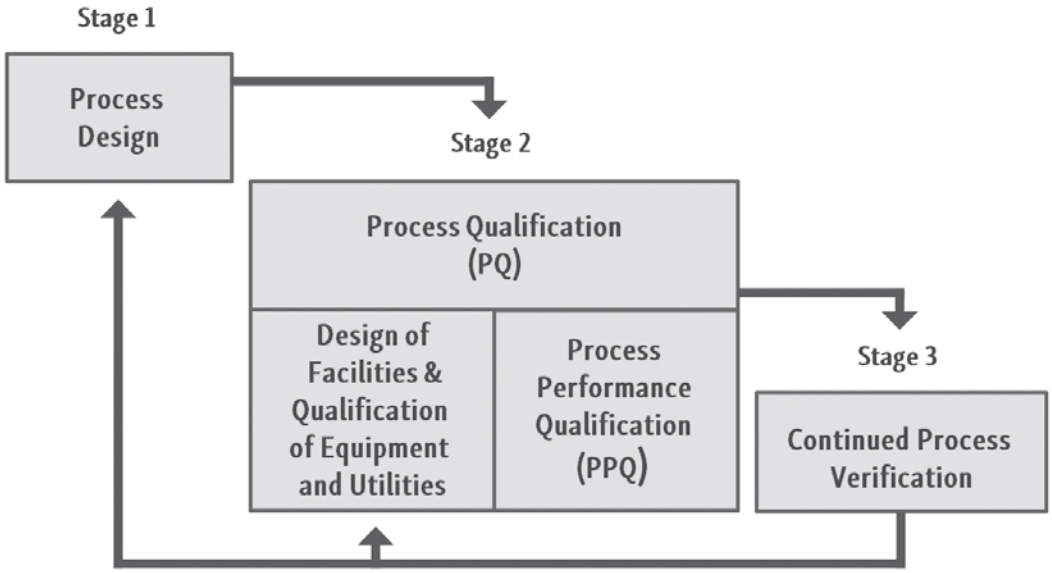
Speaker

Dr Line Lundsberg-Nielsen
Lundsberg Consulting Ltd., UK

Process Validation

Live Online Training on 25/26 April 2023



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 „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".

The EU Process Validation Guidelines incl Annex 15 of the EU GMP requires in a similar way a 3-stage life cycle approach to Process Validation: Pharmaceutical development, Process Validation and Ongoing Process Verification. In Europe 3 validation approaches are 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

Introduction

- The validation life cycle

Process Validation Life Cycle, Regulatory Requirements

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

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

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

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

Process Validation / 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

Case Study Process Validation / Process Performance Qualification

- Stage 2.1: Designing the equipment and facility qualification programme based on the control strategy
- Stage 2.2: Establishing the PPQ/PV programme based on 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

Day 2

Ongoing/Continued Process Verification

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

Case Study Ongoing/Continued Process Verification

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

Case Study Ongoing Process Verification Programme for Legacy Products

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

Wrap-up and considerations 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

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.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.


CERTIFICATE

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org.

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Reservation Form (Please complete in full)

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Date of the Live Online Training

Tuesday, 25 April 2023, 09.00 - 16.00 h
Wednesday, 26 April 2023, 09.00 - 14.00 h
All times mentioned are CEST.

Technical Requirements

We use Webex Events for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events 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 € 1,290
APIC Members € 1,390
Non-ECA Members € 1,490
EU GMP Inspectorates € 745

The conference fee is payable in advance after receipt of invoice.

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.

You cannot attend the Live 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.

Conference language

The official conference language will be English.

Organisation and Contact

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

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.

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

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