Consequences for GMP and QA Professionals

The New Pharma Directive

Consequences of the amendments to Directive 2001/83/EC

5-6 October 2011, Berlin, Germany

Highlights

- Requirements and Enforcement
  - Overview on the amendments
  - Consequences of Non-Compliance
- APIs and Excipients
  - GMP compliance for APIs
  - GMP compliance for Excipients
  - New requirements for traders, brokers and supply chain partners
- Safety features relating to packaging
  - Situation and strategies for pharmaceutical companies
  - Implementation of a System using 2D Data Matrix Code
- Compliance & Inspections
  - The new role of the QP in supply chain security
  - Inspection of third-countries
  - Future of Import/Export/Parallel Import & Repackaging

Speakers from Authorities:

Dr Katrin Nodop
European Medicines Agency (EMA)

Dr Jürgen Hoose
German Health Authority, Hamburg

Speakers from Industry:

Dr Martin Friedrich
Bayer Technology Services GmbH, on behalf of EFPIA

Dr Frank Milek
Chair of the IPEC Europe GDP and the FECC Good Trade and Distribution Practice Committee, Aug. Hedinger

Dr Iain Moore
Chair IPEC Europe Excipient Certification Committee, Croda Europe

Dr Chris Oldenhof
President of APIC/CEFIC, Leading commentator on API falsification, DSM

Dr Bernd Renger
Chairman of the European QP Association, Renger Consulting

Izzet Senol
Abdi Ibrahim

ECA
European Compliance Academy

QP Association

This Master Class is recognised for the ECA GMP Certification Programme „Certified QA Manager". Please find details at www.gmp-certification.eu

The New Pharma Directive

5-6 October 2011, Berlin, Germany

Objectives

The new amendment to the "Pharma Directive" 2001/83/EC has been finalized in February 2011 in order to combat falsified medicines. It will have a major impact on the GMP/Quality Assurance environment. Learn from officials and leading stakeholders how the amendment of the Pharma Directive will alter national medicinal law and thereby the GMP requirements on:

- GMP Compliance for APIs and Excipients
- Procurement of raw materials, intermediates or finished dosage forms
- Safety features relating to packaging
- Release of material within the global manufacturing process
- Inspection of suppliers and third countries
- Import/Export/Parallel-Import & Repackaging

Be prepared for the consequences!

Background

Due to the increasing risk by falsified medicinal products, the EU Commission proposed to amend Directive 2001/83/EC as part of the 'pharmaceutical package' in 2008. This directive is the legal basis for all national laws regarding medicinal products in Europe. Changing this Directive therefore has a wide-ranging impact within the pharmaceutical industry.

After intense discussions between working groups of the European Commission and stakeholders from industry, a final text was agreed on in December 2010 which was adopted by the European Parliament in February 2011.

The amendments of the directive affect all departments of the pharmaceutical industry involved in the manufacture, release, procurement of APIs, excipients and finished dosage forms.

Moreover, for the first time even brokers and partners within the pharmaceutical supply chain are affected by European law, bringing them into the world of GDP (Good Distribution Practice).

In detail the amendments include amongst others:

- Obligatory safety features on individual packs of prescription-only drugs for the verification of identity and authenticity of the product.
- Responsibility of manufactures to verify that their starting materials and APIs have been manufactured in compliance with GMP rules, especially when imported to the EU.
- Responsibility of wholesale distributor that their suppliers comply with Good Distribution Practices, which will be checked in inspections.
- Implementation of a European-wide reporting obligation for manufacturers and distributors for counterfeit incidences.

Target Audience

This conference targets managers and executives of the pharmaceutical industry, especially of the QA units and QPs. Moreover, it also addresses responsible persons for the procurement of APIs, Intermediates and finished forms as well as auditors and GMP Inspectors.

Moderator

Dr Bernd Renger
Chairman of the European QP Association

Block A:
The New Directive - Requirements and Enforcement

Falsified Medicines Legislation - key changes and their implementation

- Main elements of the new Directive
- Implementation plan
- Impact of the anti-falsification legislation on GMP and GDP inspections
- Revision of the Guidelines on Good Distribution Practice of Medicinal Products

Dr Katrin Nodop
European Medicines Agency (EMA) - Head of Sector Support, Sector Compliance and Inspection Section

Block B:
APIs and Excipients – Manufacture & Procurement

New Requirements related to Distributors and Brokers – Good Trade and Distribution Practice

- Changes in European regulation related to starting materials supply chain
- How to implement Good Trade and Distribution Practice
- Available standards and recommendations from IPEC and FECC
- How to identify "trusted supply chain partners"
- Frequently observed problems

Dr Frank Milek
Chair of the IPEC Europe GDP and the FECC Good Trade and Distribution Practice Committee; QP at Aug. Hedinger

New Requirements related to APIs / EU "Falsified Medicines Directive" – an Industry Point of View

- Inspections of API manufacturers and traders - What will change?
- API compliance statements by Third Countries - How will it work?
- Official List of Countries with Equivalent Regulatory System -What to expect?
- Registration of EU manufacturers, importers and traders of APIs
- The role and responsibility of the pharmaceutical manufacturers
- Export of APIs from the EU to Third Countries
- Parallel developments in the rest of the world

Dr Chris Oldenhof
President of APIC/CEFIC - Leading commentator on API falsification; DSM

New Requirements from the Directive related to Excipients

- What is required in the new Directive
- How to access the suitability of excipients – Excipact a new scheme
- Risk based evaluation
- What are appropriate GMP standards for excipients

Dr Iain Moore
Chair IPEC Europe Excipient Certification Committee; Croda Europe Ltd

Block C:
Safety Features Relating to Packaging - how to Comply?

Situation and Strategies for Pharmaceutical Companies

- Serialisation/coding/tracking&tracing – development & timelines
- Safety features as required by the EU directive
- A stakeholder governed concept for product verification
- Scope for action for pharmaceutical companies
- Conclusions & recommendations

Dr Martin Friedrich
Bayer Technology Services, on behalf of EFPIA

Implementation of a system using the 2D Data Matrix Code

- Main Driving Factors
  - Traceability of each single item during its life cycle (Pharmacovigilance, Quality, Logistics, Marketing and Sales)
  - Market Surveillance & Stock follow up
  - Faster, easier and reliable recall
  - Reimbursement Fraud

- Main Concerns
  - Limited worldwide application experience in mass serialization and product tracking.
  - Product authentication & verification problems at pharmacy level
  - Possibility of severe drop in efficiency
  - Cost increase
  - Integration with stakeholders' systems
- Project progression
  - Data management, segregation, scalability, security
  - Validation Strategy
- Integration issues
  - Integration between T&T and AI ERP
  - Integration with Ministry of Health and Licensees
  - Integration with Licensees
- Serialization Station (Datamatrix Station)
  - EquipCarton Transfer
  - Printing & Image Systems
- Lessons learnt & status

Izzet Senol
Project Leader Track&Trace, Abdi ibrahim, Turkey

Block D: Compliance & Inspections

The new Role of the QP and QA in Supply Chain Security
- The Role of the QP regarding safety features on the packaging
- New requirements related to excipients & components
- Oversight of the supply chain including wholesalers –What is expected?
- Comprehensive supplier management system and management responsibility?

Dr Bernd Renger
Chairman of the European QP Association; Renger Consulting, Germany,

GMP Inspections: Consequences from the New Directive – The Point of View of a GMP Inspector
- Inspections of manufactures of APIs and excipients and traders
- Legal basis for inspections in Europe and "Third Countries"
- GMP certificates from Third Countries – Which countries will have equivalent regulatory systems?
- Implementation in national law – What are the consequences of different procedures in the members states?

Dr Jürgen Hoose
Head of GMP Inspectorate – Competent Authority of Hamburg, Germany

Speakers

Dr Martin Friedrich
Bayer Technology Services GmbH Germany, EFPIA
Dr Friedrich studied control engineering and earned his PhD in the field of automation of chemical processes in 1993. He has held several positions within the Bayer Group, mainly in the fields of process operation and optimisation. At Bayer Technology Services, he leads a group that supplies solutions for the automation of intralogistics processes as well as Track & Trace applications. In 2009 and early 2010 he served as project manager for the EFPIA product verification pilot project.

Dr Jürgen Hoose
Head of GMP Inspectorate – Competent Authority of Hamburg, Germany
Dr Jürgen Hoose started at Hamburg Health Authority in 1985. He is responsible for supervision of domestic medicinal product manufacturers and routinely audits foreign raw material manufacturers mainly in China and India.

Dr Frank Milek
QP at Aug. Hedinger
Chair of the IPEC Europe GDP and the FECC Good Trade and Distribution Practice Committee

Speakers, cont'd

Dr Iain Moore
Croda Europe Ltd., United Kingdom
Dr Iain Moore is Product and Quality Assurance Manager at Croda Europe Ltd, a manufacturer of speciality and performance chemicals. He is one of the co-authors of the IQA PQG PS 9100:2002 guide for pharmaceutical excipients, the IPEC-PQG GMP Guide for Pharmaceutical Excipients and the EFfCI GMP Guide 2005 for Cosmetic Ingredients. Currently he is Excipients Certification Project Coordinator.

Dr Katrin Nodop
European Medicines Agency (EMA)
Dr Katrin Nodop is Principal Scientific Administrator, Head of Sector Support, Sector Compliance and Inspection Section, Unit Patient Health Protection at the European Medicines Agency.

Dr Chris Oldenhof
DSM, President of APIC/CEFIC - Leading commentator on API falsification, The Netherlands
Chris Oldenhof is Manager External Regulatory Affairs at DSM, Delft, The Netherlands. He has a Ph.D. in organic chemistry from the University of Leiden, The Netherlands. In his 32 years with DSM he has held management positions in Research & Development, in Marketing & Sales and in Regulatory Affairs. Since 2007 he is President of APIC (Active Pharmaceutical Ingredients Committee, a sector group of the European Chemical Industry Association CEFIC). Since 2004 he is a Board Member of the European Fine Chemicals Group (another sector group of CEFIC) and member of its Pharmaceutical Business Committee. In addition he has been, on behalf of APIC, from 2003 till 2010 member of the Council of Europe's ad hoc Working Group on Counterfeit Medicines (CMED).

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

Izzet Senol
Abdi Ibrahim Ilac Sanayi ve Ticaret AS
Mr Senol in an electronic and communications engineer with many years of experience in automation projects in the pharmaceutical industry. His has the position as Energy and Auxiliary Manager at Abdiibrahim Site in Istanbul, Turkey. He is also the project leader of the Track and Trace 2D code application project of the Abdiibrahim group.

Social Event

On October 5 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.

Lufthansa
Official Airline

Special Offer with Lufthansa – Discounted Travel for The New Pharma Directive 2011 Attendees

Lufthansa German Airlines offers a comprehensive global route network linking Berlin with major cities around the world. As the Official Airline to this event, Lufthansa offers special prices and conditions to all attendees. To make your reservation, please click on the link you will receive with your registration confirmation and enter the access code **DEZUPG** in the "Access to Event Booking" area. This will take you into an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

Please note that you may have to enable pop-ups on this site – otherwise the booking platform window will not open.

These promotional fares are also available via your IATA / ARC Travel Agent. Travel Agents can obtain ticketing instructions via eMail lufthansa.mobility@dlh.de by quoting the access code as an event reference.

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
Wednesday, 5 October 2011, 10.00 – 17.30 h
(Registration and coffee 09.30 – 10.00 h)
Thursday, 6 October 2011, 08.30 to approx. 12.45 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 2127 0
Fax +49 (0)30 2127 117

Fees
ECA/QP Assocation Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and dinner on the first day and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "ECA" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 15 September 2011. Early reservation is recommended.

Registration
Via 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
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Robert Eicher (Operations Director) at +49-62 21/84 44 12,
or per e-mail at eicher@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Jessica Stürmer (Organisation Manager) at +49-62 21/84 44 43,
or per e-mail at stuermer@concept-heidelberg.de.

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

_____

_____

_____

_____

_____

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

69007 Heidelberg
Germany

Registration form (please complete in full)

The New Pharma Directive
5-6 October 2011, Berlin, Germany

☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order No. (if applicable)

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-mail (please fill in)

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)!**