Joint Conference

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Nano and Micro Formulations

Bringing together Science, Authority and Industry

13 and 14 March 2018, Berlin, Germany

Speakers

DR HANS BÄUMLER
CC-Ery GmbH /Charité-Universitätsmedizin Berlin

ALEXANDER BERNHARDT
Evonik Nutrition & Care GmbH

PROF SUSANNE BREMER-HOFFMANN
Joint Research Centre (JRC) of the European Commission

PROF DAGMAR FISCHER
Universität Jena

DR SVETLANA GELPERINA
Drugs Technology LLC

DR JOHANNES KRÄMER
CEO, Phast GmbH

DR AARON KRUEGER
KBI Biopharma

DR MARCO MARENCHINO
Malvern Panalytical GmbH

DR MARGARETH R. C. MARQUES
USP

DR LUTZ MÜLLER
Dr. Regenold GmbH

JAMES NOLAN
Kyn Biopharmaceuticals

PROF. ANA PROYKOVA
Faculty of Physics, University of Sofia

DR JOHANNES REICH
Microcoat Biotechnology GmbH

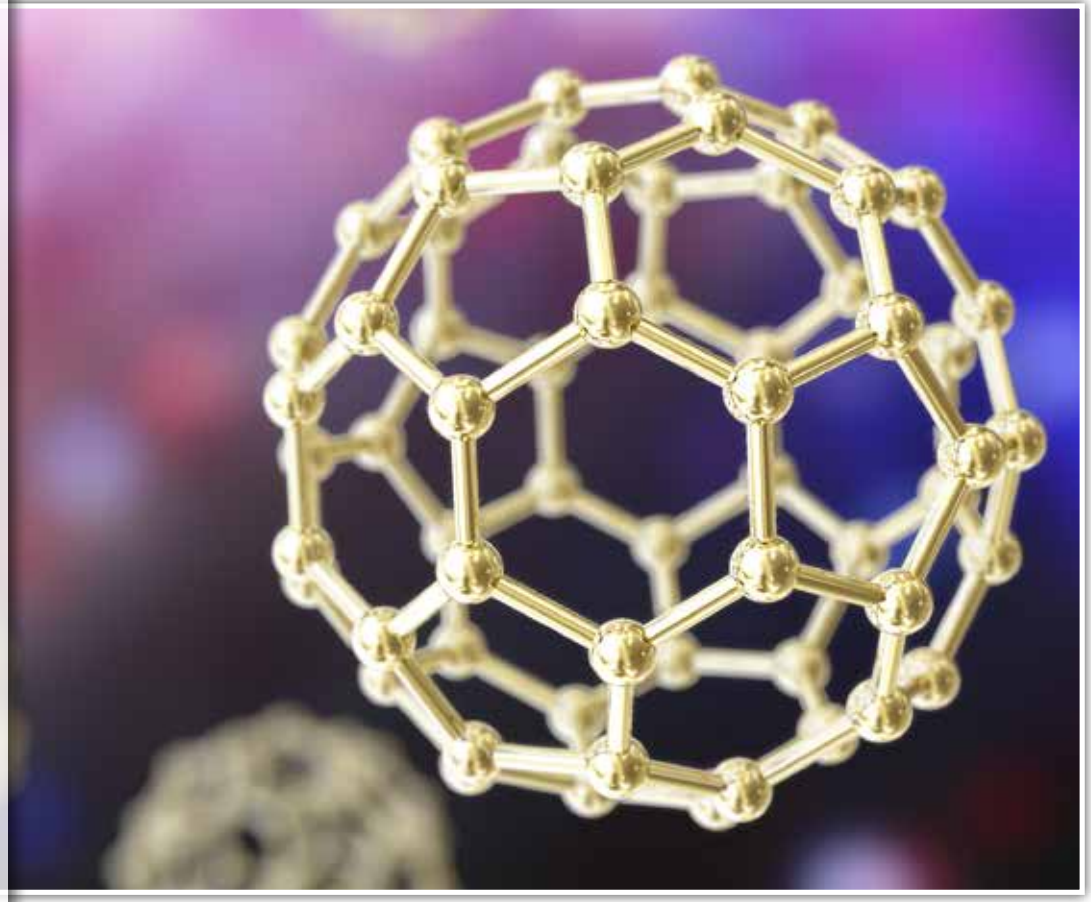
DR TOBIAS SCHULZ
Rittershaus Attorneys

DR RENÉ THÜRMER
BfArM, Federal Institute for Drugs and Medical Devices

DR EMRE TÜRELI
MJR Pharmjet GmbH

DR MATTHIAS G. WACKER
Fraunhofer IME

DR XIAOMING XU
U.S. FDA



HIGHLIGHTS:

- Regulatory Requirements, Legal Challenges and Pitfalls
- Development and Characterization
- Quality Considerations
- Drug Release Testing
- Case Study: Nanoparticle-bound doxorubicin for chemotherapy of glioblastoma: Results of clinical Phases I and II
- Fabrication of multifunctional nano and micro size biopolymer particles
- Case Study: GMP manufacturing of parenteral nanoparticles using MicroJet Reactor Technology
- Characterization of Nanomedicine Drug Product Critical Quality Attribute

Co-sponsored by Goethe University Frankfurt and Controlled Release Society, German Local Chapter, House of Pharma

GOETHE UNIVERSITÄT FRANKFURT AM MAIN | CRS Germany Local Chapter | HOUSE OF PHARMA

Nano and Micro Formulations

An ECA Academy, Loewe Center of Translational Medicine and
Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) JOINT CONFERENCE

13 and 14 March 2018, Berlin, Germany

Objectives

This conference covers the legal and scientific aspects in the development of nanopharmaceuticals, medical devices and other products containing nanomaterials:

- Physicochemical characterization and quality aspects of nanopharmaceuticals
- Requirements from authority's perspective
- Experiences from submissions and consequences for pharmaceutical development and lifecycle management
- Scientific data in regulatory submissions

Take advantage to discuss with colleagues from pharmaceutical industry, key opinion leaders from academia, manufacturers and authorities.

Background

In recent years, nanotechnology has become increasingly important for global industries. Nanopharmaceuticals and medical devices take advantage of advanced manufacturing technology and functionalized biomaterials. However, in some cases, nanomaterials may exert unexpected risks for human health and the environment.

In the light of the ongoing controversy, the use of nanomaterials and novel technologies in the pharmaceutical formulation pipeline will be presented. Furthermore, case examples for market applications will be presented and the effect of a growing regulatory framework on market perspectives will be highlighted.

The comprehensive program of the workshop will address these pressing concerns over how to develop novel nanoproducts, how to characterize them for submission or registration and how to deal with safety concerns

Target Audience

This seminar addresses pharmaceutical professionals in R&D as well as in quality control, production of pharmaceutical industry and excipient manufacturers.

Moderation

PROF DR CORNELIA KECK
DR JOHANNES KRÄMER
DR FRANK STIENEKER
DR MATTHIAS G. WACKER

Programme

Module 1: Background and Legal Challenges

Introduction to Nanomaterials
- The complex nano landscape
- Challenges and pitfalls in the nano development
- Nanosafety: Real risk or inadequate experiments?

PROF DAGMAR FISCHER, UNIVERSITY OF JENA

Multi-Parameter Characterization of Liposomes by Nanoparticle Tracking Analysis, Dynamic Light Scattering, and Electrophoretic Light Scattering
- Optimal conditions for extruding liposomes stability under different conditions
- Limit of detection for fluorescently labeled liposomes
- Charactization by Nanoparticle Tracking Analysis (NTA) and Dynamic and Electrophoretic Light Scattering
- Using the data for optimizations

DR MARCO MARENCHINO, MALVERN

Legal Challenges and Pitfalls
- Introduction and general considerations
- The European legal framework for nanomaterials in medicinal products
- Nanomaterials according to the new EU-MDR 2017/745

DR TOBIAS SCHULZ, RITTERSHAUS ATTORNEYS

Complementary Technologies for Characterization of Particles in the Nano/Colloidal Range
- Particle characterization techniques can be applied across a wide variety of sample types.
- Multiple particle techniques can be used to adequately characterize therapeutic products or nanomedicines and particle populations
- Advances in analytical technology for characterization and identification of particles provides a tremendous amount of new data
- Careful interpretation of data and in-depth understanding of the method limitations is of utmost importance for complementary methods

DR AARON KRUEGER, KBI BIOPHARMA

Module 2: Development and Characterization

USP Perspectives for Drug Products Containing Nanomaterials
- Nomenclature and definition of pharmaceutical dosage forms containing nanomaterials – Harmonization with the US FDA
- In-vitro release tests (dissolution/drug release)
- Physical-chemical characterization techniques

DR MARGARETHA MARQUES, USP

Characterization of Nanomedicine Drug Product Critical Quality Attribute
- Correlation between biological performance and quality attribute
- Identification and characterization of certain nanoparticle quality attributes
- Impact to efficacy
- Impact to safety of clinical stage product

DR JAMES NOLAN, KYN THERAPEUTICS

Quality Considerations and Regulatory Perspectives for Drug Products Containing Nanomaterials: FDA Perspective
- Nanomaterial definitions and considerations
- Drug products containing nanomaterials
- Physicochemical characterizations and performance testing for quality considerations

DR XIAOMING XU, FDA

Challenges in the Drug Release Testing of next-generation Nanomedicines
- PLGA nanoparticles, microparticles and liposomes
- Physicochemical characterization and drug release testing
- In vitro drug release testing using the dispersion releaser technology
- In vitro-in vivo correlation

DR MATTHIAS WACKER, FRAUNHOFER IME

Analysis of Drug Release from Nanoparticulate Dosage Forms without Phase Separation
- Nanoparticulate dosage forms based on PLGA vs. complex lipid vesicles
- Assay for residual content
- In situ analysis of drug release kinetics
- Derivative spectroscopy

DR JOHANNES KRÄMER, PHAST

Module 3: Further Challenges for Nanopharmaceuticals and Medical Devices

Regulations in the Area of advanced Engineered Nanomaterials
- Behaviour of advanced engineered nano & micro particles
- Applications in phase changing and porous materials, polymers
- Micro/nano scale modelling of new materials
- Risk assessment of nano/micro materials usage

PROF ANA PROYKOVA, UNIVERSITY OF SOFIA

Sometimes an unexpected Pitfall - Bacterial Endotoxin Testing in Nanomaterials
- Relevance of endotoxin testing in nanoparticle samples
- Common endotoxin test methods
- Interference of nanoparticles with common test methods
- Interaction of nanoparticles with endotoxin

DR JOHANNES REICH, MICROCOAT

A European Perspective on Regulatory Issues for Drug Products Containing Nanomaterials
- How the EU promotes the development of new nanomedicines by
  - Publishing guidance
  - Scientific advice
  - Convergence of scientific requirements to support the quality, safety and efficacy of nanomedicines
- Regulatory challenges deriving from the use of an innovative technology that crosses different platforms

DR RENE THÜRMER, BFARM

Introduction into the European Nanomedicine Characterisation Laboratory (EUNCL Aims and Objectives of the EUNCL)
- Introduction into the service and process
- Collaboration with regulators

DR SUSANNE BREMER-HOFFMANN, JRC, EUROPEAN COMMISSION

Smart Formulations for parenteral Administration with bio-degradable RESOMER® Polymers
- Overview RESOMER product portfolio for parenteral formulations
- FormEZE microencapsulation process
- Nanoparticulate dosage forms based on PLGA polymers

ALEXANDER BERNHARDT, EVONIK

Module 4: Case Studies: Quality and Manufacturing

Quality Requirements on IMPD and Module 3 for particular Systems
- Requirements for specific clinical phase
- Differences clinical studies versus marketing authorisation

DR LUTZ MÜLLER, DR. REGENOLD GMBH

Case Study: Nanoparticle-bound Doxorubicin for Chemotherapy of Glioblastoma: Results of clinical Phases I and II
- Nanoparticles for brain delivery: proof of the concept
- Preclinical studies
- Technological issues
- Clinical development

DR SVETLANA GELPERINA, DRUGS TECHNOLOGY LTD

Fabrication of multifunctional Nano and Micro Size Biopolymer Particles

DR HANS BÄUMLER, CC-ERY GMBH/CHARITÉ-UNIVERSITÄTSMEDIZIN BERLIN

Case Study: GMP Manufacturing of parenteral Nanoparticles using MicroJet Reactor Technology
- Requirements for GMP manufacturing of nanoparticles
- Preparation of nanoparticles with precipitation using MicroJet Reactor Technology
- Validation of nanoparticle manufacturing method using MicroJet Reactor Technology
- Downstream processing of nanoparticles
- In process controls for nanoparticle manufacturing

DR EMRE TÜRELI, MJR PHARMJET

Speakers

DR HANS BÄUMLER
CC-ERY GMBH/CHARITÉ-UNIVERSITÄTSMEDIZIN BERLIN

PD Dr Hans Bäumler, one of the founders and one of the Managing Directors of CC-Ery GmbH received his doctorate and habilitation in biophysics and medical physics at the Humboldt-Universität, Berlin. Since 1994, he leads the research department of the Institute of Transfusion Medicine at Charité-Universitätsmedizin Berlin. Until the end of 2019 he is responsible for one of the main tasks in the BIOCAPAN-Project of Horizon 2020.

ALEXANDER BERNHARDT
HEAD OF PARTICLE FORMULATION LABORATORY, EVONIK NUTRITION & CARE GMBH, DARMSTADT, GERMANY

Alexander Bernhardt is a pharmacist and laboratory manager in the Drug Delivery Group at Evonik Nutrition & Care GmbH. He acts as project manager and scientific lead in various projects and activities referring to innovative drug delivery technologies and formulation development. After his pharmacy studies, he worked as research associate at the Institute of Pharmaceutical Technology and Biopharmacy at the University of Münster, Germany, where he focused on the analytical characterization of pharmaceutical nanoparticle formulations.

DR SUSANNE BREMER-HOFFMANN
EUROPEAN COMMISSION, DIRECTORATE GENERAL JOINT RESEARCH CENTRE

Dr rer nat Susanne Bremer-Hoffmann, obtained her PhD from the Charité University Hospital Berlin. In 1995 S. Bremer joined the Centre for the Validation of Alternative Methods (EURL-ECVAM) hosted by the European Commission's Joint Research Centre (JRC). Currently, she is responsible for the laboratory assessing the interaction of nanomaterials with biological systems which is part of the JRC Nanobiotechnology Laboratory. S. Bremer provides her expertise on in-vitro toxicology and takes care on biocompatibility/toxicity studies of (nano) materials. She liaises the European Nanomedicine Characterization Laboratory (EUNCL) with the regulatory community and participates in the nanomedicine working group of the international pharmaceutical regulators forum.

PROF DR DAGMAR FISCHER
UNIVERSITY OF JENA, GERMANY

Dagmar Fischer studied pharmacy before obtaining her doctorate in pharmaceutical technology and biopharmacy from the Philipps University of Marburg in 1997. After a period spent at Texas Tech University Health Sciences Centre (USA), she gained several years experience as Director of Preclinical Research & Development at Antisense Pharma GmbH before accepting a professorship in Pharmaceutical Technology at Friedrich Schiller University Jena in 2008. Her work concentrates on the development of nanoparticulate carrier systems from natural and synthetic polymers with an especial focus on inflammation, infection and cancer.

DR SVETLANA GELPERINA
DRUGS TECHNOLOGY LLC, KHIMKI, RUSSIA

Svetlana studied at the Moscow Lomonosov Institute of Fine Chemical Technology and hold a PhD from Topchiev Institute of Petrochemical Synthesis, Russian Academy of Sciences. She worked as Senior Researcher, then Leading Scientist at Institute of Medical Ecology and later at the Institute of Molecular Medicine, Moscow Sechenov Medical Academy. 2007-2015 she was Research Director at Nanosystem LTD. Today she is Head of Laboratory for Drug Delivery Systems: Drugs Technology LLC. Her research is focused on two main directions: delivery of drugs to the brain by nanoparticles and development of new nanoparticle-based therapies for intracellular infections.

DR JOHANNES KRÄMER
CEO, PHAST GMBH

Dr Krämer is the founder and managing director of the "PHAST group" with sites in Germany, France, and Switzerland. Since 1987, he is working in the field of dosage form performance testing. He obtained his degree from Frankfurt University and his Phd from Heidelberg University. Dr Krämer is an elected member of the USP Dosage Forms Expert Committee. At EDQM he is member of Group 12„Dosage Forms and Methods" and is working with several other expert groups.

DR AARON KRUEGER
KBI BIOPHARMA, SCIENTIST II , PARTICLE CHARACTERISATION CORE FACILITY

His work focuses on subvisible particle identification and characterization and biophysical characterization, especially on methods for nanoparticle tracking analysis and resonant mass measurement and stability assessment of biomolecules using differential scanning calorimetry and other biophysical methods.

DR MARCO MARENCHINO
BIOSCIENCE CONSULTANT, MALVERN PANALYTICAL GMBH

Dr Marco Marenchino has a degree of Pharmaceutical Chemistry and Technology from the University of Torino, and a PhD in Natural Sciences from the ETH Zurich. He possesses sound knowledge in label-free technology as well as in the most relevant techniques aimed at studying interaction and/or solution-state of macromolecules. For the last 4 years Marco worked at GE Healthcare where he focused on Biacore and MicroCal. Following the acquisition of MicroCal by Malvern Instruments, Marco worked as Sales and Application Specialist for MicroCal products and since 2017 as Bioscience Consultant for Malvern Panalytical.

MARGARETH R. C. MARQUES
UNITED STATES PHARMACOPEIA

She has a B.Sc. and an M. Sc. both in Pharmacy by the University of Sao Paulo, Brazil and a PhD in Analytical Chemistry by the State University of Campinas, Brazil. She managed analytical laboratories at Ciba-Geigy, Sandoz, and Astra. Her current responsibilities are scientific liaison at the Science Department at USP and to the Expert Committee on Dosage Forms working on general chapters for performance tests (dissolution/drug release), and for some pharmaceutical dosage forms (products applied to the skin, ophthalmic products, etc.).

DR LUTZ MÜLLER
HEAD OF CHEMISTRY, MANUFACTURING AND CONTROLS, DR. REGENOLD GMBH

Dr Lutz Müller has a PhD in chemistry from the University Kaiserslautern. He worked as production supervisor in drug substance manufacturing for an US company on a German site. In 1997, Dr Müller joined Dr. Regenold GmbH where he built up the regulatory affairs and CMC departments. Today Lutz Müller is authorised officer and head of chemistry, manufacturing and controls at Dr. Regenold GmbH. He is supporting clients in strategic regulatory affairs and pharmaceutical development questions and leads the group which prepares the CMC dossiers (IMPDs as well as modules 2.3/3) for clinical trials and marketing authorisation applications, respectively for a variety of different products including chemical defined and biotechnological products.

Speakers

JAMES NOLAN
SR. DIRECTOR, HEAD OF CMC, KYN THERAPEUTICS, USA

Jim is the Head of CMC operations at Kyn Therapeutics. Prior to Kyn, he led the process and analytical development efforts related to the research and clinical stage nanoparticle programs at BIND Therapeutics (acquired by Pfizer). Previously, Jim spent over 10 years in various roles within EMD Serono's Bioprocess development organization, including leading units responsible for process analytics and downstream process development. Jim has over 15 years of experience in pharmaceutical development and analytical characterization of clinical stage therapeutics, including monoclonal antibodies, immune-cytokines, Fc-fusion, PEGylated therapeutics and polymeric nanoparticle drug products. Mr Nolan holds a B.S. in Biology and Biotechnology from Worcester Polytechnic Institute, a M.S. in Biological Sciences from the University of Massachusetts- Lowell and a M.B.A. from Worcester Polytechnic Institute.

PROF ANA PROYKOVA
FACULTY OF PHYSICS, UNIVERSITY OF SOFIA

Ana Proykova is president of the National Center on Nanotechnologies, hosted by the Bulgarian Academy of Sciences (BAS), she was advisor at Horizon 2020 Scientific Program of the European Commission, Member of the High Level Group of EU Member States and H2020 Associated Countries on Nanosciences, Nanotechnologies and Advanced Materials, Delegate to the European Strategy Forum on Research Infrastructures and Member of the Program Committee NanoMaterials Production+Biotechnology, Horizon 2020.

DR JOHANNES REICH
MICROCOAT BIOTECHNOLOGY GMBH, GERMANY

Johannes Reich holds a PhD from the University Regensburg. He focused his research on the aggregation and interaction behaviour of lipopolysaccharides as well as the related activity in limulus based detection systems. In 2016, Johannes joined Microcoat Biotechnology GmbH and has recently been appointed General Manager. Johannes Reich also received a degree in Business administration from University of Applied Science in Regensburg, Germany. While pursuing his degree, he worked as Product Manager for the department "Drugs of Abuse" at Profos AG.

DR TOBIAS SCHULZ
RITTERSHAUS ATTORNEYS, GERMANY

Dr Schulz studied at the Universities of Bonn and Madrid. He received his PhD in 2013. 2012-1015 he was trainee lawyer at the district court Düsseldorf. Additionally he holds a Master of Laws ("Innovation, Technology and the Law"), University of Edinburgh. His current focus is on regulation of high technologies, especially bio- and nanotechnology.

DR RENÉ THÜRMER
BFARM - FEDERAL INSTITUTE FOR DRUGS AND MEDICAL DEVICES, GERMANY

Dr René Thürmer received his diploma in chemistry and his PhD in biochemistry from the University of Tübingen. He joined the BfArM (Federal Institute for Drugs and Medical Devices, Bonn, Germany) in 2000. He currently serves as a CMC reviewer and is Deputy Head of the Unit Pharmaceutical Biotechnology. His experience is in the field of formulation, manufacture and control of medicinal products, in particular in the field of oligonucleotides, peptides, proteins, liposomes, sustained release polymer drug products, depot formulations, polymer-conjugated drug products, natural and synthetic surfactants, nanomedicine and others.

DR EMRE TÜRELI
MJR PHARMJET GMBH, GERMANY

Dr Emre Türeli is the CEO of MJR PharmJet. He has more than 10 years of international R&D experience in the nanotechnology industry. He held R&D positions in various pharmaceutical companies where he had the chance to walk through different stages of drug and formulation development. His focus is on the development of innovative formulations using the MJR nanotechnology for pharmaceutical applications.

DR MATTHIAS WACKER
FRAUNHOFER IME

Dr Matthias G. Wacker received his PhD in Pharmaceutical Technology in 2010. His research is focusing industrial nanotechnology with emphasis on the optimization of manufacturing processes for nanocarrier devices as well as methodology for assessing the release of drugs and drug candidates from nanoscaled dosage forms. He is a member of the Center for Drug Research Development and Safety and joined the Fraunhofer-Institute for Molecular Biology and Applied Ecology (IME) in 2013. There he is heading the Division of Pharmaceutical Technology and Nanosciences. Since 2015 his department is part of the LOEWE research centre Translational Medicine and Pharmacology (TMP).

DR XIAOMING XU
CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION

Dr. Xiaoming Xu received his B.S. and M.S. degree in Pharmaceutics from China Pharmaceutical University, and his PhD in Pharmaceutical Sciences from the University of Connecticut. He is currently the Senior Staff Fellow in the Office of Testing and Research at the US FDA. Dr Xu is a member of the FDA/CDER Nanotechnology Working Group and is co-leading the Nanotechnology Reviewer Network at CDER. He serves as the government liaison to the USP Expert Committee on excipients (2015 to 2020).

Social Event

In the evening of the first conference day, 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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date

Tuesday, 13 March 2018, 09.00 – 18.00 h
(Registration and coffee 08.30 - 09.00 h)
Wednesday 14 March 2018, 09.00 -18.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
email berlin@steigenberger.de

Fees (per delegate plus VAT)

Non-ECA Members € 1,790
ECA Members € 1,590
APIC Members € 1,690
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable. There is a limited number of participations with a reduced academic rate available. Please ask for academic rates.

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 course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

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

Conference language

The official conference language will be English.

Organisation and Contact

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

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For questions regarding content please contact:

Mr Axel H. Schroeder (Operations Director) at +49-62 21/84 44 10 or per e-mail at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation, etc. please contact:

Mr Rouwen Schopka (Organisation Manager) at +49-62 21/84 44 13 or per e-mail at schopka@concept-heidelberg.de.

Important Information!
There will not be any print-outs at the conference. Instead you will receive all presentations prior to the conference as Downloads. All conference delegates will also receive the presentations on a USB stick at the registration center.

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Nano and Micro Formulations

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13 and 14 March 2018, Berlin, Germany

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1. We are happy to welcome a substitute colleague at any time.
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- until 2 weeks prior to the conference 10 %,
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