ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Validation Manager

Speakers

Lynn Bryan
Ballygan Consulting, UK

Dr Line Lundsberg-Nielsen
Lundsberg Consulting Ltd, UK

Dr Wolfgang Schumacher
form. Hoffmann-La Roche, Switzerland

Dr Norbert Skuballa
Biologische Arzneimittel Heel, Germany

The Validation Manager

in the Pharmaceutical Industry

Live Online Training on 26/27 March 2025

Overview of the cGMP requirements on the whole range of validation/qualification

Highlights

- Regulatory Requirements
- Risk Assessment
- Validation Master Plan
- Qualification
- Validation
- Computer Validation
- Cleaning Validation
- Qualification/Validation in API Manufacturing
- Change Control
- Case Study Qualification
- Case Study Validation

New overview about Analytical Method Validation

Programme

Objective

For years, the topic Validation/Qualification has been among the top deviations in FDA's warning letter statistics. This is true both of pharmaceutical manufacturers and of the API industry. Other frequent citations refer to the related topics Cleaning Validation and Change Control. What is also checked during inspections – and mentioned in warning letters – is Computer Validation.

In order to give you a **broad overview** of the cGMP requirements on the **whole range of Validation/Qualification**, we have designed this practice-oriented 2-day Validation Manager GMP Education Course. In many pharmaceutical and API enterprises, the Validation Manager has become an established function.

One focus will be on the **FDA Guidance on Process Validation** of 2011. What are differences, what are similarities to European validation guidelines?

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

Risk Assessment

- Why is Risk Assessment necessary?
- ICH Q9
- Risk Assessment techniques
- Case study

Validation Master Plan

- Target
- Format
- Content
- Differences between PIC/S and Annex 15
- New requirements regarding Annex 15 revision
- Validation Master Plan and Lost Guide

Overview Analytical Method Validation

- ICH Q 2
- ICH Q 14

Qualification

- Why do we do this - history
- Update Annex 15 requirements
- DQ, IQ, OQ, PQ – how the stages of validation fit together
- How to handle qualification logistics?
- Re-qualification
- Qualification of equipment in use

Case Study Qualification

The case study describes how a purified water system can be qualified according to cGMP.

Process Validation

- The Validation Life Cycle
- Prospective vs concurrent validation
- Is retrospective validation still allowed?
- Are 3 runs still valid?
- What does Hybrid Approach mean?
- Revalidation vs Continued Process Verification and Ongoing Process Verification
- Similarities/differences between Process Validation expectations in US and EU
- Pitfalls
- Overview Analytical Method Validation

Case Study Process Validation

The case study describes a Process Validation study of a tabletting process.

Computer Validation

- Organisation of Computer Validation
- Classification (GAMP 5)
- Risk analysis
- Change control
- Audit Trail
- Legacy systems
- CSA – Computer Software Assurance
- Data Integrity

Cleaning Validation

- Validation protocol
- Risk Assessment
- Sampling
- Which limits are acceptable?
- The new PDE approach in Annex 15 revision
- Case study

Qualification/Validation in the Field of Chemical API Manufacturing

- Guidelines focused on Qualification/Validation aspects for API production
- GMP requirements for Qualification/Validation in the field of API manufacturing
  - Differences to drug manufacturing
  - Retrospective qualification
  - Revalidation
  - Pitfalls

Change Management

- Technical Change Management
- Regulatory Change Management
- Change Management documentation

Speakers

Lynn Bryan, BSc. (University of Liverpool), P.G.C.E (University of Reading), Ballygan Consulting, U.K.

Lynn has had Qualified Person status within the industry for mor than 10 years and has her own QA/Validation consultancy business. Previously Lynn headed different management position e.g. Quality Manager at a radiopharmaceutical manufacturer, the Technical Manager at a veterinary manufacturer, validation manager at a pharmaceutical company,, production support manager responsible for calibration, validation and new product introduction. Lynn has been presenting on training courses on validation, training approach, GMP and water/steam systems for over 15 years.

Dr Line Lundsberg-Nielsen, Lundsberg Consulting Ltd

Dr Line Lundsberg-Nielsen is a Global Technology Partner at NNE Pharmaplan. 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 and has had different chairing roles supporting QbD, PAT and PV implementation. She has practical experiences from interaction with the FDA and EMA on QbD, PAT and RTRT aspects.

Dr Wolfgang Schumacher, form. Hoffmann-La Roche, Switzerland

Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. From 2001 to 2016 he was Head of the department of Quality Computer Systems at F. Hoffmann-La Roche, Basle. He is a member of the ECA Advisory Board.

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.

Q & A sessions

Four Q &A sessions (two on each day of the training) ensure interaction and that your questions are answered.

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.

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

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings

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Reservation Form (Please complete in full)

The Validation Manager in the Pharmaceutical Industry, Live Online Training on 26/27 March 2025

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Wednesday, 26 March 2025, 08.30 - 18.00 h
Thursday, 27 March 2025, 08.30 - 18.00 h
All times mentioned are CET.

Technical Requirements

We use Webex 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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
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.

Conference language

The official conference language will be English.

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.

Organisation and Contact

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