ECA
European Compliance Academy

The EU GMP Certification & Manufacturing Authorisation

How to get approval for Medicinal Products, APIs and Excipients

4 – 5 December 2012, Budapest, Hungary

Highlights

- How to authorise a manufacturing facility for Medicinal Products
- Marketing Authorisation Procedures – what you need to know
- How to get a GMP certificate – the inspection process
- The Site Master File
- Regulatory requirements for importation in and transportation to the EU
- The CEP procedure for certification of APIs
- Case Study: from development to marketing authorisation of a new medicinal product
- Preparing for inspections – gap analysis and mock inspections
- Getting a medicinal product to market – the release process
- The new EXCiPACT™ Scheme – GMP compliance for excipients
- The GMP gradient from excipients to finished pharmaceutical Products

Speakers:

DR RAINER GNIBL
GMP Inspector, District Government of Upper Bavaria

DR JOSEF HOFER
EXDRA GmbH, Germany

DR JEAN-DENIS MALLET
SNC Lavalin, France form. Head of the French Inspectorate (AFSSAPS)

DR RAINER MAUE
Genericon Pharma GesmbH, Austria

DR IAIN MOORE
Chair IPEC Europe Excipient Certification Committee; Croda Europe

DR HEINRICH PRINZ
Apceth GmbH, Germany

DR WILHELM SCHLUMBOHM
Berlin, Germany

This course is recognised for the ECA GMP Certification Programme „Certified Regulatory Affairs Manager". Please find details at www.gmp-certification.eu

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Objectives

You will get a detailed overview about all important aspects of the EU regulatory requirements and you will get to know

- How and when Manufacturing Licences and the respective certificates are issued
- What are the key aspects to be considered regarding the CEP and ASMF procedure
- Which are the basic requirements to get a drug approved and what rules have to be followed
- How can pharmaceutical excipients be certified

Understanding the complexities of the EU regulatory world will enable you to improve your strategic planning and to reach your regulatory goals faster.

Background

When starting business in the European Pharma Market, the following important regulatory aspects need to be considered prior to commencement of product supply:

- You need to know how to obtain the European Key GMP Documents like **Manufacturing Licence, GMP Certificate, Import Licence**
- You need to know how to document the quality of the Drug Substance like for example with a Certificate of Suitability (CEP) or an Active Substance Master File (ASMF)
- You need to know how to get your product approved and to understand the European Marketing Authorisation Procedures (decentralised procedure, the centralised procedure and the mutual recognition procedure) and the provisions of the new Variations Regulation.

Target Audience

This conference has been designed for personnel from start-up companies inside and outside the EU, but also for personnel from non-EU pharmaceutical companies who would like to supply the EU with their medicinal products. Furthermore, the course will be of interest to new staff members from Regulatory Affairs and Quality Units of the Pharmaceutical and API industry.

Programme

The European Key GMP Documents – How to Authorise a Manufacturing Facility for Medicinal Products

- Manufacturing Licence
- GMP Certificate
- Import Licence
- Site Master File

GMP Certificates – The Preconditions and the Inspection Process

- GMP certificate and manufacturing licence
- European regulatory requirements and guidelines
- Important GMP requirements
- How to prepare a GMP inspection
- Inspection and follow-up
- Experiences and frequent findings

What you Need to Know about Importing into and Transporting through the EU

- Starting materials, APIs, excipients, bulk- and medicinal products
- Transfer within Europe and import from non-European countries to Europe
- How to obtain an import licence/ GMP certificate
- Exchange of information between competent authorities (EMA compilation of community procedures)
- Written confirmation for active substances imported into EU for medicinal products for human use (GMP conformity statement of exporting country)
- EMA falsified medicines legislation

The Site Master File and its Importance for Quality Assurance, Audits and Inspections

- The PIC/S Explanatory Notes on the preparation of a Site Master File
- The purpose of a Site Master File
- Content of a Site Master File
  - Quality Management of the manufacturer
  - Personnel, premises and equipment
  - Documentation, production and quality control
  - Distribution, complaints and product recall

What you need to know about Marketing Authorisations in the EU

- The Centralised Procedure
- The Mutual Recognition (MRP) and Decentralised Procedure
- National Procedures
- Specific Dossier requirements
- Structure of the CTD
- Best practices for MRP for industry

How to get Certification for APIs – The CEP Procedure

- Chemical pharmaceutical documentation for active substance(s) – Regulatory requirements in EU, USA
- Types of active substances – types of documentation
- CTD Module 3, CEP and ASMF (former DMF)
- CEP for a substance for TSE risk assessment

Case Study: The Process from Developing a new Medicinal Product to Marketing Authorisation

- Patent research
- Development and production site evaluation for API and finished dosage form
- Bio equivalence site evaluation and study performing
- Selection of appropriate marketing authorisation procedures
- Selection of suitable launch countries and timing

From Gap Analysis to Mock Inspection

- When to perform a GAP Analysis
- How to run the analysis
- Advantage of a GAP Analysis
- Preparation for a Mock Inspection
- Alignment of the GAP Analysis with the Mock Inspection

Release of a Medicinal Product to Market

- Preparation of the documentation
- Batch record review
- How to organise/optimise the batch record review
- Duties of the Qualified Person
- Quality Management System for a batch record review

Excipients Certification - Schemes and Auditable Standards

- Why excipients certification?
- New requirements from the Counterfeit Directive
- What are the appropriate GMP standards for excipients
- How to access the suitability of excipients
- Excipient classification
- The certification procedure
- 3rd Party Auditing

GMP Gradient from Excipients to Finished Pharmaceutical Products

- GMP requirements for Excipients
- GMP requirements for APIs
- GMP requirements for finished medicinal products
- How to align these requirements
- Building up a "GMP Gradient"
- Examples for a gradient

Speakers

Dr Rainer Gnibl is pharmacist and GMP inspector for the district government of Upper Bavaria and the EMA and performs GMP inspections regarding APIs and medicinal products worldwide since 2002. He holds a lectureship at the University Erlangen/Nürnberg and was also working for the Bavarian ministry of environment and health. He is member of several nationwide pharmaceutical expert groups.

Dr Josef Hofer is Managing Director of EXDRA GmbH (Excellence in Drug Regulatory Affairs.). Working for and in international pharmaceutical industry since 1980. He holds a lectureship at the University in Bonn for Drug Regulatory Affairs.

Dr Jean-Denis Mallet is a pharmacist. He was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps). He also used to work in or with the pharmaceutical industry during many years at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. He has also been auditor of the International Red Cross. Now he is member of the ECA advisory board and works for SNC LAVALIN.

Dr Rainer Maue is Director Business Development, Technical Operations and International Business of Genericon Pharma and CEO of Genericon Pharma doo, in Zagreb, Croatia. He also is board member of GE Pharmaceuticals in Botevgrad, Bulgaria. He is Pharmacist by education and fills a position as Qualified Person Pharmacovigilance (QP PV).

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 Heinrich Prinz worked with Boehringer Mannheim before he joined Biotest where he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division. Since 2003 he works as a freelance consultant and part of his time he is the Senior Supervisor 'Production and Quality Assurance' at Apceth, a biotech company.

Dr Wilhelm Schlumbohm has been working more than 20 years with German drug licensing authorities. He is responsible for the assessment of the CMC parts of new drug applications. He is expert for the Certification Procedure of the European Pharmacopoeia.

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, 4 December 2012, 09.00 h – 17.45 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 5 December 2012, 09.00 h – 15.45 h

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

Conference fees
ECA Members EUR 1,590.- per delegate plus VAT
APIC Members EUR 1,690.- per delegate plus VAT
Non-ECA Members EUR 1,790.- per delegate plus VAT
EU GMP Inspectorates EUR 895.- per delegate plus 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 (room rate: single room € 125,- per night, inkl. breakfast). You will receive a room reservation form when you have registered for the conference. Reservation should be made directly with the hotel not later than 22 October 2012. 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 Gerhard Becker (Operations Director) at +49-62 21/84 44 65, or per e-mail at becker@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Nicole Bach (Organisation Manager) at +49-62 21/84 44 22, or per e-mail at bach@concept-heidelberg.de

Social Event
On 4 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.

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

Registration form (please complete in full)

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☐ 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)!**

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