

## 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 Instruments 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

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 Society, German Local Chapter,  
 House of Pharma

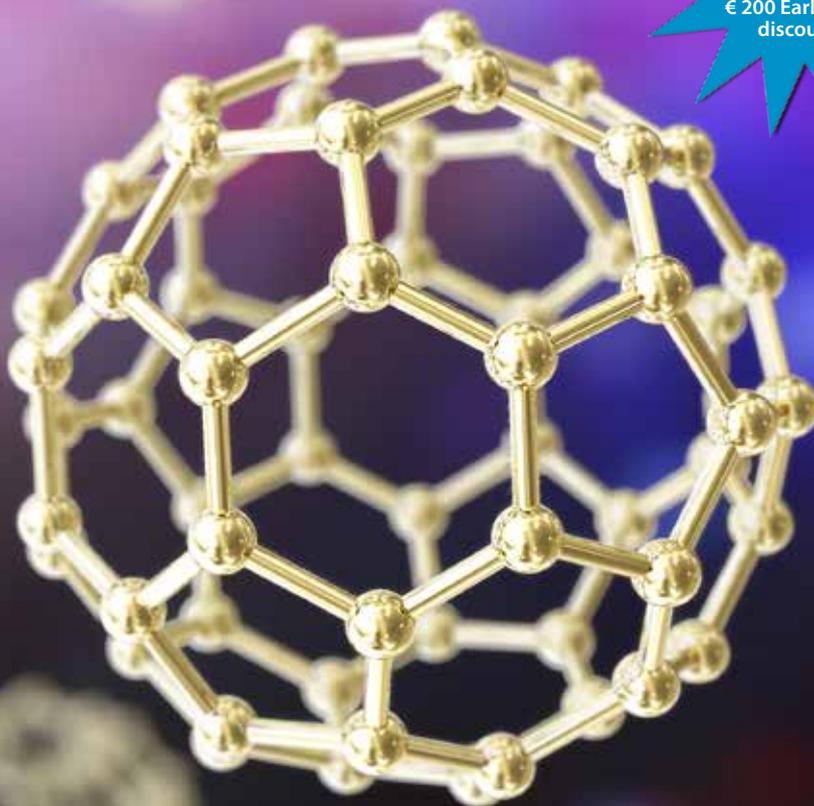


# Nano and Micro Formulations

Bringing together Science, Authority and Industry

13 and 14 March 2018, Berlin, Germany

Register before  
 December 31  
 and benefit from  
 € 200 Early-bird  
 discount



## 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

# 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 nano-products, 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
- ▷ Characterization 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) 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

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### **DR HANS BÄUMLER**

#### **CC-ERY GMBH/CHARITÉ-UNIVERSITÄTSMEDIZIN BERLIN**

PD Dr Hans Bäumlér, 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 zu 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 then 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**

#### **KNI BIOPHARMA, SCIENTIST II , PARTICLE CHARACTERISATION CORE FACILITY, KBI BIOPHARMA**

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 INSTRUMENTS 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 Instruments.

### **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.

### **JAMES NOLAN**

#### **SR. DIRECTOR, HEAD OF CMC KYN THERAPEUTICS, USA**

Prior to Kyn, Jim led the process and analytical development efforts related to the research and clinical stage nanoparticle programs at BIND Therapeutics. Prior to joining BIND Therapeutics, 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 holds a BS in Biology and Biotechnology from Worcester Polytechnic Institute, a MS in Biological Sciences from the University of Massachusetts-Lowell and a MBA from Worcester Polytechnic Institute.

## Speakers

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### **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. 2012-2015 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

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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.

**Register before December 31 and benefit from € 200 Early-bird discount!**  
(This is not valid for Inspectorates and Academics)

### 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](http://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.

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
69007 Heidelberg, Germany  
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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](mailto: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](mailto: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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Reservation Form (Please complete in full)

### Nano and Micro Formulations

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13 and 14 March 2018, Berlin, Germany

Mr  Ms

\_\_\_\_\_  
Title, first name, surname

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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 %
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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).  
German law shall apply. Court of jurisdiction is Heidelberg.

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