



The Quality Documentation
of Biological IMPs

How to write the Quality Part of an IMPD

Requirements on chemical and pharmaceutical
quality documentation for an IMP dossier

13 – 14 November 2012, Vienna, Austria

SPEAKERS:

Dr Wolfram Eisenreich
*Boehringer Ingelheim Pharma
GmbH & Co. KG, Germany*

Dr Siegfried Giess
Paul-Ehrlich-Institut, Germany

Dr Hiltrud Horn
*Horn Pharmaceutical Consulting,
Germany*

Dr Claus-Dieter Schiller
*F. Hoffmann-La Roche AG,
Switzerland*

PROGRAMME:

- Drug substance and drug product quality data – what has to be considered
- Substantial amendments and notification obligations
- Stability Considerations
- Quality information of comparator products and placebos
- IMPD for biotech products
- Manufacture of clinical trial formulations
- Planning of an IMPD



How to write the Quality Part of an IMPD

13 – 14 November 2012, Vienna, Austria

Objectives

This education course 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 was published in January 2010 entitled “Guideline on the Requirements for Quality Documentation concerning Biological Investigational Medicinal Products in Clinical Trials” which is still in a draft status but will be finalised soon.

Target Group

This education course 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 course will be of interest in particular for personnel from Regulatory Affairs as well as for personnel from Quality Assurance, Quality Control and Production.

Programme

Why do we need an IMPD? - Legal Framework and Regulatory Requirements

- Regulatory Requirements
- Challenges
- Practical Hints
- Sources of Information

General Requirements to an IMPD

- Structure and Content
- Planning
- Preparation
- Submission

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 – Description of the Manufacturing Process

- Control of critical steps and intermediates
- Control of Impurities
- Analytical Procedures and validation requirements
- Justification of specifications and stability data

Writing of the Drug Product Section of an IMPD

- Key aspects
- Practical examples

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

Case Study: Planning of an IMPD

This workshop will focus on the essentials of clinical trials. The participants will get practical advice on how to successfully plan and prepare IMPDs.

How to Manage and Document Changes to IMP Quality Data – Substantial Amendments

- Changes that need to be notified
- Amendments that are to be regarded as “substantial”
- When have changes to be notified?
- Some examples

Social Event

On 13 November 2012, 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.



Speakers

Dr Wolfram Eisenreich,

Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Dr Eisenreich is a pharmacist by training and received his PhD at the Ludwig-Maximilians-University Munich in 2002. In 2003 he joined Boehringer Ingelheim and headed formulation development groups in Biberach, Germany and Ridgefield, USA. Since 2010 he is heading 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 Siegfried Giess,

Paul Ehrlich Institute, Germany

In his present position, Dr Giess works at the Paul-Ehrlich-Institut, the Federal Institute for Vaccines and Biomedicines in Germany. He is deputy head of the Department of Immunology and head of the Immunology-chemistry-Section. He is engaged in testing activities of the OMCL-network and involved in the quality assessment of immunoglobulins, immunosera and monoclonal antibodies. Dr. Giess is nominated expert of the CHMP at the European Medicines Agency (EMA). He is member of the Working Party Monoclonal Antibodies of the EP Commission and belongs to the USP Monoclonal Antibodies Expert Panel. He is member of the Heads of Medicines Agencies Working Group on Product Testing and member of the BWP Drafting Group for the “Guideline on the Requirements for Quality Documentation concerning Biological Investigational Medicinal Products in Clinical trials”

Dr Hiltrud Horn,

Horn Pharmaceutical Consulting, Germany

Dr Hiltrud Horn is managing director of HORN PHARMACEUTICAL CONSULTING. From 1990 to 1997, she was employed by Hoffmann-La Roche in Quality Control/Quality Assurance. From 1997 to 1999, she dealt with medical writing in the ‘International Drug Regulatory Affairs and Project Management’ department of the same company. In 1999, she joined Knoll AG as head of the departments ‘Regulatory Compliance and CMC Documentation’ and ‘Dossier Production and Compliance’ for international drug registration. In 2002, she started at Cap Gemini Ernst & Young, where she was the responsible consultant for questions concerning biotechnology and life sciences.

Dr Claus-Dieter Schiller,

F. Hoffmann-La Roche AG, Switzerland

Since 1995, Dr Schiller is working in Global Technical Registration of F. Hoffmann-La Roche. Dr Schiller has held different positions within Technical Registration dealing with different aspects of filings of synthetic products ranging from clinical trials, NDAs to post-approval changes. In his present position he is group manager of Documentation & Training. Dr Schiller has been a member of the former Quality adhoc Group of EFPIA.

Lufthansa is Mobility Partner for all ECA Events



As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And this is how it works: Once you registered for a course or conference you will receive

a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the “Access to Event Booking” area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

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

+ 49 6221 84 44 34

Reservation Form (Please complete in full)

How to write the Quality Part of an IMPD

13 - 14 November 2012, Vienna, Austria

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)

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG

P.O. Box 101764

Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg

GERMANY

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 2 weeks prior to the conference 10 %
 - until 1 week prior to the conference 50 %
 - within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG 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 HEIDELBERG 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. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed!).

Date

Tuesday, 13 November 2012, 9.00 - 17.30 h
(Registration and coffee 8.30 - 9.00 h)
Wednesday, 14 November 2012, 9.00 - 15.45 h

Venue

Renaissance Wien Hotel
Linke Wienzeile/Ullmannstraße 71
1150 Vienna, Austria
Phone +43 (0)1 89 102
Fax +43 (0)1 89 102 300

Fees

ECA Members € 1,590.- per delegate plus VAT
APIC Members € 1,690.- per delegate plus VAT (does not include ECA Membership).
Non-ECA Members € 1,790.- per delegate plus VAT
EU GMP Inspectorates € 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 has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention "xxxxxxx" to receive the specially negotiated rate (single room € xxxxxxx,- per night incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than xxxxxxxx 2012. Early reservation is recommended.

Registration

Via the 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
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:

Dr Gerhard Becker (Operations Director) at
+49 (0) 62 21 / 84 44 65, or per e-mail at
becker@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Marion Weidemaier (Organisation Manager) at
+49-62 21/84 44 46, or per e-mail at
weidemaier@concept-heidelberg.de.