

SPEAKERS

MARK-THOMAS BECKMANN

Bayer Pharma AG

DR HILTRUD HORN

Horn Pharmaceutical
Consulting

TORSTEN KNEUSS

Bayer Pharma AG

STEPHAN MAY

IAB GmbH

DR BERND RENGER

European QP Association

DR FRANZ SCHÖNFELD

GMP Inspectorate
Upper Bavaria

TIMO USINGER

Vetter Pharma-Fertigung

MARTIN WESCH

Wesch und Buchenroth -
Attorneys and Accountants



Procurement meets GMP

GMP Requirements for Purchase and Procurement

29 – 30 October 2013, Prague, Czech Republic

HIGHLIGHTS:

- Regulatory Requirements
- Supplier Qualification
- Contract Management
- Cooperation of Purchase and QM
- GMP and Packaging Materials
- Change Control
- Procurement for Development and Clinical Phases
- Document Management
- GMP Requirements for Raw Materials, Excipients and Disposables

Procurement meets GMP

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Objectives	During this conference, experts from purchase, quality management, consultants and authorities will show you the critical fields of purchase and procurement for pharmaceutical manufacturing. Furthermore you will be acquainted with examples of the coordination and practical implementation of the GMP requirements on QC, supplier qualification, packaging materials and maintenance. And last but not least, the speakers team provides you information about the expectations of the responsible authorities and the relevant guidelines.
Background	During the last years, the developments of computer technologies gave purchasers a lot of possibilities to optimise content management and merchandise management, reduction of suppliers. Direct connection with suppliers systems enabled a faster, clearly arranged and more effective procurement. The World Wide Web, online tendering and auctions made the comparison of suppliers and costs easier than ever before. But for the manufacturing of products under the regulations of drug licensing and GMP, like drug substances, drug products and medical devices, during all optimisation of purchase and procurement, purchasers must be aware of these regulatory requirements. Especially the change of suppliers, process relevant materials or parts of the qualified production plant must be planned in a direct cooperation with the quality management. Such changes necessities maybe a new validation of the process, a new qualification of the manufacturing plant and for sure, a change control procedure. This can effect additional costs, maybe more then the saving effect of the change and in a worst case, a not coordinated change can cause the lost of a product licensing.
Target Audience	This conference is for those involved in purchase and procurement for GMP regulated manufacturing as well as for responsible persons from QC and QA who are in cooperation with the purchase and procurement of their companies.

Programme

Procurement for GMP Manufacturing – Regulatory Requirements and Expectations

- Supplier qualification
- Qualification and validation
- Manufacturing and import licensing
- Marketing authorisation

Regulatory and Legal Requirements on Supplier Qualification and Ensuring the Supply Chain

- Guideline 2011/62 EU, delegated acts and expectations
- National implementation
- EU GMP Guideline, revisions and draft revisions
- USP <1083> Good Distribution Practices – Supply chain integrity
- How can the requirements be implemented?

Retention Time for GMP Documents – Legal Requirements

- Defense against legal claims
- Liabilities
- Limitations

Purchase and Quality – Integration of both Expectations in one Supplier Management

GMP Requirements on Packaging Materials

- Related guidelines (e.g. GMP)
- Requirements for manufacturers of packaging materials (e.g. ISO 15378)
- Specifications and other important documents
- Change management (e.g. in case of material change)

Materials and Differences of Cleanroom Disposables

- Overview of available materials for disposables (gloves, coveralls etc.)
- Standards and regulations
- Benefits and disadvantages
- Practical demonstration for suitability testing

Qualification of Technical Suppliers - a Risk-based Approach

- Technical equipment and utilities
- Analytical equipment & reagents
- Supplies, disposables and consumables - What regulations apply?
- Risk-based qualification and procurement

Where will GMP start? Procurement for Development and Clinical Phases

- Considerations for EU and USA?
- Why should we know ICH Q7, Q8, Q9, Q10 and Q11?
- What is essential for development?
- Changes for routine manufacturing?
- Case Study

GMP Requirements for Raw Materials and Excipients

- What is pharmaceutical quality for excipients?
- GMP for starting materials, final intermediate & API
- Requirements for different dosage forms
- Impact of the „Falsified Medicines Directive“ on supplier qualification
- Supplier qualification & „GiveMePaper“

Change Control

- What does it mean?
- Impact and consequences?
- Examples for typical changes

Supplier Contract Management

- Quality and risk management
- Technical agreements
- cGMP requirements
- Control of content

Speakers

Dr Mark-Thomas Beckmann, Bayer Pharma AG

Dr Beckmann worked as scientist in the analytical laboratory for quality control of medicinal products and API. He was head of a laboratory for chemical development and in 2008 he switched to pharmaceutical development and headed a laboratory for excipients and pharmaceutical analytics.

Stephan May, IAB Cleanroom Products GmbH

He started his career in development and manufacturing of non-woven and woven fabrics at companies in Belgium and Germany. He changed to cleanroom business at Basan, Germany and became director of sales. He then joined IAB Cleanroom products. His task is to optimize the product and service portfolio. He holds a Diploma as Management Expert /Economist, is a certified Hygiene expert and GMP Consultant.

Dr Hiltrud Horn, Horn Pharmaceutical Consulting

Dr Horn is managing director of Horn Pharmaceutical Consulting providing consulting services for the pharmaceutical and biotech industry in EU and US. After working at Hoffmann-La Roche, Basel in QC/QA, she was responsible for medical writing and project management in the "International Regulatory Affairs" department. In 1999, she joined Knoll AG as Head of "Regulatory Compliance and CMC Documentation" and later "Dossier Production and Compliance" for International RA. In 2002, she worked as consultant at Cap Gemini Ernst & Young (biotechnology and life sciences) prior to starting her own business.

Torsten Kneuss, Bayer Pharma AG

He joined Schering AG / Bayer Schering Pharma AG in 1996 and has been working with pharmaceutical packaging materials, including several years within the field of packaging QC. Since 2007 he has been employed in packaging development, lately as an Application System Development expert. In this position he was responsible for several development projects, mainly pre-filled syringes. He now is working as project coordinator within Contract Manufacturing Biotech, and as Operations Manager he is responsible for pre-filled syringes.

Dr Bernd Renger, Bernd Renger, Immediate Past Chair QP Association

Dr Bernd Renger is a member of the ECA Advisory Board and former Chairman of the European QP Association. Since 2011, is running his own consultancy business. Before that he was Director of QC at Vetter Pharma-Fertigung. He started his career at Hoechst AG as a research and development chemist. Since then, he has held several quality positions at Mundipharma, Altana Pharma and Baxter.

Dr. Franz Schönfeld, Regierung von Oberbayern

Dr Schönfeld is a pharmacist by training. After his graduation he worked at the clinical centre Nürnberg North and as pharmacist at the Markt Pharmacy in Bayreuth. Since 2007 he has been working for the centralised inspectorate for medicinal products of the government of upper Bavaria. He is head of the experts working group 7 for APIs and deputy head of the Radiopharmaceutical expert working group.

Dipl. Kfm. (FH) Timo Usinger, Vetter Pharma Fertigung GmbH & Co. KG

He started his career at the former Hoechst AG. He then joined Intervet International with responsibilities in global production planning and was head of materials management at Sandoz Industrial Products. Since 2007, he is Director Procurement at Vetter Pharma Fertigung in Ravensburg/Germany.


Dr Martin Wesch, Lawyer at Wesch & Buchenroth

Dr Martin Wesch is a lawyer specialising in medical and industrial law and working for the Stuttgart-based firm of lawyers Wesch & Buchenroth, which he founded in 2001. Since April 2002, he has been teaching industrial law at the University of Stuttgart. From 1994 to 2011, Martin Wesch was Managing Director of the Gütegemeinschaft Pharma-Verpackung e.V., a quality association for pharmaceutical packaging.

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, 29 October 2013, 09.30 – 18.00 h
(Registration and coffee 09.00 - 09.30 h)
Wednesday, 30 October 2013, 09.00 – 16.00 h

Venue

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

Fees

ECA Members: € 1,590,- per delegate + VAT
APIC Members: € 1,690,- per delegate + VAT
EU GMP Inspectorates: € 895,- per delegate + VAT
Non-ECA Members: € 1,790,- 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 both 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:

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.:
Ronny Strohwalde (organisation manager) at +49-62 21/84 44 51 or per e-mail at strohwalde@concept-heidelberg.de.




Social Event

On 29 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.

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

Procurement meets GMP

29-30 October 2013, Prague Czech Republic

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

CONCEPT HEIDELBERG
P.O. Box 10 17 64
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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

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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)!