Blood, Blood Products, and Plasma

QUALITY AND SAFETY
18 & 19-20 April 2016, Vienna, Austria

Conference Highlights
- Regulations to Blood and Source Plasma
- Donor Vigilance and Hemapheresis vigilance
- Microbiological Safety – Bacteria, Viruses (HEV), Endotoxins
- Donor Management
- Zika Virus – Current Developments

Pre-Conference Workshop Highlights
- Immunology behind haemophilia
- Regulatory experiences with recombinant coagulation factors – quality and safety issues
- From bench to bedside - monitoring evolving FVIII inhibitors
During this conference, speakers from authorities, industry, sciences and donation services provide you with information about the current developments and revisions of the regulatory requirements, e.g. for virus safety or for process validation. You will also find out more about the strategies to accomplish the goal of a European standard. Furthermore, the developments in microbial safety – requirements and methods – will be introduced. You will benefit from experts presenting their practical experiences and knowledge in the field of quality and safety of blood, blood products and plasma.

Other information provided during this course includes Donor Vigilance, quality requirements of plasma fractionators and preparative plasmapheresis issues.

During the next years, blood donation services, plasma establishments and the plasma industry expect an increasing need of plasma for fractionation. Due to patient blood management and the decreasing recovered plasma this problem can be solved only by extension of plasmapheresis and increased procurement of source plasma in Europe and worldwide. Especially new indications of blood products – e.g. the use of IVIG in immunologic disorders – will cause a growth of plasma derived medicinal products. Against this background, the number of donations must be increased to ensure the patient centred care as well as the supply of the industry. The amount of imported plasma for fractionation between the European countries as well as from USA will also increase. The necessary base for a comprehensive and sufficient maintenance in the EU countries is a consistent and standardised level of quality and safety of blood and plasma donations.

Based on the regulations of the European Union, e.g.

- the “Plasma Master File”;
- the European Pharmacopoeia or
- the EDQM “Guide to the preparation, use and quality assurance of blood components”

integrative procedures for all countries are essential. Donor screening, microbial testing, donation practises and later on storage, distribution and look back systems should be on the same level in all member states.

Additionally, new guidelines and guideline drafts related to microbiological safety issues – like those related to HEV transmission or to classic GMP issues like process validation – have an impact on the field of blood and plasma products.

This conference is designed for people from

- Donation services/Blood services
- QA Staff
- National and international Authorities
- Plasma Fractionation
- Control Laboratories

who are involved in regulatory affairs, quality assurance, quality control and manufacturing of blood, blood products or plasma.

Prof. Helmi Storch
Axel H. Schroeder

On 19 April 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
FDA Requirements for blood and blood components intended for transfusion or further manufacturing use

- Overview
  - US blood collection in 2015
  - US Legal Framework for regulating blood and blood components
  - FDA's final rule
- Intent of the Rule
- Organization
- Selected Provisions
  - Relevant Transfusion-transmitted Infection
  - Control of Bacterial Contamination of Platelets
  - Medical Supervision
  - Donor Eligibility
  - Donor Acknowledgement
  - Donation suitability
- Zika Virus - the New FDA Guideline
  Dr Martin Ruta

ISBT standard for surveillance of complications related to blood donation

- Donor health and vigilance
- Towards common language and understanding
- Experiences in the Netherlands
  Arlinke B. Bokhorst

PPTA contributions to donor safety

- Donor Adverse Event Reporting
- Volume Replacement
- Cross Donation Check System
  Mary Gustafson, PPTA

Volume displacement during plasmapheresis

- Pros and Cons for a volume replacement
- Physiology during plasmapheresis
- Common adverse events during plasmapheresis
- Set washing to reduce red blood cell losses
  Dr Stephan Kiessig

Donor vigilance. Actual data from German Red Cross Blood Transfusion Service North-East

- Donor vigilance system and participating centers
- Own Classification of side effects
- Actual data (2011-2014) whole blood donation and plasmapheresis
- Donor vigilance and donor management
  Dr Thomas Burkhardt

Haemapheresis vigilance: an Internet system to assess complications in plasmapheresis and other haemaphereses

- International internet-based system to assess donor complications in haemapheresis procedures
- Incidence of unexpected events by apheresis type
- Comparison of own data with published data
- Pros and cons of different classifications of unexpected events
  Dr Hans-Gert Heuft

The German Haemophilia Registry: Do registries contribute to quality, safety and efficacy of transfusion products and transfusion therapies?

- Aspects of Regulatory Science
- Aspects of Clinical Medicine
- Aspects of Health Services Research
  Dr Dorothea Stahl

QM in European blood establishments

- EDQM and blood quality management
- Survey about QM in blood establishments in Europe
- Learning tools
  Marie-Laure Hecquet

Risk assessment - fractionation process
  Bodo Kornführ
Microbiological safety in blood components
- Incidence and reasons for Transfusion-Transmitted bacterial infections and contaminations of blood products
- Role of multidrug resistant pathogens in this context
- Negative-to-date versus rapid Methods for Detection of contaminations
- Current View of Zikavirus
  Dr Isabelle Bekeredjian-Ding

HEV and Plasma Product Safety: the Industry’s View
- The more recent realized circulation of HEV and the the safety margins of plasma-derived medicinal products. Review of epidemiological situation of HEV as well as HEV inactivation and removal data
- Zika Virus – background and evaluation
  Prof. Thomas R. Kreil, Baxalta

HEV: Point of view in a transfusion service
- Prevalence of HEV in blood donors
- Transmission of HEV through blood components
- Relevance of HEV infection in recipients
- Zika Virus
  Dr David Juhl

The importance of effective virus reduction in the safety of human blood and plasma-derived medicinal products.
- The current risks of transfusion transmissible viruses like West-Nile Virus or Chikungunya
- Increasing importance of virus reduction
- Available technologies and how they have been implemented with existing products
- The importance of robustness for virus reduction
  Dr Andy Bailey

The novel applications for INTERCEPT treated plasma incl cryo, lyo and convalescent
  Dr Johannes Irsch

Endotoxin testing in plasma, method development and validation for Plasmasafe®
- Plasmasafe®, composition and endotoxin limits
- Overcoming LAL interferences
- An example of LER (Low Endotoxin Recovery), RSE vs NOE
- Successful validation of the LAL test
- Applied risk assessment to move away from the pyrogen test
  Dr Antonio Avitabile/Dr Claudia Di Paola

European self sufficiency with plasma for PDMP - the role of EPCC
- Legal framework (e.g. Blood Directive)
- Structure of European plasma supply and the role of EPCC members
- Contribution of international quality plasma for safety of plasma
- Is European self-sufficiency for PDMP feasible per country or an European effort?
  Dr Stephan Walsemann

Donor management in blood and plasma donation to achieve self-sufficiency in Europe
- Self-sufficiency in plasma and Plasma derived medicinal products in Europe
- Ethical principles supporting voluntary non-remunerated donations: a renewed vision
- Proposed ways forward towards self-sufficiency
  Dr Gilles Folléa

Pre-Conference Workshop on Recombinant Factors

The workshop is focused on recent developments in haemophilia treatment, i.e. use of recombinant coagulation factors. There are single full-length as well as domain-deleted factors, but also fusion proteins, linking a coagulation factor with another molecule, that lead to a prolonged half-life of the respective factor in plasma due to retarded factor disintegration. As haemophilia requires lifetime medical treatment and numerous administrations of factor substitutes, the use of long-acting coagulation factors would lead to less frequent replacement therapy and hence contributes to patient’s well-being. The immunological impact of the different modifications on patients is one of the last open issues. The workshop will be a good opportunity to discuss and share regulatory as well as companies experiences on those products.

Target Audience
- This workshop is designed for persons from Research and Development, Manufacturing, Marketing Authorisation, Authorities dealing with recombinant factors.

Moderators
- Dr Stephan Kießig, Axel Schroeder
Programme

Immunology of FVIII
- Overview on Factor VIII deficiencies
- How factor VIII is seen by the immune system
- Epitope recognition by antibodies
- Epitope, neotope, cryptotope
Dr Stephan Kiessig

From bench to bedside - monitoring evolving FVIII inhibitors
- Neutralizing antibodies against FVIII as the major complication in the replacement therapy of haemophilia A patients with FVIII products
- Current understanding of the root cause for the development of FVIII inhibitors
- Novel approaches to monitor evolving FVIII inhibitors in patients
Dr Birgit Reipert

Regulatory experiences with recombinant coagulation factors – quality issues
- Different types of coagulation factors – full-length, domain-deleted, fused
- Testing issues
- Adventitious agents
Dr Manuela Leitner

Assessing, managing and evolving safety and efficacy of coagulation factors
- Aspects of Regulatory Science
- Aspects of Clinical Medicine
- Aspects of Health Services Research
Dr Dorothea Stahl

Panel Discussion

Speakers

Dr Antonio Avitabile, Responsabile Laboratorio Biologico, Kedrion, Italy
Dr Antonio Avitabile holds a Degree in Biology and a Post-degree in Biotechnology. After gaining extensive research experience in a university laboratory as well as at the Italian Council of Research, he joined Kedrion S.p.A. in 2000. Antonio entered the company as head of the biology/microbiology laboratory. Later he became the head of the biochemistry laboratory. In his current position in GMP services Antonio is in charge of the validation of analytical methods and process validation.

Dr Andy Bailey, ViruSure GmbH, Vienna, Austria
Dr Bailey has been actively involved in the pathogen safety of biopharmaceuticals for over 11 years. Originally a Biochemist, Dr Bailey served for nine years at the MRC Virology Unit in Glasgow, Scotland. In 1995, he moved as Director of Virus Validation services to Q-One Biotech Ltd, and in 2001 to the Pathogen Safety group of Baxter Healthcare in Vienna, Austria. He was the main founder of ViruSure GmbH, a specialist virus safety testing company in Vienna, Austria, in 2005. Over the last 10 years, Dr Bailey has presented at numerous regulatory agencies on virus and prion safety, either in support of products or as an invited speaker at expert workshops, including the UK MHRA, German PEI, French AFFSAPS, US FDA, EMEA and JMHLW (Japan).

Dr Isabelle Bekeredjian-Ding, Paul-Ehrlich Institut, German Agency for Vaccines and Biomedicines
Dr Bekeredjian-Ding is the head of microbiology at the Paul-Ehrlich institute (PEI). She studied medicine in Heidelberg, Germany, Padova, Italy and New York, NY, USA. She received a PhD equivalent in immunology and is a board-licensed medical microbiologist who received scientific and clinical training in Munich, Dallas, TX and Heidelberg, Germany. Before being appointed to the PEI in 2015 she worked as laboratory head and senior consultant at the Medical Microbiology unit of the University Hospital Bonn.

Arlinke B. Bokhorst, TRIP Foundation, The Netherlands
Arlinke studied at Erasmus University Rotterdam and received her MD. From 1993 – 2001, she worked as manager donor services at Sanquin Blood services. After that, she was Medical director at the BIS Foundation, later Member of the Executive Board of BSLIFE. Since 2012, she is director of the Trip Foundation.

Dr Thomas Burkhardt, German Red Cross Blood Transfusion Service North-East
Thomas Burkhardt studied at the FSU Jena and received his degree 1991, 1997 he became the qualification in Transfusion Medicine. Since 2006 he works for the German Red Cross Blood Transfusion Service in the Institute for Transfusion Medicine in Plauen. He is the assistant medical director, the head of Production and donor department at this Institute.

Dr Gilles Folléa, EFS, French Blood Establishment, France
Gilles Folléa, MD, holds a master in Clinical haematology, in Immunology and a PhD in Transfusion Medicine. During his career, he held different positions in different establishments like Head of plasma fractionation plant (150,000 L/year), Vice Director of Strasbourg BE, Director of the EFS BE of Pays de la Loire, Nantes. In 2010 He was appointed as the first Executive Director of European Blood Alliance. Now retired from this position (May 2015), he currently pursues his activities as Europe Attaché at EFS (part time), and still acts as vice chair of the ISBT working party on blood supply management, member of the ISBT Standing Committee on Ethics, and member of a working group of the Council of Europe Committee on Blood Transfusion, on Plasma Supply Management (TS093).
Speakers

Mary Gustafson, Vice President Global Medical & Regulatory Policy, PPTA, USA
Prior to joining PPTA, Ms Gustafson served as Senior Director, Regulatory Affairs at Nabi Biopharmaceuticals, Boca Raton, FL and in regulatory positions at the U.S. Food and Drug Administration (FDA). At FDA, she directed the Division of Blood Applications, Office of Blood and Research and Review, Center for Biologics Evaluation and Research, as well as holding earlier positions in biologics and sterile drug compliance and product certification. Before her regulatory career, she worked in clinical blood banking at the National Institutes of Health and several hospitals. Ms. Gustafson has a MS degree in Pathology, is certified as a medical technologist and specialist in blood banking by the American Society for Clinical Pathology, and quality manager and auditor by the American Society for Quality. Ms. Gustafson is a current member of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA).

Marie-Laure Hecquet, EDQM, France
Marie-Laure holds a tri-national Degree in Biotech Engineering from the university of Strasbourg, Karlsruhe, Basel and Freiburg. After her Engineers degree, she was employed at EFS, French Blood Establishment. In 2007 she joined EDQM as Scientific Programme Assistant and was in charge of the elaboration of a monograph on PDMPs. Since 2010 she is Scientific Programme Officer at EDQM with responsibilities in the field of Proficiency Testing Scheme programme and Quality Management of Blood Establishments. Since 2014 she is Lecturer at the European Management School in Strasbourg in Quality Management. She is member of the ISBT Quality Management Working Party on Quality Management and is certified IRCA auditor.

Dr Hans-Gert Heuft, Medical University, Hannover, Germany
Hans-Gert studied at the FU Berlin and received his degree 1987. 1993 he became the qualification as Internist and 1998 in Transfusion Medicine. 1999 he became assistant medical director of the Institute of Transfusion Medicine of the Medical University Hannover. Since 2002 he is executive medical director and deputy head of the institute. Additionally he was from 2006-2010 Head of the section “Preparative and therapeutic Haemapheresis” of the DGTI.

Dr Johannes Irsch, Cerus B.V. Amersfoort, The Netherlands
Johannes Pirsch studied at the University of Cologne. After a post-doc period he joined 1997 Miltenyi Biotec as Scientist and technical specialist, later as Clinical Marketing Manager. Since 2006 he works for Cerus B.V. in the Netherlands. His current position is Senior Director Scientific Affairs, EMEA. He has expertise in Clinical Immunology and Genetics, cellular therapies and transplantation, blood banking and transfusion, pathogen inactivation.

Dr David Juhl, University Hospital Schleswig Holstein, Germany
David Juhl studied medicine at the Justus-Liebig-University Gießen. After working as assistant physician at clinical center of the University Greifswald and as medical specialist for transfusion medicine, he get his PhD 2007. Since 2013, he is assistant medical director at the Institute for Transfusion Medicine of the University Schleswig-Holstein.

Dr Stephan Kiessig, Ruhr-Plasma-Center, Bochum, Germany
He studied human medicine at the University Leipzig and Berlin, he is a specialist in immunology. From 1981 – 92 he was at the AIDS Test group Charité Berlin, 1992-2002 in R&D of IMMUNO later Baxter as medical head for several plasma centres, European marketing manager hyperimmunes, 2002-05 director quality management of DGH, 2005-08 CSO at LipoNova developing a tumour vaccine, 2008-13 medical head and QP at Haema, since 2013 at Ruhr-Plasma.

Bodo Kornführer, Octapharma, Germany

Dr Thomas R. Kreil, Associate Professor of Virology, Senior Director Global Pathogen Safety, Baxalta, Austria
Thomas Kreil studied Biochemistry at the University of Vienna. After several years of post-doctoral research with a focus on antiviral immunology and specifically the role of antiviral antibodies, he joined Baxter (Immuon), to transition into working in the area of pathogen safety of biopharmaceuticals. His current position is Senior Director, Global Pathogen Safety. Furthermore he is Associate Professor at the Medical University of Vienna, Chairman of Plasma Protein Therapeutics Association’s (PPTA) Pathogen Safety Steering Committee and Steering Committee member of the Consortium on Adventitious Agent Contamination in Biomanufacturing (CAACB).

Dr Manuela Leitner, AGES – Austrian Agency for Health and Food Safety
She studied Veterinary Medicine at the University of Veterinary Medicine Vienna. From 1999 to 2002 she was Scientific assistant at that university. 2002 she joined Wyeth Whitehall Export GmbH as drug safety officer and 2004 CoaChrom Diagnostics, Since 2006 she is employed at the AGES. Her current position is Quality Assessor for plasma derived Medicinal Products and Plasma Master File. Since 2008 she is an EMA expert.

Dr Birgit Reipert, Baxalta, Vienna, Austria
Birgit Reipert is currently Senior Director R&D, Research & Innovation at Baxalta in Austria. In addition, she has got a lectureship at the Medical University of Vienna (Austria). She received her PhD from the Ernst-Moritz Arndt University, Greifswald (Germany), and postdoctoral training at the Institute for Medical Immunology at the Charité, Berlin (Germany), at the Department of Immunology of the Institute for Cancer Research, Berlin, and at the Paterson Institute for Cancer Research, Manchester (UK). Birgit Reipert joined IMMUNO AG in 1994 and Baxter AG in 1997. Birgit Reipert has a long standing interest in the immunogenicity of therapeutic proteins and in the search for new approaches to prevent unwanted immune responses to these proteins.
Claudia Di Paola holds a Master's Degree in Chemical and Pharmaceutical Technology. She has extensive experience in the pharmaceutical industry. Claudia started her professional career in a R&D laboratory of an Italian pharma company where she worked on the development and validation of chemical QC assays. In 2007, she joined Charles River as a LAL test specialist. During the past 8 years Claudia has collaborated with numerous clients in the development and validation of the LAL test. The comprehensive number of projects in which she has been involved allowed her to gain thorough knowledge and expertise enabling her to meet client's and authorities’ expectations for this particular biological test.

Dr. Martin Ruta, FDA, USA
Dr. Ruta serves as a regulatory counselor in the Office of Blood Research and Review at the Center for Biologics Evaluation and Research, FDA. Dr. Ruta earned his Ph.D. in Biochemistry from the University of Oregon Health Sciences Center working on tumour viruses and “oncogenes”. He worked as a postdoctoral fellow at the NIH on “oncogenes” and growth factor receptors. Dr. Ruta joined in the FDA in 1988. While working at the FDA, he earned a Juris Doctor degree from the American University School of Law and is admitted to the Maryland and D.C. Bar. Dr. Ruta has been extensively involved with developing blood policy and regulations.

Dr. Dorothea Stahl, Paul-Ehrlich Institut, Federal Institute for Vaccines and Biomedicines, Germany
Dorothea studied human medicine at the Ruhr-University Bochum (1985-1991) and received her doctoral degree in 1991 following a experimental thesis in microbiology / immunology. Dorothea worked thereafter at the Institute for Immunology, Heidelberg, at INSERM U430 (Immunopathologie humaine) in Paris, France and as Assistant Medical Director at the Institute for Transfusion Medicine and Transplantation Immunology at the University Clinic of Munich, Germany. In 2006, she became Head of the University Clinic for Blood Group Serology and Transfusion Medicine in Salzburg, Austria, and Professor for Blood Group Serology and Transfusion Medicine at the Paracelsus Private Medical University, Salzburg, Austria. She additionally served as Deputy Medical Director at the Landeskrankenhaus Salzburg, Austria. Dorothea holds qualifications as specialist Transfusion Medicine, specialist Medical Quality Management, Consultant Immunologist and University lecturer for Transfusion Medicine and Clinical Immunology. In 2010, she concluded an international MBA course as MBA (Health Care Management). Currently, Dorothea is Head of Section Transfusion Medicine at the Paul-Ehrlich-Institute, the Federal Institute for Vaccines and Biomedicines, an Agency of the German Federal Ministry of Health.

Dr. Stephan Walsemann, Managing Director KEDPLASMA GmbH, Munich, Germany
Stephan Walsemann studied IT at the Technical University in Brunswick, and medicine at the Georg August University in Goettingen, where he received his degree in medicine. After residency in pharmacology and toxicology and internal medicine, Dr Walsemann joined pharmaceutical industry for a decade holding managerial and executive positions in sales and marketing in Germany and Switzerland. The following 6 years, he worked at the Bavarian Red Cross Transfusion Service in Munich as Director of the Finished Goods Division, being responsible for therapeutic products as well as products for industry. In 2009 Dr. Walsemann joined KEDPLASMA GmbH as managing director. In 2013, Dr Walsemann was elected as Chairman of the European Plasma Collector Committee (EPCC) of PPTA.

Use the GMP App at no costs!

The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings - simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app just enter app.gmp-compliance.org in your browser and the WebApp opens immediately.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:
- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager

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.
Pre-Conference Workshop
Monday, 18 April 2016, 12.00 - 17.00 h
(Registration and coffee 11.30 - 12.00 h)

Conference
Tuesday, 19 April 2016, 09.00 – 18.00 h
(Registration and coffee 08.30 - 09.00 h)
Wednesday, 20 April 2016, 08.30 - 15.30 h

Venue
Austria Trend Hotel
Park Royal Palace Vienna
Schlossalle 8
1140 Vienna, Austria
Phone: +43/1/891 109 050
Fax: +43/1/891 109 050

Pre-Conference Workshop
Non-ECA Members € 690
ECA Members € 590
APIC Members € 640
EU GMP Inspectorates € 345

Conference
Non-ECA Members € 1,790
ECA Members € 1,590
APIC Members € 1,690
EU GMP Inspectorates € 895

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
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:
Mr Axel 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.:
Ms Nicole Bach (Organisation Manager) at
+49-62 21/84 44 22, or per e-mail at
bach@concept-heidelberg.de.

Pre-Conference Workshop
Non-ECA Members € 2,090
ECA Members € 1,890
APIC Members € 1,990
EU GMP Inspectorates € 1,045

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the second day, lunch on second and third day and all refreshments. VAT is reclaimable.

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

Accommodation
CONCEPT HEIDELBERG CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the conference. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference
The official conference language will be English.

Reservation Form (Please complete in full)

☐ Pre-Conference Workshop on Recombinant factors, 18 April 2016, Vienna Austria
☐ Conference Blood, Blood Products, and Plasma – Quality and Safety 19-20 April 2016, Vienna, Austria
☐ Conference AND Workshop, 18-20 April 2016, Vienna, Austria

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company’s VAT ID Number
Purchase Order Number, if applicable

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

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, we will charge the following processing fees: Cancellation of an event.
   - until 1 week prior to the conference 100%.
   - until 2 weeks prior to the conference 50%.
   - until 3 weeks prior to the conference 25%.
   - after 3 weeks prior to the conference 10%.
   CONCEPT HEIDELBERG reserves the right to change the dates and/or the place 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 airline 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款项, you are entitled to participate in the conference (receipt of payment will not be confirmed! (As of January 2012).

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, we will charge the following processing fees: Cancellation of an event.
   - until 1 week prior to the conference 100%.
   - until 2 weeks prior to the conference 50%.
   - until 3 weeks prior to the conference 25%.
   - after 3 weeks prior to the conference 10%.
   CONCEPT HEIDELBERG reserves the right to change the dates and/or the place 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 airline penalties or other costs incurred due to a cancellation.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed! (As of January 2012).

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and used. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.