ECA Academy
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How to provide Process Validation Data in a Regulatory Submission

SPEAKERS:

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Dr Nils Jost
Gründau, Germany

Dr Wilhelm Schlumbohm
Berlin, Germany

Dr Norbert Skuballa
Biologische Arzneimittel Heel, Germany

27 – 28 November 2018, Barcelona, Spain

PROGRAMME:

- Dossier requirements for description of the manufacturing process validation
- How to provide manufacturing process data in an NDA – FDA requirements
- Key aspects of traditional process validation and continuous process verification with regard to regulatory submissions
- Providing stability data in regulatory submissions
- Process validation and GMP issues
- How to handle post-approval changes
- Process validation of biotech-derived APIs

This education course is recognised for the ECA GMP Certification Programme „Certified Regulatory Affairs Manager“. Please find details at www.gmp-certification.eu

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Objectives

This education course focuses on how to compile and provide information and data from process validations for Drug Substances and Drug Products both of chemical and biotechnological origin. You will learn

- How to prepare and process the data derived from validation runs of drug product manufacturing processes
- What needs to be documented about drug substance manufacturing processes
- How to manage and document post approval changes in manufacturing processes
- What to consider for compiling stability data for the dossier
- How to provide validation data of biotech manufacturing processes

Background

Process validation can be defined as documented evidence that the process, operated within established parameters, can perform effectively and reproducibly to produce a medicinal product meeting its predetermined specifications and quality attributes. In general there are two options to validate a manufacturing process: a traditional approach or an enhanced approach where continuous process verification is applied. Irrespective of which approach is used the manufacturing process should be validated before the product is placed on the market. Therefore complete data have to be provided in the dossier at the time of regulatory submission. These data should cover the validation for all manufactured strengths, batch sizes, pack sizes and proposed manufacturing sites.
Guidance on process validation information to be provided in regulatory submissions is given in 2 EMA Guidelines: *"Guideline on process validation for finished products – information and data to be provided in regulatory submissions"* and *"Guideline on process validation for the manufacture of biotechnology-derived active substances and data to be provided in the regulatory submission"*. Provisions of both GMP compliant manufacture and dossier requirements are laid down in FDA's Guidance for Industry entitled *"Process Validation: General Principles and Practices"*.

Target Audience

This education course is designed for all persons involved in the compilation of dossiers for regulatory submissions who want to become familiar with the requirements for the documentation of process validation data. The course will be of interest in particular for personnel from Regulatory Affairs as well as for personnel from Quality Assurance, Production and Quality Control.

Programme

Process validation of manufacturing processes – Dossier requirements in the EU

- Relevant guidance documents
- Finished product process validation
- Traditional and enhanced approaches
- Process validation schemes
- Standard vs. non-standard processes

Traditional Process Validation and Continuous Process Verification

- What are the opportunities and challenges?
- What are the key aspects for the CTD?
- What should you consider for selecting the right validation strategy?
- What should you know about design space?
- What are typical validation questions to be addressed?

How to provide stability data in regulatory submissions

- Stability data from drug substances and drug products in the CTD
- Long term and accelerated conditions, in-use stability
- Requirements for the different climatic zones
- Stability summary and conclusion
- Process parameters with potential impact on drug substance/drug product stability
- Changes in the process: what has to be considered regarding stability?

Manufacture of active substances – Process validation and GMP issues

- API manufacture – What needs to be documented in the dossier?
- Process validation for APIs – Key aspects
- GMP for APIs

Case Studies on typical Validation Projects

- Standard and non-standard processes
- Validation approach for drug substances and drug products
- Validation strategy and planning from development to registration
- Specific points to be considered for EU and US

Basic requirements and expectations of the FDA regarding process validation

- Approach to and considerations for process validation
- Process Design
- Process qualification and process performance qualification (PPQ)
- The PPQ protocol – execution and report

Handling Post-Approval Changes in manufacturing processes

- Which GMP and regulatory aspects need to be considered (e.g. site /process changes)?
- How to define the validation strategy?
- What are the challenges?
- How to be successful?

Process validation for the manufacture of biotech-derived APIs – process evaluation and verification

- Process evaluation
- Critical quality attributes (CQAs) of the active substance
- Small scale models
- Process verification studies and data
- Number of batches to be presented
- Design space option
- Evaluation of the upstream process
- Criticality assignment of process parameters
- Potential impact of raw materials
- Verification of upstream process
- Single use equipment
- Evaluation and verification of downstream process
- Comparability of products manufactured in different sites

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.

Speakers

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany
Dr Hiltrud Horn is managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs (EU and US). She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche in Basel and Knoll (now Abbott) in Ludwigshafen with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing. She was consultant for the biotech and life science industry at Cap Gemini Ernst & Young prior to starting her own business more than 13 years ago. She is pharmacist with a Ph.D. and holds a Diploma in Pharmaceutical Medicine (Basel). Furthermore she is specialised pharmacist for pharmaceutical analytics and for drug information.

Dr Nils Jost
Gründau, Germany
Dr Nils Jost is an expert for the assessment of CMC dossiers for clinical trial applications, EMA centralized marketing authorizations, and national marketing authorizations for biological medical products. He studied biology at the Ruhr-University Bochum and the University of Essen-Duisburg.

Dr Wilhelm Schlumbohm,
Berlin, Germany
Dr Schlumbohm worked more than 25 years with German drug licensing authorities in the field of assessment of the CMC parts of new drug applications. He is a member of the Working Group on Active Substance Master File procedures..

Dr Norbert Skuballa,
Biologische Arzneimittel Heel, Germany
Norbert Skuballa is head of the Pharmaceutical Compliance Management function at Heel and responsible for development and coordination of all compliance related GxP and regulatory affairs processes. He has been working in the pharmaceutical industry since 1991, mainly for Schering (now Bayer Pharmaceuticals) in Research, Production and Quality Management.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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Date

Tuesday, 27 November 2018, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 28 November 2018, 9.00 - 15.00 h

Venue

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 (93) 503 53 00
email sants@barcelo.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 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.

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