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

Free Download:
ECA´s „Integrated Qualification and Validation Good Practice Guide" - A guide to effective qualification based on Customer – Supplier Partnership.

The Validation Manager

in the Pharmaceutical Industry

29 - 31 March 2023 | Heidelberg, Germany

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

Add-on:
Qualification and Validation – Basic Requirements Aide Memoire (GMP Inspectors Guide).

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 3-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?

Parallel workshops on risk analysis and detailed case studies on qualification and validation help to consolidate the theory and demonstrate the practical implementation.

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.

Note: The number of participants is limited to 40 persons.

Social Event

In the evening of the first 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.

Add-on:
Qualification and Validation – Basic Requirements Aide Memoire (GMP Inspectors Guide)

The Guide is developed by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) – English translation. This 20 pages document covers responsibilities, risk assessments, documentation (VMP protocols, reports), inspection of premises and equipment, qualification requirements (URS, DIOPQ), qualification of identical equipment, requalification).

Programme

Overview

Regulatory Requirements on Qualification / Validation Aspects - From History to PAT

- EU GMP guideline and annexes
- Revision of Annex 15 – what is new?
- PIC/S guidelines
- Systematics of plant qualification and process validation
- New approaches to validation
- The FDA Guidance on Process Validation

Industrial View

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

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 Equipment Qualification

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

Case Study Process Validation

The case study describes a process validation study of a tabletting process.

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
- Pitfall

Computer Validation

- Organisation of computer validation
- Classification (GAMP® 5)
- Risk analysis
- Change control
- Legacy systems

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
- Update Annex 15 requirements

4 Parallel Workshops

We offer four parallel workshops. **You can take part in one of these workshops.**

Workshop 1: Organisation of Validation
An interactive workshop to find out and discuss how validation activities can be implemented in an existing QM System and how to write a Validation Master Plan

Workshop 2: Risk Assessment Qualification
In the workshop you look at risk assessment associated with qualification activities in a typical production environment. You will assess a new filling line as per the ISPE baseline guide to create an impact assessment plan. This plan will then be translated into requirements for validation and the resultant tests associated with the validation steps of DQ through to OQ.

Workshop 3: Risk Assessment Process Validation
An interactive workshop with practical examples and exercises on the application of Quality Risk Management for validation of a tabletting process

Workshop 4: Risk Assessment Cleaning Validation
An interactive workshop to find out and discuss GMP-relevant aspects of the validation of cleaning with the focus on calculating acceptance criteria.

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.

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CONCEPT HEIDELBERG
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

The Validation Manager in the Pharmaceutical Industry, 29 - 31 March 2023, Heidelberg, Germany

Please choose one of the following Workshops

☐ *Workshop 1: Organisation of Validation*
☐ *Workshop 2: Risk Assessment Qualification*
☐ *Workshop 3: Risk Assessment Process Validation*
☐ *Workshop 4: Risk Assessment Cleaning Validation*

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:
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- Cancellation until 1 weeks prior to the conference 50 %
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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 January 2012).
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

Wednesday, 29 March 2023, 09.30 - 18.00 h
(Registration and coffee 09.00 - 09.30 h)
Thursday, 30 March 2023, 8.30 - 17.30 h
Friday, 31 March 2023, 8.30 - 13.15 h

Venue

Hotel NH Heidelberg
Bergheimer Straße 91
69115 Heidelberg
Phone +49 (0) 62 21/1327 0
nhheidelberg@nh-hotels.com

Fees (per delegate, plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
Including: Conference documentation, lunch and social event on the first day, lunch on the second day, all refreshments.

Accommodation

CONCEPT HEIDELBERG 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.

Registration

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

Conference language

The official conference language will be English.

GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. 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.

Organisation and Contact

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