go wrong"**
- What are the methods to predict vulnerable sites that may affect stability and potency?
- What are the pitfalls in various methods of stress?

**DR JOHN WANG,** *Genentech*

**Poster Presentations**

**What's important for the Development of Biotech Products?**
- GMP and Regulatory Aspects
- Ways to success
- Practical Examples

**DR HILTRUD HORN,** *Horn Pharmaceutical Consulting*

**Introduction to the site visit**
- Reasonable and worth knowing details for the following site visit

**DR FRIEDRICH HAEFELE,** *Boehringer Ingelheim*

**Programme (cont.)**

## Site Visit at Boehringer Ingelheim

### Boehringer Ingelheim's High Tech Site in Biberach

Image: Bosch/Zünder

Boehringer Ingelheim operates one of the largest cell culture plants for the manufacturing of biopharmaceuticals in Biberach, Germany. The service portfolio covers the whole range from cell line development, up-stream and down-steam process development to formulation development. The flexible scales from 400 L to 15.00 L allow the global supply of material for clinical studies up to commercialization. Proprietary technologies in up-stream and down-stream development support fast track development for time to clinic and time to market development of biopharmaceuticals.

Boehringer Ingelheim has the capabilities to manufacture finished drug product according to state of the art aseptic technologies i.e. using RABS and Isolator Systems- for all application forms like lyophilized and liquid vials, prefilled syringes and cartridges.
At the cell culture site in Biberach more than 1500 employees work in process science, manufacturing, protein analytics and microbiology labs, QA and logistics for global supply of biopharmaceuticals.

**Day 3**
**Chaired by**
**Dr Christian Schröter**

### The diversity of single use bioreactors: identifying the ideal solution

- Differences between the different technologies
- Pathway to properly evaluate and identify the ideal solution for a specific process

**DAVY DE WILDE,** *Sartorius Stedim Biotech*

### Fill and Finish – Requirements HVAC/ Rooms / Clean air devices

- What the GMPs say
- Cleanroom standards family to help set specifications
- Some other issues to consider
  - Sustainability
  - Hazard containment
- Technical solutions
  - Cleanrooms
  - RABS
  - Isolators

**GORDON FARQUHARSON,** *Critical Systems*

### Characterization of biopharmaceutical products by Analytical Ultracentrifugation

- Minimising artefacts by combining a gentle separation method with a optical detection
- Data analysing tool
- Practicle examples

**ALEXANDER BEPPERLING ,** *TU München*

### Advanced Barrier Systems – RABS and Isolators

- Regulatory Aspects
- Definitions
- Design Principles
- Decision Process: What?, When?, How?

**DR INGO PRESSER,** *Boehringer Ingelheim*

### A Validation Strategy for Automated Visual Inspection

- Development and execution of validation
- Regulatory strategies
- Two recently finalized introductions (an automated vial and an automated syringe inspection line) as an example to provide an overview of a validation strategy and its execution in practice,
- The regulatory feedback and learnings in general

**BORKE VAN BELLE,** *Cilag*

**Social Event**

On 8 June 2011 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

**BORKE VAN BELLE,** *Cilag AG/Johnson & Johnson, Schaffhausen, Switzerland*
Borke Van Belle graduated as Bio-engineer in Chemistry in 1998 at the University of Gent, Belgium. He started his career at Johnson & Johnson in 1998 with Janssen Pharmaceutica, Beerse (Belgium) as Quality Assurance Expert. In his last position he was Senior Manager Quality Assurance for some Pharmaceutical Production Units. In December 2005, he transferred to Cilag AG, Schaffhausen (Switzerland) to take the role of Associate Director Lyophilisation Production Facility.

**ALEXANDER BEPPERLING,** *Technical University Munich*

**DR MICHELE DOUGHERTY,** *FDA, USA*

**GORDON FARQUHARSON,** *Critical Systems Ltd.*
Gordon Farquharson, B.Sc.(Hons), C.Eng., is a Chartered Consulting Engineer with more than 30 years experience of quality & safety critical processes, facilities and systems used by the Healthcare and Life Science sector. In recent years he has focused on new technologies such as isolators, barrier/containment technology, and mini-environments, and has been responsible for the development of technical solutions in research, product development, primary manufacturing, medical device, and dosage form manufacturing. He works for his international consulting business; Critical Systems Ltd based in the UK.Standards and regulatory compliance issues in the Pharma/Life Science sectors are one area of major interest and expertise. In this context, he has a high degree of expertise in the practical interpretation & application of EU, PIC-S, WHO, and US FDA cGMP requirements, and in dovetailing differing regulatory requirements together.

**SAMUEL FOX,** *Beckman Coulter United*

**DR FRIEDRICH HAEFELE,** *Boehringer Ingelheim*
Dr Haefele has been in the pharmaceutical industry for almost 20 years now. In May 2006 Dr Haefele joined Boehringer Ingelheim Pharma as Vice President in the business domain Biopharmaceuticals. He is responsible for the department Biopharma Operations, managing the Aseptic Processing of Biopharmaceuticals to Drug Products filled into Vials and Prefilled Syringes.

**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.

**DR INGO PRESSER,** *Boehringer Ingelheim, Biberach*
Dr Ingo Presser is a Pharmacist and received his PhD in pharmaceutical technology working on new online methods for freeze drying processes at the University of Munich. He joined Boehringer Ingelheim in 2003. As Head of Manufacturing Science he was responsible for the implementation of new products and trouble shooting. Since 2007 he is Head of an aseptic filling and freeze drying unit within the department of Biopharmaceutical production.

**DR THEODORE RANDOLPH,** *University of Colorado, Unites States*
T. Randolph is Gillespie Professor at theCenter for Pharmaceutical Biotechnology and Co-Director. He studied at B.S., University of Colorado (1983) and got his Ph.D. University of California, Berkeley (1987)

**DR VICTOR VINCI,** *Eli Lilly, Unites States*
Dr Vinci is currently Director of Purification Development and Viral Safety at Eli Lilly and Company in Indianapolis. His responsibilities include managing downstream process development and viral safety activities for recombinant proteins and monoclonal antibodies in clinical and commercial development. Dr Vinci received his doctorate in Microbiology from The Ohio State University in 1988.

**DR JOHN WANG,** *Genentech, United States*
Dr Wang received Ph.D. from the University of Michigan, is a Fellow of the America Association of Pharmaceutical Scientists. He worked for Squibb, Ortho, Scios, Bayer and currently is with Genentech, in Late Stage Pharmaceutical and Process Development.

**PROF ROLF WERNER,** *Boehringer Ingelheim, Biberach, Germany*
Prof Dr Rolf G. Werner is Corporate Senior Vice President of the Corporate Division Biopharmaceuticals at Boehringer Ingelheim GmbH and responsible for the strategic orientation and the worldwide business of biopharmaceuticals.

**DAVY DE WILDE,** *Team Leader Product Management Disposable Bioreactors Sartorius Stedim Biotech*
Graduated as a master in Biomedical Sciences. He joined Sartorius Stedim Biotech in 2005. Today he is team leader product management single use bioreactors for Europe & Asia. In this function he is working on the development of the single use bioreactor platform at Sartorius Stedim Biotech and responsible for a team of application specialists supporting the single use bioreactor industry.

**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.

**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 +49-6221/84 44 10, or per e-mail at schroeder@concept-heidelberg.de.
**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.

**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 200 EUR 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.

**Special offer with Lufthansa – discounted travel for 7th Bio Production Forum attendees**

Lufthansa
Official Airline

Lufthansa German Airlines offers a comprehensive global route network linking Stuttgart, München with major cities around the world. As the Official Airline to this event, Lufthansa offers special prices and conditions to all attendees.

To make your reservation, please click on this link http://www.lufthansa.com/event-booking_en and enter the access code DEFZM in the "Access to Event Booking" area. 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.
Please note that you may have to enable pop-ups on this site – otherwise the booking platform window will not open.

These promotional fares are also available via your IATA / ARC Travel Agent. Travel Agents can obtain ticketing instructions via eMail lufthansameetingsandevents.ber@dlh.de by quoting the access code as an event reference.

## 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
Wednesday, 8 June 2011, 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)
Thursday, 9 June 2011, 08.30 – 18.00 h
(Registration and Coffee 08.00 – 08.30h)
Friday, 10 June 2011, 08.30 – 13.00 h

### Venue
Maritim Hotel Ulm
Basteistraße 40
89073 Ulm (near Stuttgart)
Phone 0049 731 923 0, Fax 0049 731 923 2002

**1. Bus Shuttle Stuttgart Airport to Conference Hotel**
There will be a bus shuttle free-of-charge from Stuttgart Airport to Maritim Hotel Ulm on Tuesday, 7 June 2011 h at 19.00 h. On 10 June a free-of-charge bus will transfer to Stuttgart Airport after the end of the conference (transfer time approx. 75 minutes)

**2. By Train**
Alternatively there is a train connection from Stuttgart to Ulm. Please use S-Bahn (interurban train) Line 2 or 3 to Stuttgart Hauptbahnhof (Mainstation) and from there the IC or ICE train directly to Ulm.

**3. Private Shuttle Services**
Flughafen Transfer Services 24
Phone 0049 (0) 7026 3710153
Mobile 0049 (0) 3710153
Offers shuttle services from Stuttgart Airport to Ulm to appropriate fees (per car)

### Fees
**Option I: Day 1 and Day 2**
Non-ECA Members EUR 1,590.- per delegate plus VAT
ECA Members EUR 1,390.- per delegate plus VAT
APIC Members EUR 1,490,- 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 1,390.- per delegate plus VAT
APIC Members EUR 1,490,- 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 1,790.- 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.

**Students/Scientists for Poster Session**
(contact Axel H. Schroeder at schroeder@concept-heidelberg.de)
Day 1 – Day 3 – EUR 450.- per delegate plus VAT

### 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 6850 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 21 April 2011. Early reservation is recommended.

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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

### Bio Production Forum
Ulm (near Stuttgart), Germany, 8 – 10 June 2011

☐ 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**

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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 HEIDELBERGwill 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)!

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