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Modern Validation - Case Studies

Implementation of EU GMP Annex 15 and FDA requirements

SPEAKERS

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Head of ECA´s Validation Group , Denmark

23-24 February 2017, Hamburg, Germany

HIGHLIGHTS:

- Validation History
- Annex 15 vs FDA Process Validation Guidance – Similarities and Differences
- Lean Qualification meeting Annex 15 requirements - is this possible?
- Continuous Process Verification – the ICH Q8 way for Process Validation
- Ongoing Process Verification – how to get there?
- Transport Verification
- Packaging Validation
- Cleaning Validation – PDE Concept

This conference is recognised for the ECA GMP Certification Programme „Certified Validation Manager“.
Please find details at www.gmp-certification.eu

Modern Validation – Case Studies 23-24 February 2017, Hamburg, Germany

Objectives

The revised Annex 15 is valid since October 2015. With the revision new requirements have been implemented regarding:

- Validation Master Plan
- Qualification
- Process Validation
- Cleaning Validation
- Transport Verification
- Packaging Validation

In **6 Case Studies** will be explained how companies implement the new Annex 15 requirements. Also, the differences to the FDA Process Validation Guidance will be discussed.

Background

Since 2001, the Annex 15 was state of the art for Validation and Qualification. In the meantime, ICH Q 8-11 has been published. The FDA has implemented most of these ICH guidelines and introduced a Validation Process Life Cycle in its Process Validation Guidance from 2011. The EMA has published a revision of its Note for Guidance on Process Validation to implement this new aspects too. This is also the reason why the Annex 15 has been revised. The Annex 15 revision is valid since October 2015.

Target Audience

Everyone who may be influenced by the Annex 15 revision.

Moderator

Gert Mølgaard, Moelgaard Consulting, Denmark

Programme

History of Validation with regard to Annex 15

- Validation in the 70´s – focus on sterile production
- FIP Validation Guideline
- PIC Validation Conference 1982
- The mother guideline of Validation: FDA's Process Validation Guideline 1987
- PIC/PH 1/96
- Annex 15 2001
- EMEA Note for Guidance on Process Validation
- FDA Guidance CPG 7132.c08
- WHO Process Validation Guideline
- FDA Process Validation: Guidance for Industry
- EMA Guideline on Process Validation
- Annex 15 Revision
- WHO revision of Validation Guidelines
- EMA: Biotech Process Validation Guideline

Annex 15 vs FDA Process Validation Guidance – Similarities and Differences

- History of Annex 15 and FDA Process Validation Guidance
- Role of EMA Process Validation Guideline vs. Annex 15
- Similarities Annex 15 vs FDA Process Validation Guidance
- Differences Annex 15 and FDA Process Validation Guidance

Lean Qualification meeting Annex 15 requirements – is this possible?

- Annex 15's 8-stage Qualification
- ASTM 2500 as an alternative
- Case Study Qualification regarding ASTM 2500

Continuous Process Verification –ICH Q8 as starting point for Process Validation

- ICH Q 8
- Continuous Process Verification
- Case Study
  - Design Space
  - PAT Application
  - Design Space Verification
  - Process Governance during DP life cycle

Ongoing Process Verification – how to get there

- Ongoing Process Verification vs. Continued Process Verification
- Case Study
- Outlook

Transport Verification

- Qualification, Validation, Verification
- Requirements of Annex 15
- Guideline Good Transportation Practice
- Case Study

Packaging Validation

- Requirements of Annex 15
- Qualification of packaging lines
- The validation of primary vs secondary packaging processes
- Case Study

Cleaning Validation

- Requirements of Annex 15
- EMA guidance on PDE
  - PDE and ADE similarities and difference
  - Setting cleaning limit – risk assessment approach

Speakers

DR MARC EGEN, BOEHRINGER INGELHEIM, GERMANY
Marc Egen has studied chemistry at Bergische Universität Wuppertal and received a PhD in macromolecular chemistry from Johannes-Gutenberg-Universität in Mainz. He is with Boehringer Ingelheim since 2003 and currently Director of Manufacturing Science & Technology .

WALID EL AZAB, STERIS CORPERATION, BELGIUM
Walid El Azab is a Technical Services Manager for the Life Sciences Division of STERIS Corporation. He currently provides technical support related to cleaning chemistries, disinfectants and sterility assurance products and their application and validation. His areas of expertise include both upstream and downstream biopharmaceutical operation and validation. Walid has held various positions including Project Manager, Inspection Readiness Manager, Quality and Regulatory Manager, and Qualified Person (QP). Walid earned a Master's degree in Industrial Pharmaceutical Sciences from the University of Liege, Belgium and is green belt certified.

TIMUR GÜVERCINCI, MERCK GROUP, GERMANY
Timur Güvercinci has worked in the pharmaceutical and medical device industry for more than 10 years in various quality positions for different companies. Currently he is working as a head of validation qualification and engineering in the quality assurance at Merck KGaA in Germany. Based on the different fields of activities he acquired extensive experience in validation for the regulatory requirements as well as the technical implementation. Timur is a graduate engineer for pharmaceutical engineering from the Technical College of Albstadt-Sigmaringen.

PETER KRALINGER, CARRYMED PHARMA & TRANSPORT GMBH, AUSTRIA
Peter Kralinger is Managing Director of Carrymed, the first licensed pharma company providing international transport of temperature sensitive pharmaceuticals. Before that he was in charge of the global transportation activities for all manufacturing sites in Europe of a large manufacturer of the pharmaceutical industry.

DR JEAN-DENIS MALLET, ECA, FORMER HEAD OF THE FRENCH INSPECTION DEPARTMENT AFSSAPS, NNE PHARMAPLAN, FRANCE
Jean-Denis Mallet is a pharmacist. He was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps=ANSM). He also used to work in or with the pharmaceutical industry during many years at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. He has also been auditor of the International Red Cross. He is member of ECA´s validation group and works for NNE Pharmaplan.

GERT MØLGAARD, MOELGAARD CONSULTING, DENMARK
Gert Mølgaard has more than 25 years experience in the pharmaceutical and biotech industry, including several years of experience in process control, automation, computer systems validation and process validation as well as process engineering and consulting. He has previously worked in Novo Nordisk, Novo Nordisk Engineering and NNE Pharmaplan. From 2009-2012 Gert Mølgaard was been involved in training FDA's investigators at FDA's internal training on the 2011 Guidance on Process Validation and has contributed to several books and technical guidelines. Gert is currently Head of ECA´s Validation Group.

Easy Registration

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www.gmp-compliance.org

Date
Thursday, 23 February 2017, 09.30 – 18.00 h
(Registration and coffee 09.00 – 9.30 h)
Friday, 24 February 2017, 08.30 – 15.30 h

Venue
Barcelo Hamburg
Ferdinandstr. 15
20095 Hamburg, Germany
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Fees (per delegate plus VAT)
ECA Members € 1,490
APIC Members € 1,590
EU GMP Inspectorates € 845
Non-ECA Members € 1,690
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all days and all refreshments. VAT is reclaimable.

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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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