



## Speakers



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



Dr Rainer Gnibl  
EU-GMP Inspector,  
Bavarian Government, Germany



Dr Josef Hofer  
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# GMP meets Regulatory Affairs

15/16 October 2020 | Hamburg, Germany



*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 1-5
- Relevant GMP documents for a marketing authorisation application
- The Quality Overall Summary
- Certificate of Suitability (CEP) and Drug Master Files/Active Substance Master Files
- Regulatory Compliance and Authority Inspections
- Handling variations and changes in a global environment

## Objectives

During this course 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 education course is designed for all persons involved in the compilation of pharmaceutical dossiers for global marketing authorisations in the EU and USA. Furthermore the courses 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?

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

#### Drug Approvals in the ICH countries: prerequisites and procedures

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- 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

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- 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 2- The Quality Overall Summary: Importance and Benefits

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- Regulatory background of QOS
- Benefits (and why you can call it „Queen of Submission“)
- Frequent deficiencies, examples
- Optimising the submission

#### CTD Module 3 – Quality of the Drug Product: relevant GMP documents

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- 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)

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- 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

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- 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

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- 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

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

## Maintaining a Marketing Authorisation – The interaction between GMP and Regulatory Affairs

### Handling changes in the ICH countries

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- 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

Ms van Dalen is the global regulatory specialist in the regulatory group dedicated to APIs, with almost 30 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she participates in the Japan task force, Emerging markets task force and the Quality metrics task force. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, ICH 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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## 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.

## Organisation and Contact

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

CONCEPT HEIDELBERG

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For questions regarding content:

Ms Anne Günster (Operations Director) at +49(0)62 21/84 44 50, or per e-mail at [gunster@concept-heidelberg.de](mailto:gunster@concept-heidelberg.de).

For questions regarding reservation, hotel, organisation etc. please contact:

Mr Niklaus Thiel (Organisation Manager) at +49(0)62 21/84 44 43, or per e-mail at [thiel@concept-heidelberg.de](mailto:thiel@concept-heidelberg.de).

## Date

Thursday, 15 October 2020, 09.00 – 18.00 h

(Registration and coffee 08.30 – 09.00 h)

Friday, 16 October 2020, 08.30 – 15.00 h

## Venue

Park Hyatt Hamburg

Bugenhagenstr. 8

20095 Hamburg, Germany

Phone +49(0)40 3332 1234

Email [hamburg.park@hyatt.com](mailto:hamburg.park@hyatt.com)

## Fees (per delegate, plus VAT)

ECA Members € 1,590

APIC Members € 1,690

Non-ECA Members € 1,790

EU GMP Inspectorates € 895

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 has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

## Social Event



In the evening of the first course day, 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.