

SPEAKERS



BRIGITTE BASTYNS
Johnson&Johnson



**RITA HATTEMER-
APOSTEL**
Verdandi AG



ANDREAS JUNGK
Lawfirm Jungk



HELENA LINDBERG
GCP Inspector, Swedish
Medical Products Agency



DR CLAUDIO LORCK
AbbVie



**DR ANDREAS
SCHWINN**
Roche Pharma



LENKA TAYLOR
University Hospital of
Heidelberg



MARIA WÄNGELIN
GDP/GMP Inspector,
Swedish Medical
Products Agency



GMP meets GCP

Management, Supply and Quality Assurance of Clinical Trials

13 – 15 October 2015, Prague, Czech Republic

HIGHLIGHTS:

- Rules and Regulations
 - Applicable legislation and GMP/GCP interfaces
 - Duties and responsibilities
 - Typical inspection findings
- Supply Management
 - Packaging, labelling, distribution
 - Shelf-life extensions
 - Handling of comparators
 - GMP requirements at the investigational site
 - Trials outside the EU
- Study Management
 - Key tasks and responsibilities
 - The role of the hospital pharmacy
 - IMP-related documentation
- The Role of the QP in Clinical Trials
 - When does the QP responsibility end?
 - Oversight of the supply chain
- International Contracts and Agreements
- Workshops and Case Studies

Co-sponsored by
European QP Association

GMP meets GCP

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Objectives

During this course, **well-experienced specialists** will share their **expert knowledge** about important aspects of IMP Supplies and the Management of Clinical Trials. Hear essential aspects about the organisation and management of the supplies, their distribution, things to consider during the study and **learn how the various regulations lead the way**. During this event, the **important interfaces between GMP and GCP** will be elaborated.

Background

In the development of new pharmaceutical products, it is a challenge to design and initiate sound and appropriate studies. **Compliance with GMP and GCP regulations is mandatory**. A prerequisite for a successful study is the **thorough planning of the clinical trial supplies**. Beginning with the order, the manufacturing and supply of the IMPs, an efficient study management and full compliance with applicable rules and regulation will lead to satisfactory results. **GMP and GCP requirements need to be considered and understood from all parties involved**.

Trials outside the EU and contracts and agreements are two other aspects which require particular attention.

This event has been designed by the ECA to enhance and broaden your knowledge and to **consolidate the various aspects** which need to be taken into account for an efficient management of clinical trials.

Target Audience

Specialists, managers and executives from R&D dealing with the various aspects of IMP supply and clinical trial management. It addresses representatives from IMP manufacturing, packaging, QP certification and supply as well as from the study design and management and the respective Quality Assurance units. It is also directed to CROs and members of inspectorates and authorities.

Social Event

On 13 October 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.



Programme

Case Studies

- How things can go wrong

Interface between GMP and GCP

- Examples of why GMP and GCP do have an impact on what happens during clinical trials

CTS Planning

- Supply Chain Planning
- Comparators: selection, procurement, pedigree
- Blinding
- NIMPs
- Shelf-life assignment
- Outsourcing
- IRT: Pros and Cons to use for a particular study

Packaging and Labelling of IMPs

- Blinding aspects in packaging
- Packaging technology
- Unblinding risks during packaging
- Just-in-time labelling
- Relabeling
- Reconstitution

QC Aspects

- CMC Aspects of comparator modifications
 - Comparative dissolution, Stability, BE studies
 - Shelf-life Assignment for Comparators
- Stability concepts for comparator studies
- Shelf-life Assignment
- Assessment of temperature deviations
- Mean kinetic temperature
- QC approach for site transfer

GCP and GMP Inspections

- The inspection and monitoring process
- Typical and recurrent compliance issues
- Typical issues at the interfaces
- Inspections in Europe and beyond

Distribution of IMP Supplies

- Distribution concept and prerequisites
- IRT
- Temperature controlled shipments
- Temperature deviations
- Site transfer
- Depots
- Customs

GCP Aspects to Consider for IMPs

- Roles and responsibilities: Sponsor, CRA, Investigator
- ICH GCP
- Storage of IMPs
- Reconstitution
- Accountability and Reconciliation
- Sponsor: Achieving and Maintaining the Blind
- IMP return and destruction
- IMP related documentation

The Role of the QP in Clinical Trials

- When does the QP responsibility end?
- Dealing with deviations during distribution
- How to handle deviations at investigator's site
- Extension of shelf-life
- Oversight of distribution and transport
- The responsibility for comparators

Three Workshops on Case Studies

Evaluate and discuss with the other delegates and the speakers case studies on:

1. Study Planning: Challenges from a CTS coordinators perspective
2. Case Studies: Open Discussion of QP Tasks and Challenges in Clinical Trials
3. GCP Aspects: Handling IMPs at the Investigator's Site

You will be able to attend all 3 workshops.

Handling IMPs at a Hospital Pharmacy

- The role of the hospital pharmacy: manufacturing, organisation, consultancy
- The interface of manufacturing IMPs at a hospital pharmacy and the daily work
- Investigator-Initiated Trials (IITs)
- FAQs: things you need to consider
- Challenges and problem solving

International Contracts and Agreements in the Management of Clinical Trials

- Applicable law and jurisdiction
- Representations and warranties
- Indemnification and liability
- Frequently asked questions

A last Case Study - how things can go wrong

- How would you have reacted?

Speakers



BRIGITTE BASTYNS

Janssen Pharmaceutica NV (part of Johnson & Johnson), Belgium

Brigitte Bastyns is Manager QA of the Clinical Supply Chain and delegate QP. She is releasing IMPs for J&J sponsored clinical trials globally. In her role, she is also first point of GMP contact for GCP issues, escalations, inspections and process improvements.



RITA HATTEMER-APOSTEL

Verdandi AG, Switzerland

Rita Hattemer-Apostel is founder and CEO of Verdandi AG, an independent Quality Management Consultancy for GCP/QA. She has worked in Pharma and CRO industry and has many years of clinical QA experience. She has been President of SPAQA, the Swiss Professional Association of Quality Assurance and Editor-in-Chief of the Quality Assurance Journal.



ANDREAS JUNGK

Lawfirm Jungk, Germany

Andreas Jungk worked as an attorney-at-law at a German-French law office focusing on civil law, international sale and purchase contracts and arbitration. In 1998 he founded his own law office focusing on medicines law, medical devices law and contracts in the field of clinical research.



HELENA LINDBERG

GCP Inspector, Swedish Medical Products Agency

As a Pharmaceutical Inspector in the GCP area, Helena Lindberg performs national inspections of clinical trials in Sweden and international inspections on behalf of EMA. Before joining the MPA in 2010 Helena Lindberg worked as Clinical Research Manager and Project within the biotech and pharmaceutical industry for 18 years.



DR CLAUDIO LORCK

AbbVie Deutschland GmbH, Germany

Claudio Lorck is QP Lead for Clinical Product Supply EU. Before that he was Head of the Business Unit 'Clinical Trial Materials' and Qualified Person (QP) at Temmler. He was also working in Pharmaceutical Development, as Quality Control Manager, Quality Manager R&D, QP for IMPs and Head of Clinical Trial Materials at various pharmaceutical companies.



DR ANDREAS SCHWINN

Roche Pharma AG, Germany

Dr Andreas Schwinn is Qualified Person for IMP Release and Head of the Release Preparation Group. Before that he was Director Clinical Supplies and QP at Nuvisan Pharma Services, where he has developed a group to provide Clinical Packaging, Manufacturing and Pharmaceutical Development Services for the Pharmaceutical Industry.



DR LENKA TAYLOR

Pharmacy of the University Hospital Heidelberg, Germany

Dr Lenka Taylor is a Pharmacist, working at the Clinical Trial Department within the Pharmacy of the University Hospital Heidelberg. She is managing clinical trials within InPhaSol, the production unit of the University Hospital, as well as commercial clinical studies. She is also lecturer at the University of Freiburg (Pharmacy).



MARIA WÄNGELIN

GDP/GMP Inspector, Swedish Medical Products Agency

As a Pharmaceutical Inspector in the GDP and GMP area, Maria Wängelin performs national and international inspections. Before joining the MPA in 2012, Maria Wängelin has worked as Pharmaceutical Production Manager and later as a Leadauditor at Kemwell. Before that she was Sterile Production Manager at Pfizer.

Conference Exhibition



The European Compliance Academy offers you the opportunity to present your company, your products and services to your target group almost without any scattering losses. The costs for an exhibition space at this event are € 1,490,-. You will find details and a registration form on our website www.gmp-compliance.org. Just follow the link „Conferences“ on the homepage.

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to 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. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website <http://www.gmp-compliance.org>

What Are the Benefits of ECA?

During the membership, you enjoy a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

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 seminar is recognised within the GMP Certification Programme Module "Pharmaceutical Development Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- ECA Validation Manager
- ECA QA Manager
- ECA API Production Manager
- ECA Quality Control Manager
- ECA Technical Operations Manager
- ECA Computer Validation Manager
- ECA Regulatory Affairs Manager
- ECA Microbiological Laboratory Manager
- ECA Sterile Production Manager
- ECA Biotech Manager
- ECA Pharmaceutical Development Manager
- ECA GMP Auditor
- ECA GDP Compliance 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.

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 October 2015, 9.30 h – 17.30 h
(Registration and coffee 9.00 h – 9.30 h)
Wednesday, 14 October 2015, 8.30 h – 17.30 h
Thursday, 15 October 2015, 8.30 h – 15.30 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone + (0) 420 261 191 111
Fax + (0) 420 261 225 011

Fees (per delegate plus VAT)

ECA Members: € 1.790
EQPA Members: € 1.790
APIC Members: € 1.890
EU GMP Inspectorates: € 995
Non-ECA Members: € 1.990

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

Accommodation

CONCEPT HEIDELBERG CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the conference. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
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For questions regarding content:

Wolfgang Schmitt (Operations Director) at
+49-62 21/84 44 39, or per e-mail at
w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Susanne Ludwig (Organisation Manager) at
+49-62 21/84 44 44, or per e-mail at
ludwig@concept-heidelberg.de.

If the bill-to-address deviates from the specification to the right, please fill out here:

Reservation Form (Please complete in full)

 +49 6221 84 44 34

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Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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69007 Heidelberg
Germany

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions

If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare, penalties or other costs incurred due to a cancellation.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-

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

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