

# Pharmaceutical Sourcing Conference

Cost-effective and GMP-compliant Procurement

6-7 December 2007, Berlin, Germany

## Speakers

**Richard M. Bonner**  
*Formerly with Eli Lilly, United Kingdom*

**Diana Eifler**  
*F. Hoffmann-La Roche AG,  
Switzerland*

**Prof Dr Claus W. Gerberich**  
*Prof Gerberich & Partner International  
Consultancy, Germany*

**Alfred Keusch**  
*Baxter AG, Austria*

**Karl Metzger**  
*Welding GmbH & Co. KG, Germany*

**John Taylor**  
*Medicines & Healthcare Products  
Regulatory Agency (MHRA), UK*

## Highlights

- What procurement should know about supplier qualification, change management, contracts and dealing with brokers
- Strategic vs. operational purchases
- Global category management  
Management of success in procurement
- Key performance indicators in procurement - the management cockpit
- Cost reduction through third-party audits
- Cost management in procurement



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## Objectives

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As turnover growth is slowing down, cost management becomes the focus of attention in the pharmaceutical companies. The procurement is required to make its contribution. There is a whole range of concepts: integrating the buying departments at an early stage of product development, make-or-buy decisions and supplier management are strategic approaches that have to be driven forward by the procurement. However, many procurement measures, like e.g. choosing a new API manufacturer or contract manufacturer, are regulated by the authorities. The worldwide marketing of medicinal products and the different requirements on post-approval changes increase the complexity. Whether indirect costs for audits and stability programmes or direct costs for notification of changes to authorities – the additional costs caused by changes are enormous. This is why strategic sourcing concepts in close interaction with quality assurance play a pivotal role in pharmaceutical manufacture.

Therefore, **pharmaceutical sourcing** has to:

- **be cost-optimised**  
and at the same time
- **comply with the pharmaceutical regulations.**

Due to the ICH Q7A Initiative „GMP for Active Pharmaceutical Ingredients“, which is now mandatory in Europe, the US and Japan, regulations have been set up for dealing with traders and brokers, which also have to be observed by the procurement. There is also a growing tendency to include the manufacturers of excipients into the GMP system.

In terms of supply chain management, the sourcing is more and more closely linked to other departments (like regulatory affairs, production, quality control, quality assurance). Under EU-GMP Guide Chapter 2.8, this comprehensive approach requires more frequent training measures in the field of procurement. Often the procurement is also involved within the framework of supplier qualification. It starts with the first contact established by the procurement, refers to audits and supplier contracts and ends with supplier evaluation and complaint processing carried out by the procurement.

The question is now: How can the procurement perform its strategic core competency - i.e. reducing sourcing costs - in spite of the strict regulatory requirements?

This conference will give you the answers. Its objective is to shed a critical light on the regulatory and GMP-relevant aspects of pharmaceutical sourcing, e.g.

- Consequences of the EC Directives 2001/83 and 2004/27 for procurement
- What procurement should know about supplier qualification, change management, contracts and dealing with broker

Strategies for optimisation and cost reduction are dealt with in detail, for instance:

- Strategic vs. operational purchases
- Global category management
- Management of success in procurement
- Key performance indicators in procurement – the management cockpit
- Cost reduction through third-party audits
- Cost management in procurement

## Target Group

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Buyers, supply chain managers, traders and suppliers in the pharmaceutical industry who would like to inform themselves about the GMP requirements to be observed and about optimisation strategies for cost reduction. The conference is also directed at employees who work in those departments that interact with procurement (regulatory affairs, production, quality assurance and quality control) and who are involved in procurement activities.

## Programme

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### Part 1: Regulatory Compliance

#### Current GMP Aspects of Purchasing Active Substances and Excipients from the Authorities' Point of View

- Content of the EC Directives 2001/83 and 2004/27
- „For Cause“ inspections of EMEA, EDQM and national monitoring, also abroad
- The planned compliance register of EMEA for producers of active substances and excipients
- WHO's guideline of excipients
- Consequences when using non-GMP APIs?
- Regulatory Change Management: EC Regulations 1084/2003 & 1085/2003 and their upcoming revision

#### What Procurement Should Know about GMP

- Supplier qualification and reduced testing.
- Change management
- GMP contracts. Who is responsible for what ?
- The contract, addendums and frequency of updates.
- Complaints
- Regulatory interactions
- Analytical approvals
- Technical support
- How to determine the critically of a supplier and audit frequency
- Dealing with brokers
- GMP training for procurement staff ; what and why?

### Part 2: Cost-effective Procurement

#### Strategic vs. Operational Purchases

- The role of the purchasing in the supply chain
- The concept of category management
- Case study on cost reduction

## Global Category Management

- Change management on globally organising the procurement
- Development of category strategies
- Globalisation of relationships with suppliers
- Key data and measuring systems

## Global Sourcing of Active Substances

- Design to costs and examinations on life cycle costs
- Sourcing strategies for the Far East
- Field report

## Management of Success in Procurement

- The new role of procurement
- The value contribution of procurement
- The ROCE and cash flow contribution
- The major influences of success in procurement
- The success factors in supplies management
- Materials and suppliers portfolio
- Efficient purchasing processes
- Total cost of ownership in procurement

## Key Performance Indicators in Procurement – The Management Cockpit

- The house of procurement
- The key performance indicators in procurement
- Benchmarks and best-of-class performance
- The role and function of cockpit charts
- Check-up for a successful procurement

## Cost Reduction through Third-Party Audits

- SMACS: The new WHO Pharmaceutical Starting Materials Certification Scheme
- GMP requirements and Third-Party Audits
- Which Third-Party Audit models exist on the market (PDA, IPEC, APIC)?
- Advantages and disadvantages of different models
- Cost / benefit analysis

## Social Event

On 6 December 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.



## Speakers



### **Richard M. Bonner, Formerly with Eli Lilly, UK**

Mr Bonner is currently located in the UK and works as a consultant to the Pharmaceutical Industry. Previous to his current role he was a Senior Quality Adviser for Eli Lilly and Company. He had 31 years experience within the pharmaceutical industry working in production, technical services and both Quality Control and Quality Assurance functions. He has been involved in multiple inspections from the MHRA, FDA and other authorities. Mr Bonner is a Qualified Person in Europe. He is now Associate Partner with Concept Heidelberg.



### **Diana Eifler, F. Hoffmann-La Roche AG, Switzerland**

In 2000, after gaining experiences in different industries locally and abroad, Ms Eifler joined F. Hoffmann-La Roche AG, Basel. Up to now, she is responsible in the logistic center at Roche for supply of different FDA relevant printed packaging-, marking- and auxiliary materials. Finally, she earned the CPIM designation (APICS) and gives lectures at the University of Cooperative Education, relative to the topics SCM, enterprise resource planning, logistics and e-procurement.



### **Prof Dr Claus W. Gerberich, Prof Gerberich & Partner International Consultancy, Germany**

Professor Gerberich is managing partner of the consultancy. He studied mechanical engineering and business management in Mannheim, Karlsruhe and at the MIT in Cambridge. He worked 24 years in the industry, including 16 years as a board member of Schöller Lebensmittel, adidas AG, Batelle Europe, and finally Staff Leuchten.



### **Alfred Keusch, Baxter AG, Austria**

Alfred Keusch is an engineer and business manager and since 1990 responsible for the centralised purchasing at Baxter AG in Austria. Since 2000 he is Director Strategy & Operations for the Global Category Management and the procurement for the European sites of the division BioScience.



### **Karl Metzger, Welding, Germany**

After several years experience in different GMP projects in chemical and pharmaceutical industry, Karl Metzger joined Weldings's QM&RA unit in 2001. There his focus is on Weldings's Integrated Management System, GMP projects, audits, warehousing. Currently he is a member of FECC's GTDP (Good Trade and Distribution Practice) Committee. Furthermore he is an APIC certified ICH Q7a Auditor.



### **John Taylor, Medicines & Healthcare Products Regulatory Agency (MHRA), UK**

John Taylor is Quality and Standards Manager Acting and Group Manager, Enforcement and Intelligence of the UK Medicines and Healthcare Products Regulatory Agency. Mr Taylor is currently responsible for all quality matters within the Inspection and Enforcement Division. He is a Chartered Chemist, a Fellow of the Royal Society of Chemistry and a member of the British Institute of Regulatory Affairs.

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Reservation Form (Please complete in full)

**Pharmaceutical Sourcing Conference**  
**Cost-effective AND GMP-compliant Procurement**  
6-7 December 2007, Berlin, Germany,

Mr.  Ms.

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**IMPORTANT: Please indicate your company's VAT ID number!**

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CONCEPT HEIDELBERG  
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GERMANY

## Date

Thursday, 6 December 2007, 10.00 h - 17.30 h  
(Registration and coffee 09.30-10.00 h)

Friday, 7 December 2007, 08.30 h - 13.00 h

## Venue

Mövenpick Hotel Berlin  
Schöneberger Strasse 3  
10963 Berlin  
Phone 030 - 230060  
Fax 030 - 23006199

## Fees

Non-ECA Members € 1,690.- per delegate plus VAT  
ECA Members € 1,521.- per delegate plus VAT  
EU GMP Inspectorates € 845.- per delegate plus VAT  
APIC Members € 1,605.- per delegate plus VAT (does not include ECA membership)  
The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event with dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

## Accommodation

CONCEPT has reserved a limited number of rooms in the Mövenpick Hotel Berlin. Reservation should be made directly with the hotel not later than 6 November 2007. You will receive a room reservation form when you have registered for the conference. Please use this form for your room reservation or be sure to mention ECA/CONCEPT to receive the specially negotiated rate for the duration of your stay. 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.

## General Terms of Business

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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT 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 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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**

## Organisation and Contact

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