

SPEAKERS

RITA HATTEMER-APOSTEL
Verdandi AG, Switzerland

DR PETER C. MEIER
ETH Zurich (Swiss Federal
Institute of Technology) and
GMP Consulting GmbH,
Switzerland

DR ANDREAS SCHWINN
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Germany

DR LENKA TAYLOR
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Hospital Heidelberg, Germany

MARTINE TRATSAERT
Johnson & Johnson,
Belgium



GMP meets GCP

Management, Supply and Quality Assurance of Clinical Trials

Budapest, Hungary, 8 – 10 November 2011

HIGHLIGHTS:

- **Rules and Regulations**
 - Applicable legislation and GMP/GCP interfaces
 - Duties and responsibilities (sponsor, manufacturer, CRO)
 - Typical inspection findings
- **Supply Management**
 - Packaging, labelling, distribution
 - Shelf-life extensions
 - Handling of comparators
 - BA and BE Testing Samples
 - Trials outside the EU
- **Study Management**
 - Key tasks and responsibilities
 - The role of the hospital pharmacy
 - IMP-related documentation
 - Misconduct and fraud
- **The Role of the QP in Clinical Trials**
 - When does the QP responsibility end?
 - Oversight of the supply chain



GMP meets GCP

8-9 November 2011, Budapest, Hungary

Objectives	<p>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.</p>
Background	<p>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. A fact which is often not the case.</p> <p>Trials outside the EU and suspected misconduct and fraud are two other aspects which require particular attention.</p> <p>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.</p>
Target Audience	<p>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.</p>
Programme	<p>Case Studies</p> <ul style="list-style-type: none">■ How things can go wrong <p>Interface between GMP and GCP</p> <ul style="list-style-type: none">■ Examples of why GMP does have an impact on what happens during clinical trials■ The EMA GCP and GMP Inspectors Working Group reflection paper on the use of IVRS <p>The Management of IMP supplies</p> <ul style="list-style-type: none">■ The „Order“ (requisition process)■ Interfaces between bulk manufacturing, packaging, quality control and release■ Blinding and randomisation■ Interfaces between headquarter and local site■ Handling and Retention of BA and BE Testing Samples (FDA)■ Traceability from patient to API■ Communication between study management – manufacturer – CRO – sponsor■ Prolongation of IMP expiry date / retest Date <p>Packaging and Labelling of IMPs</p> <ul style="list-style-type: none">■ What has to be on the label■ Labelling of smalls kits and special formulations■ Different authorities - different opinions■ Labelling at investigator' site■ Extension of expiry date <p>Management of IMPs for trials outside the EU</p> <ul style="list-style-type: none">■ Challenges, pitfalls and possible solutions■ How to comply with EU GMP and GCP requirements■ Cold and Cool Chain controls <p>GCP and GMP Inspections</p> <ul style="list-style-type: none">■ The inspection and monitoring process■ Typical and recurrent compliance issues■ Typical issues at the interfaces■ Inspections in Europe and beyond

Programme (cont'd)

Distribution of IMP Supplies

- Distribution of IMPs to investigator sites
- Challenges in Clinical Trial Supply Management - IMP-specific vs. commercial supplies
- Ambient – cold chain – frozen
- IVRS
- Import, Export, Depots

IMP-related Documentation

- Documents required by GMP
- Documents required by GCP
- Trial Master File – Investigator Site File – Pharmacy File

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. Management of IMPs and Comparators
2. The Role of the QP in Clinical Trials
3. 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

Suspected Misconduct and Fraud in Clinical Trials

- Incidence and Impact of Misconduct and Fraud in Clinical Research
- Potential Indicators
- Some Examples from Audits
- Follow-up to suspected misconduct and fraud

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

DR PETER C. MEIER

ETH Zurich (Swiss Federal Institute of Technology) and GMP Consulting GmbH, Switzerland

Dr Peter C. Meier graduated from ETH Zurich (Swiss Federal Institute of Technology), where he then spent ten years of research and teaching. He worked 25 years in pharmaceutical. He has recently retired as Director of Quality Assurance of Cilag's pharmaceutical R&D division in Schaffhausen, Switzerland. He is now lecturer at the Pharmacy School of the ETH and runs his own consultancy business.

DR ANDREAS SCHWINN

Nuvisan Pharma Services GmbH & Co. KG, Germany

Dr Andreas Schwinn is Director Clinical Supplies and registered QP at Nuvisan Pharma Services, the former AAI Pharma. He joined AAI Pharma in 1995 working in Quality Assurance. In 1997 he took on the responsibility for the Pharmacy of the companies Phase 1 Clinic. Since then he developed this 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 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 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.

Social Event

On 8 November you are cordially invited to a social event in Budapest. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



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, 8 November 2011, 9.30 h – 17.30 h
(Registration and coffee 9.00 h – 9.30 h)
Wednesday, 9 November 2011, 8.30 h – 17.30 h
Thursday, 10 November 2011, 8.30 h – 15.00 h

Venue

Hilton Budapest WestEnd
Váci út 1-3
1062 Budapest, Hungary
Phone +36 1 288 5500
Fax +36 1 288 5588

Fees

ECA 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 has reserved a limited number of rooms in the conference hotel. Please make your reservation via the Personalised Online Group Page <http://www.budapest-westend.hilton.com/ECA0711> where you also can modify/cancel your reservation

until 26 September 2011 without any penalty. 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

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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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8 - 10 November 2011, Budapest, Hungary

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69007 Heidelberg
Germany

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)!