The Validation Manager in the Pharmaceutical Industry
19 - 21 February 2020 | Barcelona, Spain

Speakers

Lynn Bryan
Ballygan Consulting, UK

Dr Line Lundsberg-Nielsen
NNE Pharmaplan, U.K.

Dr Norbert Skuballa
Biologische Arzneimittel Heel, Germany

Dr Wolfgang Schumacher
form. Hoffmann-La Roche, Switzerland

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

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

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

Update regarding Annex 15 revision and EMA Process Validation Guideline
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.

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

Case Study Validation
The case study describes a process validation study of a tabletting 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

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.)
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

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 10 years and has her own QA/Validation consultancy business. Previously Lynn was the Quality Manager at a radiopharmaceutical manufacturer, the Technical Manager at a veterinary manufacturer and a validation manager at a pharmaceutical company manufacturing blood products and vaccines in sterile liquid and freeze dried form. Lynn also worked as the production support manager responsible for calibration, validation and new product introduction at a contract aerosol manufacturing company. The company produced MDIs, DPIs, pump spray and aerosol products to the US and Europe. Lynn has been presenting on training courses on validation, training approach, GMP and water/steam systems for over 15 years.

Dr Line Lundsberg-Nielsen, NNE Pharmaplan, U.K.
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 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.

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.
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 2 weeks prior to the conference 10 %,
   - Cancellation until 1 weeks prior to the conference 50 %,
   - Cancellation within 1 week prior to the conference 100 %.

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As of January 2012.

German law shall apply. Court of jurisdiction is Heidelberg.

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Reception Form (Please complete in full)

The Validation Manager in the Pharmaceutical Industry, 19 - 21 February 2020, Barcelona, Spain

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)

Date

Wednesday, 19 February 2020, 09.30 h - 18.00 h

(Registration and coffee 09.00-09.30 h)

Thursday, 20 February 2020, 8.30 h - 17.30 h

Friday, 21 February 2020, 8.30 h - 13.15 h

Venue

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain

Phone +34 (93) 503 53 00
Fax +34 (93) 490 60 45
e-mail sants@barcelo.com

Fees (per delegate, plus VAT)

- ECA Members € 1,790
- EU GMP Inspectorates € 995
- Non-ECA Members € 1,990
- APIC Members € 1,890

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.

Certificate of Attendance

Shortly after the event, you will receive your certificate of attendance by e-mail.

Registration

Via the attached registration form, by e-mail or by fax message. You register online at www.gmp-compliance.org and www.eca-compliance.org.

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