ECA Academy
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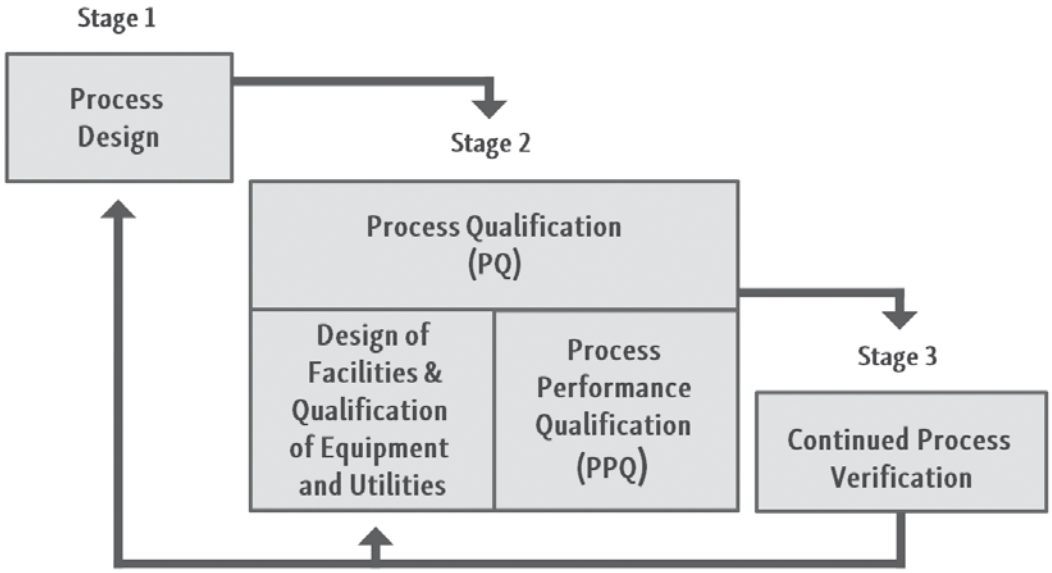
GMP Certification Programme
Certified Validation Manager

Speaker

Dr Line Lundsberg-Nielsen
Lundsberg Consulting Ltd., UK

Process Validation

Live Online Training on 14/15 July 2020



Three Q & A sessions make it lively

Highlights

- EU and FDA View
- The link between Quality by Design and Process Validation
- The benefits of applying DoE and PAT during development
- Establishing the control strategy
- Process validation life cycle – how to implement
- Process Validation case study
- Ongoing process Verification for legacy products

- Free Download: ECA's Good Practice Guide „Integrated Qualification and Validation"

Objective

With the publication of the Guidance for Industry "Process Validation: General Principles and Practices" 2011, the FDA requires a new direction. Validation is now a „Life Cycle Process" with 3 stages:

- Process Design
- Process Qualification
- Continued Process Verification

The focus is on process knowledge and process understanding. Both should be a result of development and verified in routine production. The "magic" 3 batches are not mentioned any more. What is very important nowadays is the term „scientific sound", and explicit statistics are mentioned. Six Sigma elements (e.g. Design of Experiments, DoE) are also mentioned directly or indirectly. There is also a stage in routine production called „continued process verification".

With the revision of Annex 15 EU GMP Guide in 2015 the EU is going in the same direction: Validation is a lifecycle with pharmaceutical development as basis and also a stage 3 is mentioned, called Ongoing Process Verification. In Europe 3 validation approaches are now possible – traditional, continuous and hybrid.

- How can the requirements be achieved?
- How fit the FDA requirements into European guidelines and vice versa?
- How can process knowledge and process understanding be demonstrated on the basis of development studies?
- When is a process valid now?
- Which parameters can be used for knowledge and understanding studies?
- How can „continued/ongoing process verification" be realised?

These questions are at the centre of this online-course.

Background

Since 1987 the FDA Guideline on Process Validation has been the basis for qualification and validation. Within the FDA programme "Pharmaceutical cGMPs for the 21st Century" there was an announcement for a revision of the guideline. A FDA Policy Guide of 2004 gave some hints to the new validation approach. In November 2008 the "Guidance for Industry Process Validation: General Principles and Practices" was published as a draft and came into operation in January 2011. That is now FDA's „current thinking". The chapter 1 of the EU GMP Guide gives hints for more emphasises on process capabilities and varieties within process validation also in Europe. EMA´s Process Validation Guidance and also the revised Annex 15 from 2015 takes a life cycle approach to process validation nowadays.

Target Audience

The addressees of the event are qualified staff charged with or responsible for validation activities, such as commissioners for validation, heads of quality assurance, department heads, etc. It also addresses members of validation teams (e.g. engineers, chemists, pharmacists, microbiologists) as well as representatives of the plant engineering industry and consultants.

Programme

Day 1

09.00 – 09.05 h
Introduction

- The validation life cycle

09.05 – 10.05 h
Regulatory Requirements

- Setting the scene for Process Validation
- Introduction to EMA's PV guides, Annex 15, and to FDA's PV guide
- Regulatory requirements

10.05 – 10.15 h
Break

10.15 – 11.15 h
Process Design

- Process Design
- Quality by Design, ICH Q8 and Q11
  - Quality Target Product Profile
  - Critical Quality Attribute
  - Critical Process Parameter
  - Design Space
  - Control Strategy
  - Continual Improvement
- Link between QbD the Control Strategy and Process Design

11.15 – 11.30 h
Break

11.30 – 12.30 h
Systems and Tools for gaining Process Understanding and establishing the Control Strategy

- Process Understanding & the Control Strategy
- Quality Risk Management
- Process Analytical Technology
- Design of Experiments
- Process Analysers
- Multivariate Data Analysis

12.30 – 13.00 h
Q&A

13.00 – 14.00 h
Break

14.00 – 14.30 h
Case Study Process Design

- Stage 1
- Applying QbD principles to design a process for an oral solid dosage formulation
- Examples of the application of DoE and PAT
- Establishing the control strategy

14.30 h – 15.30 h
PV/Process Performance Qualification

- The purpose and principles of PV/PPQ
- EU's different approaches to Process Validation
- Number of PV/PPQ batches
- Acceptance criteria
- PV/PPQ readiness
- PV/PPQ reporting and conclusion

15.30 – 15.45 h
Break

15.45 – 16.30 h
Case Study Process Performance Qualification/ Process Validation

- Stage 2.1: Designing the equipment and facility qualification programme based on the control strategy
- Stage 2.2: Establishing the PPQ/PV programme based oin the control strategy
- Justifying the number of PPQ/PV batches
- Presenting and evaluating data
- Concluding the PPQ/PV activities
- Proposing a stage 3 CPV/OPV programme

16.30 – 17.00 h
Q&A

Day 2

09.00 – 09.50 h
Ongoing/ Continued Process Verification

- EMA: Ongoing Process Verification
- FDA: Continued Process Verification
- Statistical tools
- Monitoring plan – OPV/CPV plan
- OPV/CPV for legacy products

09.50 – 10.05 h
Case Study Continued/Ongoing Process Verification

- Establishing the CPV/OPV programme
- Application of relevant statistics during stage 3

10.05 – 10.20 h
Break

10.20 – 10.50 h
Case Study OPV Programme for Legacy Products

- Establishing an OPV programme for legacy products
- Defining the relevant statistical metrics
- Running, evaluating and updating the programme

10.50 – 11.00 h
Wrap-up and consideration for Process Validation in a future Industry 4.0 manufacturing environment

- How will process validation evolve in light of more automated and self-optimising processes
- A holistic approach to validation – covering qualification of equipment, control systems, computer systems, processes and analytical technologies and methods
- The role of the control strategy

11.00 – 11.30 h
Q&A

Q&A sessions

Three Q&A sessions (two on day 1 and one on day 2) ensure interaction and that your questions are answered.

Speaker

Dr Line Lundsberg-Nielsen, Lundsberg Consulting Ltd., U.K.

Dr Line Lundsberg-Nielsen is a scientist, runs her own consultancy business focusing on applying a science and risk-based approach for pharmaceutical development, process design, technology transfer, qualification and process validation. She has many years of experience within the pharmaceutical Industry and has a theoretical as well as practical approach to QbD, PAT and RTRT from working at Novo Nordisk and Lundbeck before being a consultant. Dr Lundsberg is an active ISPE member, has had different chairing roles and is a well-recognized international speaker and instructor.

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Process Validation

Live Online Training on 14/15 July 2020

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Date of the Live Online Training

Tuesday 14 July 2020, 09.00 – 17.00 h
Wednesday, 15 July 2020, 09.00 – 11.30 h

Technical Requirements

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At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 1,290
APIC Members € 1,390
Non-ECA Members € 1,490
EU GMP Inspectorates € 745
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.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

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.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O.Box 10 17 64
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 please contact:
Mr Sven Pommeranz (Operations Director) at
+49(0)62 21/84 44 47, or at
pommeranz@concept-heidelberg.de.

For questions regarding organisation etc. please contact:
Ms Julia Grimmer (Organisation Manager) at
+49(0)62 21/84 44 44, or at
grimmer@concept-heidelberg.de.

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