ECA
European Compliance Academy




SPEAKERS

RITA HATTEMER-APOSTEL
Verdandi AG

ANDREAS JUNGK
Lawfirm Jungk

HELENA LINDBERG
GCP Inspector,
Swedish Medical Products Agency

DR CLAUDIO LORCK
Temmler Werke

DR ANDREAS SCHWINN
Roche Pharma

LENKA TAYLOR
University Hospital of Heidelberg

MARTINE TRATSAERT
Johnson & Johnson

MARIA WÄNGELIN
GDP/GMP Inspector, Swedish Medical Products Agency

GMP meets GCP

Management, Supply and Quality Assurance of Clinical Trials

08 – 10 October 2013, Basel, Switzerland

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

QP Association

This conference is recognised for the ECA GMP Certification Programme „Certified Pharmaceutical Development Manager". Please find details at www.gmp-certification.eu

GMP meets GCP

08 – 10 October 2013, Basel, Switzerland

Objectives

During this conference, **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 course, 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 lead to satisfactory results. An area where requirements of **both 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

The course is set up for 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 8 October you are cordially invited to a social event in Basel. 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 does have an impact on what happens during clinical trials

CTS Planning

- Supply Chain Planning
  - The order
  - Overage calculation
- Comparators: selection, procurement, pedigree
- Blinding
  - Principles and possibilities
  - How to modify comparators
- NIMPs
- Test Product Manufacture and Testing
  - Specification setting
  - Shelf-life assignment
- Outsourcing
  - Concepts: strategic, tactical, capacity driven, technology driven, extended workbench
- IRT
  - Definition
  - Pros and Cons to use for a particular study

Programme, cont'd

Packaging and Labelling of IMPs
- CT Packaging - peculiarities
- Blinding aspects in packaging
- Packaging technology
- Smart containers
- Unblinding risks during packaging
- Label approval
- Booklet labels
- Label text requirements and IRT
- Just-in-time labeling
- 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
- Options for temperature controlled shipments (courier, packaging, etc.)
- 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
- 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

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 18+ years of clinical QA experience. She has been President of SPAQA, the Swiss Professional Association of Quality Assurance (2003-2009) and Editor-in-Chief of the Quality Assurance Journal (2001-2011).

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. He is providing legal advice to clients in the field of pharmaceutical law, clinical research and international contracts concerning 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 Manager on an international level within the biotech and pharmaceutical industry for 18 years. She has experience from working in all phases of clinical trials, and also from clinical trials with medical devices.

DR CLAUDIO LORCK, *Temmler Werke, Germany*
Claudio Lorck is Head of the Business Unit 'Clinical Trial Materials' and Qualified Person (QP). He started his career in Pharmaceutical Development and became Quality Control Manager at Klinge Pharma. Later he was Quality Manager R&D and QP for IMPs at Fujisawa and Head of Clinical Trial Materials and QP at Astellas.

DR ANDREAS SCHWINN, *Roche Pharma AG, Germany*
Dr Andreas Schwinn is Qualified Person for IMP Release. Before that he was Director Clinical Supplies and QP at Nuvisan Pharma Services , where he has developed a group to provide Clinical Packaging, Manu¬facturing 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 in Heidelberg, as well as commercial clinical studies. Within InPhaSol, Dr. Taylor is appointed Head of Quality Control. She is also lecturer at the University of Freiburg (Pharmacy).

MARTINE TRATSAERT, *Johnson & Johnson, Belgium*
Martine Tratsaert is Senior Director Market Quality EMEA. Before that, she was the department head of the Global Qualified Person Group (GQPG), the center of excellence for QP certification of IMPs. She is an Advisory Board member of the European QP Association and responsible for the IMP Working Group.

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 is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit:
During the membership, you enjoy a EUR 200 discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG.
More information about ECA can be obtained on the Website www.gmp-compliance.org

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

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, 08 October 2013, 9.30 h – 17.30 h.
(Registration and coffee 9.00 h – 9.30 h).
Wednesday, 09 October 2013, 8.30 h – 17.30 h.
Thursday, 10 October 2013, 8.30 h – 15.00 h

Venue
Ramada Plaza Basel
Messeplatz 12
4058 Basel
Switzerland
Phone +41 (61) 560 40 00
Fax +41 (61) 560 55 55

Fees
ECA Members: € 1.790,- per delegate + VAT
EQPA Members: € 1.790,- per delegate + VAT
APIC Members: € 1.890,- per delegate + VAT
EU GMP Inspectorates: € 995,- per delegate + VAT
Non-ECA Members: € 1.990,- per delegate + VAT
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
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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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:

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CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

+49 6221 84 44 34

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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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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 HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!

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