ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

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GMP meets Regulatory Affairs

Live Online Training on 22/23 April 2021

Applying for and maintaining marketing authorisations:
What you need to know from a GMP perspective

Highlights

- Drug approvals in the ICH countries: prerequisites and procedures
- Structure of the CTD: Module 1,3,4,5
- Relevant GMP documents for a marketing authorisation application
- Certificate of Suitability (CEP) and Drug Master Files/Active Substance Master Files
- Regulatory Compliance and Authority Inspections
- GMP basics with MA & Regulatory Affairs relevance

Objectives

During this Live Online Training you will get to know the relevant aspects of applying for and maintaining a marketing authorisation in the ICH countries. You will learn what you need to know from a GMP perspective about

- the basic requirements for drug approval in Europe, the US and Japan
- the structure of the marketing authorisation dossier according to the CTD
- the input from the GMP regulated departments
- drug approval procedures in the EU and US
- documents to be provided and timelines to be observed
- how to handle changes and variations in the EU, the US and Japan

Background

For getting a drug approved it is required to demonstrate its quality, efficiency and safety. For that purpose the format of the Common Technical Document (CTD), which is mandatory in Europe since more than 10 years now, has to be used. It is also used to apply for a marketing authorisation in the US and Japan. Therefore a good understanding of the CTD structure is inevitable and a basic requirement for all persons from GMP regulated departments involved in providing and compiling documents for a marketing authorisation application.

For the maintenance of a marketing authorisation it is very important to know how to handle all the changes and variations occurring during the life cycle of a medicinal product. The rules for handling variations in Europe are laid down in the variations regulation (EC) No. 1234/2008 – being applicable as well for national marketing authorisations from August 3rd 2013 – and supporting guidelines. For handling changes in the US rules are provided in different guidances for industry and for approval of changes in Japan there are specific procedures in place to be followed. Maintaining marketing authorisations in a global scenario is a challenge and requires strategic planning and a good knowledge of the different regulations and timelines. **Efficient and smooth communication between GMP and Regulatory Affairs is a key factor of success.**

Target Audience

This Live Online Training is designed for all persons involved in the compilation of pharmaceutical dossiers for global marketing authorisations in the EU and USA. Furthermore the course will be of interest to personnel from Regulatory Affairs, Quality Assurance, Quality Control and Production and Project Management.

Programme

Getting Drugs Approved – What you need to know from a GMP Perspective

What is a Regulatory Dossier?

- Why do we need regulatory dossiers?
- Why are regulatory dossiers binding?

Drug Approvals in the ICH countries: Prerequisites and Procedures

- Centralized procedure / Decentralized procedure
- Mutual Recognition
- National Procedures
- Specific Dossier Requirements for different Medicinal Products
- Time Lines
- Generic Applications
- New Drug Application (NDA)
- IND procedure and special issues
- Abbreviated New Drug Application (ANDA) – Generics
- Pre-approval inspections
- Timelines and meetings with the FDA
- Regulatory Requirements in Japan
- GMP Regulations in Japan (J-GMP)

CTD Module 1 – Summary of Product Characteristics and other National Requirements

- Quality related aspects of the SmPC
  - Clinical particulars
  - Pharmacological properties
  - Pharmaceutical particulars
- Labelling
- Package Leaflet
- Mock ups and Specimen
- Quality Experts, Non Clinical and Clinical Experts
- Bibliographical applications
- Homeopathic Applications
- Pediatric Applications

CTD Module 3 – Quality of the Drug Product: Relevant GMP Documents

- Medicinal product – documentation of quality in Module 3
- Impurities
- Stability data
- Container and closure systems
- Critical parameters
- Optimising the submission
- Risk based approach in industry and regulatory authority

CTD Module 3 – How to document Drug Substance Quality – Certificate of Suitability (CEP) and Active Substance Master File (ASMF)

- Documentation of drug substance quality in Module 2
- The Quality Overall Summary (QOS)
- CEP and ASMF procedure – how they work in principle

- Types and format of ASMFs
- Contents of the applicants part and the restricted part
- How to apply for a CEP
- Dossier Content
- CEP assessment and CEP inspections
- DMF procedures in US and Japan

CTD Modules 4 and 5 – non clinical and clinical Documentation: GMP, GCP and GLP Aspects

- Clinical study reports
- Efficacy and safety
- Clinical summary and clinical overview
- Non clinical study reports
- Toxicology
- Pharmacokinetics
- Safety studies – decision tree
- Toxicity studies to qualify impurities
- Non clinical summary
- Critical points

Regulatory Compliance Aspects during Authority Inspections

- Types of inspections
- Essential PQS interfaces
- Change control from a GMP view
- Deviations from Marketing Authorisations
- Inspector's planning, preparation, conduction and follow-up of GMP inspections

Technical Terms of GMP Inspections – EU-GMP Requirements

- EU-GMP regulations
- Technical terms of EU-GMP guidelines
- Basic requirements for GMP inspections

Other GMP Basics with MA & Regulatory Affairs Relevance

- Required authorizations, registrations, certificates and how to get them
- How to certify/release a batch?
- Which audits are on duty?

Maintaining a Marketing Authorisation – The Interaction between GMP and Regulatory Affairs

Handling Changes in the ICH Countries

- Starting a change in your company
- The variations procedure in Europe
- General provisions of the Commission Regulation (EC) No 1234/2008
  - Supporting Guidelines
  - Best Practice Guides and Explanatory Notes
  - Classification of variations
  - Procedural handling of variations; Grouping, Worksharing
- Handling Changes in the US: Changes to an approved NDA and ANDA
- Types of changes
- Change control procedure and reporting mechanisms
- Handling changes in Japan: Change procedures and communication with the Japanese authority
- Types of changes
- Notification of changes

Speakers

Marieke van Dalen, Aspen Oss B.V., The Netherlands

Marieke van Dalen is the global regulatory specialist in the regulatory group dedicated to APIs, with over 30 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she participates in a number of task forces. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, CPhI etc.

Dr Rainer Gnibl, GMP Inspector, District Government of Upper Bavaria, Germany

Dr Gnibl is a pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Before that, he was also working for the Bavarian Ministry of Environment and Health. Dr Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Dr Josef Hofer, EXDRA GmbH, Germany

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

Dr Usfeya A. Muazzam, Bonn, Germany

Dr Muazzam worked as Senior Assessor for Quality, Division: Quality, Department: Scientific Quality Assurance, Staff Unit: Strategy and Planning of BfArM. He left the agency in 2012. He is co-author of "Gute Regulatorische Praxis, Arzneimittelzulassung - Pharmazeutische Qualität", Wissenschaftliche Verlagsgesellschaft, Stuttgart, Germany and "Guide to Drug Regulatory Affairs", Editio Cantor Verlag, Aulendorf, Germany.

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Reservation Form (Please complete in full)

GMP meets Regulatory Affairs, Live Online Training on 22/23 April 2021

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

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If you cannot attend the conference you have two options:
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- Cancellation until 2 weeks prior to the conference 10 %,
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German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Thursday, 22 April 2021, 09.00 – 16.45 h CEST
Friday, 23 April 2021, 09.00 – 14.00 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Your Benefit Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training....“ This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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