ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

Marieke van Dalen
MARA Consultancy, The Netherlands

Dr Wolfram Eisenreich
Boehringer Ingelheim Pharma, Germany

Dr Jörg Engelbergs
Paul-Ehrlich-Institut, Germany

Sonja Estermann
F. Hoffmann-La Roche, Switzerland

Dr Josef Hofer
EXDRA, Germany

How to Write the Quality Part of an IMPD

Live Online Training on 12/13 May 2026

Highlights

- Drug Substance Information
- IMP Dossier Quality Drug Product
- Substantial Amendments and Notification Obligations
- Stability Considerations
- GMP Requirements in Clinical Trial Management
- Quality Information of Comparator Products and Placebos
- IMPD for Biotech Products
- Planning of an IMPD
- Inspections on Clinical Trials e.g. GCP Inspections
- Specific Aspects for a Paediatric Q-IMPD
- Clinical Trials EU and International: Similarities and Challenges

Requirements to chemical and pharmaceutical quality documentation for an IMP dossier

Objectives

This Live Online Training highlights the key principles of the **Quality Part of an IMPD** for Investigational Medicinal Products, both of chemical and biotechnological origin. You will get to know the essential aspects relevant for compiling the IMPD Quality Part and you will learn

- How to prepare and process the quality related information for drug substance and drug product
- How to manage and document changes concerning quality data
- How to consider quality parameters of drug substance and drug product with potential clinical relevance
- How to describe the manufacturing process development for a biotech IMP
- How to process and document stability data for an IMPD of a biotech product

Background

An IMPD is required for every Investigational Medicinal Product (IMP) to be used in a clinical study, regardless of whether it is the test product itself, a reference product already authorised or a placebo. The IMPD includes summaries of information related to the quality, manufacture and control of the IMP as well as data from non-clinical and clinical studies. Furthermore, it contains an overall risk-benefit assessment and critical analyses of the non-clinical and clinical data related to the potential risks and benefits of the proposed study.

In March 2006 the CHMP "Guideline on the Requirements to the Chemical and Pharmaceutical Quality Documentation concerning Investigational Medicinal Products in Clinical Trials" was published in Chapter III of Volume 10 of EudraLex.

Another CHMP Guidance for Biologicals entitled "Guideline on the Requirements for Quality Documentation concerning Biological Investigational Medicinal Products in Clinical Trials" was adopted in March 2012 and became effective in April 2012.

Target Audience

This Live Online Training is designed for all persons involved in the compilation of IMPDs who want to become familiar with the requirements for the quality documentation of investigational medicinal products. The training will be of interest in particular for personnel from Regulatory Affairs as well as for personnel from Quality Assurance, Quality Control and Production.

Programme

Clinical Trial and IMPD: Legal Framework and Regulatory Environment

- Clinical trial authorisation process following Regulation 536/2014/EU
- GMP requirements in clinical trial management
- Inspections on clinical trials e.g. GCP inspections

IMPD: Regulatory Requirements and Life Cycle Management

- IMPD and IB (Investigator's Brochure) overlaps and differences
- Clinical Trials EU and International: Similarities and challenges

Quality Documentation for a Biotech IMPD – Manufacturing Process and analytical Characterisation

- Description of the manufacturing process, control of critical steps
- Manufacturing process development
- Characterisation and control of the active substance

Quality Documentation for a Biotech IMPD – Product Control and Stability Studies

- Control of excipients
- Specifications, batch analysis
- Stability data
- Substantial amendments

Drug Substance Information

- Description of the manufacturing process
- Control of critical steps and intermediates
- Control of impurities
- Specifications and analytical methods
- Stability studies

IMP Dossier: Quality Drug Product

- Investigational medicinal product under test
- Chemical and pharmaceutical quality of:
  - authorised, non-modified test
  - modified authorised test
  - concerning placebo products
- Chemical and pharmaceutical quality of IMPs in bio-equivalence studies, novel excipients, solvents for reconstitution and diluents and auxiliary medicinal products

Quality Information of authorised modified and non-modified Comparator Products

- Description and composition
- Summary of Product Characteristics (SmPC)
- Additional information for Phase II and Phase III clinical trials
- Quality information on existing active substances in bio-equivalence studies
- Quality information on placebo products

IMPD Planning and Organisation: Case Study

During this Case Study, we will explain and present how to plan and organise IMPDs. Take advantage of the experiences of our speakers and send us your questions and challenges prior to the Live Online Training.

IMPD Quality Data – Changes, Modifications and Amendments

- Categorisation substantial / non-substantial modification
- Documentation and processing
- Strategies and timing

How to handle Paediatric Formulations

- What is a Paediatric Investigation Plan (PIP)? Legal framework and content of the Quality Part
- Specific aspects for the formulation development (Taste, Preservatives, etc.)
- Specific aspects for a Paediatric Q-IMPD

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, as Global Regulatory Specialist. 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 Wolfram Eisenreich, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Dr Eisenreich is a pharmacist and joined Boehringer Ingelheim in 2003, heading formulation development groups in Biberach, Germany and Ridgefield, USA. Since 2010 he is the head of the Central Clinical Trial Bulk Manufacture Solids group at Boehringer Ingelheim. Amongst other things, he is now responsible for blinding of comparator products, development of matching placebo products and authoring of the respective IMP documents.

Dr Jörg Engelbergs Paul-Ehrlich-Institut (PEI), Germany Federal Agency for Vaccines and Biomedicines

Dr Engelbergs studied biology at the university of Düsseldorf and Duisburg-Essen. After his PhD he worked in different positions at the German Cancer Center before he joined the PEI in 2006 as Scientific-Regulatory Expert Biomedicines (Quality, Non-Clinic, Pers. Medicines - Biomarker/CDx).

Sonja Estermann F. Hoffmann-La Roche Ltd, Switzerland

Ms Estermann has more than 20 years experience in regulatory, working since 2004 at F. Hoffmann-La Roche Ltd as Global Technical Regulatory Manager with expertise in paediatrics. Prior to Roche she worked in Regulatory Affairs at Pfizer Switzerland. She started her career as a community pharmacist and head of QC/FTL "Qualified Person" in the Pharmacy Hotz/Galepharm Switzerland. Ms Estermann holds an M.S. in Pharmacy from the University of Basel, Switzerland and a post diploma HF in Business Economics.

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.

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Reservation Form (Please complete in full)

How to Write the Quality Part of an IMPD
Live Online Training on 12/13 May 2026

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)

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Tuesday, 12 May 2026, 09.00 – 16.30 h
Wednesday, 13 May 2026, 08.30 – 16.30 h
All times mentioned are CEST.

Technical Requirements

We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 1,890
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.

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 22345.

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.

You cannot attend the Live Online Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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