ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

Marieke van Dalen
MARA Consultancy, The Netherlands

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

Dr Josef Hofer
EXDRA GmbH, Germany

Dr Cornelia Nopitsch-Mai
Bonn, Germany

GMP meets Regulatory Affairs

24/25 March 2026 | Vienna, Austria

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
- Handling Variations and Changes in a Global Environment
- GMP Basics with MA & Regulatory Affairs Relevance

Including the ICH M4Q revision

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, which was latest amended in 2024, 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 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

Where do RA and GMP actually meet? – Setting the Scene for the Training

- The ICH CTD guidance
- GMP data in the regulatory filings
- Regulatory filings as a basis for inspections

Drug Approvals in the ICH Countries: Prerequisites and Procedures

- Centralized procedure
- Decentralized procedure
- Mutual recognition
- National procedures
- Specific dossier requirements for different medicinal products
- Timelines
- 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 – How to Document Drug Substance Quality around the World

- How to provide CMC information
- What information is required in Module 3.2.S
- Differences in interpretation of the requirements
- Differences in format
- Procedures in the various regions: US, EU, Japan

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 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 Variations and Changes

- Why do we need to file changes?
- Handling changes within an API company
- Impact of a change: categorization of changes
- Change procedures around the world: EU (ASMF and CEP), US, Japan

Speakers

Marieke van Dalen, MARA Consultancy, The Netherlands

Ms van Dalen is a global API regulatory specialist leading her own small consultancy in the Netherlands. She has 38 years of experience in the API industry, always in the regulatory field. Her latest position was with Aspen API in the Netherlands. She was for a long time a Board member of APIC (the European API organisation) and represented APIC often in meetings and symposia with health Authorities all around the world.

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 Cornelia Nopitsch-Mai, formerly Quality Assessor, Germany

Dr Nopitsch-Mai was scientist at the Federal Institute for Drugs and Medical Devices in the assessment of the quality part of the dossier since 1991. Since 2000 she was assessor for the Certification Procedure (EDQM) in Strasbourg. She was member of the Technical Advisory Board (EDQM) from 2001 until 2010; in that time, she was chairperson from 2005 until 2010. From 2007 until 2011 she was a member of the EMA Quality Working Party.

Social Event

On the evening of the first 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.

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GERMANY

Reservation Form (Please complete in full)

GMP meets Regulatory Affairs, 24/25 March 2026, Vienna, Austria

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

E-Mail (Please fill in)

General terms and conditions
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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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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. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
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
Tuesday, 24 March 2026, 09.00 - 17.15 h
(Registration and coffee 08.30 - 09.00 h)
Wednesday, 25 March 2026, 09.00 - 15.00 h

Venue
Doubletree by Hilton Vienna Schönbrunn
Schlossallee 8
1140 Vienna, Austria
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Fees (per delegate, plus VAT)
ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice and includes 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.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. **Please note that no printed materials will be handed out on site** and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22232.

Conference language
The official conference language will be English.

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