ECA Academy
Your GMP/GDP Information Source

SPEAKERS

EVA BAUMGARTNER
Syntacoll

DR CLEMENS BORKENSTEIN
ZETA

FRANCO CASINELLI
Johnson and Johnson

DR BERTHOLD DÜTHORN
Syntegon

RALF GENGENBACH
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DR RAINER GNIBL
GMP Inspector

PETER LARSSON
Novo Nordisk A/S

GERT MOELGAARD
Moelgaard Consulting, Head of ECA's Validation Group

ALICE REDMOND
Commissioning Agents

THOMAS RÜCKER
Letzner

Launch Conference

Final version: ECA's Integrated Qualification and Validation Guide

Working with Suppliers towards modern Qualification and Validation

All delegates receive the final Guide with a lot of examples and templates.

Live Online Conference
27/28 October 2020

HIGHLIGHTS:

- Regulatory perspective from EU: view on Annex 15 and the integrated approach
- Customer and Supplier Cooperation: Integrated Qualification
- New ISPE Commissioning & Qualification guides: From version 1 (2001) to version 2 (2019) - and other related guides
- Qualification terms (commissioning, verification…) – are Babylonian times back?
- Equipment Categorisation – one way to an effective qualification
- Qualification and Validation: An integrated approach
- 4 Case Studies
  - **How to Benefit from the Supplier and Customer/User Collaboration when proofing Equipment´s Fitness for Use**
  - **Water Systems**
  - **Risk Managed Qualification in Capital Projects**
  - **Update Transforming Novo Nordisk´s qualification and validation concept to focus on GEP and supplier collaboration**

This conference is recognised for the ECA GMP Certification Programme „Certified Validation Manager". Please find details at www.gmp-certification.eu

Launch Conference – Final version: ECA's Integrated Qualification and Validation Guide

Live Online Conference, 27/28 October 2020

Welcome

This year is a special year and will be remembered for a long time. The **Covid-19 pandemic** is shaping our professional environment as well as our private lives. But life goes on.

Therefore, the ECA has decided to offer this conference as a Live Online Conference.

Best regards,
Gert Moelgaard
Chairman of the Validation Group

Objectives

Qualification and Validation regulations have changed in both Europe and USA in recent years. Many pharmaceutical companies and suppliers are still using methods and documentation from previous practice although a risk-based approach has become a regulatory expectation since years. Also many companies have very little integration between their activities, so the overall qualification and validation effort is complicated, expensive and time consuming. Only few companies have leverage their qualification and validation programs to a fully integrated approach, as the EU Annex 15 and the FDA Process Validation guide enables.

Qualification is an activity with a history of more than 20 years, but it is still hotly debated. Even modern approaches, aimed at time and cost optimization, do not seem to bring about the expected improvement. A non-harmonized terminology emerges as one of the main problems, especially when it comes to the integration of good engineering practice. An attempt to create clarity here could be a signpost for a future optimized approach. This attempt will be made in the context of this conference.

The Conference is also about time saving integrated qualification and validation activities. Suppliers are an important factor in this modern approach.

A team of pharmaceutical companies, engineering companies and suppliers have further developed ECA`s Good Practice Guide "Modern Qualification".Integrated are now from the last years feedbacks from regulators, the pharmaceutical industry and suppliers to improve the document to more needs of the users. The revised guide "Integrated Qualification and Validation – a guide to effective qualification based on Customer – Supplier Partnership! will be presented in the final version.

The speakers are team members or reviewers of the guide So you have the opportunity to discuss the contents, technical aspects of the guidance document, its scope and practical application during Q&A sesssions. All delegates will receive a copy of the guide free of charge as download. **Case studies** explain how to work together with suppliers and how to use an integrated approach.

Background

Qualification of equipment and validation has been mandatory since the late 80s (FDA Guideline on Process Validation) and the early 90s (EU GMP Guide). Due to inspection results at that time, qualification activities increased significantly and very often, the focus on the patient was lost. The original purpose behind qualification, which is to show that equipment is fit for its intended use, was lost. A white paper from the ISPE "Risk-based qualification for the 21st century tried to amend this. With reference to this paper, ECA´s Validation Group has now further developed a Good Practice Guide on Modern Qualification to Integrated Qualification and Validation. This guide is supposed to assist pharmaceutical companies and suppliers with how to qualify equipment in a lean way and how to integrate the qualification into validation. Like in the GAMP-Guide, examples build the core of this further developed Good Practice Guide on Integrated Qualification.

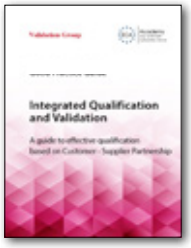
Target Audience

Everyone who may be influenced by the Annex 15 revision and FDA Process Validation Guidance regarding Qualification/Verification and Process Validation activities and wants to see how an integrated approach to qualification and validation can enable successful, lean projects.

Moderator

Gert Moelgaard, Head of ECA´s Validation Group, Denmark

Programme



Introduction to Integrated Qualification and Validation

- Development of ECA's Integration and Validation guideline

Integrated Qualification and Validation acc. EU GMP Annex 15: Inspector´s View

- Qualification Life Cycle (Overview)
- Boundaries & possibilities of Annex 15
- What is a must, what is a nice to have?
- Linking of Qualification & Validation possible?

A Qualification Case using Elements of the new ECA´s Good Practice

- Content of the guideline
- About necessary activities and explanations/interpretations
- How to establish the basis for understanding of involved parties
- The success and the areas for improvement in the future

ISPE Commissioning & Qualification Guide Version 2 (2019)

- ISPE Baseline guide 5 Update
- Key aspects/features of the ISPE Baseline
- How do we do a GAP assessment of current practices vs the new BG-5?
- Implementation program for BG-5 and sustaining operations

Case Study: Water System

- Risk workshop
- DQ the central qualification element
- GEP
- ECA Guideline

Equipment Categorisation – One Way to Streamline Qualification

- Equipment categorization helps to select an appropriate effort for qualification activities and helps to avoid excess work
- What is the perfect timing for equipment categorization?
- Categorisation of manufacturing systems
- Questionnaire for a categorisation

Qualification Terms – Are Babylonian Times back?

- What activities are required in qualification?
- What are the terms used for it (EU, US)?
- How are the different terms (FAT, SAT, Testing, Qualification, Verification) related?
- How to solve the problem in daily projects?
- The framework: Good Documentation Practice /Good Engineering Practice

Case Study: Risk Managed Qualification in Capital Projects

- Why does capital project delivery need to change
- What are the key principles of a project delivery
- How risk managed qualification is embedded in the capital projects and what are the steps and relevant content (from requirement to release)
- How supplier can create value

Qualification and Validation: An Integrated Approach

- Process Qualification - the „marriage“ of qualification and process validation
- Development as basis
- Integration of critical process parameters into qualification
- The real goal is Process Validation/PPQ
- Key performance indicators
- Equipment qualification: view of a pharmaceutical company

Case Study: Update – Transforming Novo Nordisk´s Qualification and Validation Concept to Focus on GEP and Supplier Collaboration

- The transition from traditional qualification to a science-and risk-based integrated CQV process
- What is good quality in qualification and validation
- Core principles for Novo Nordisk
- Tailor-made project execution based on risk

Electronic Documentation in Qualification Projects – First Ideas

- Scanned classical paper qualification documentation vs. tests being prepared, executed and documented in electronic format
- Requirements for electronic documentation in qualification

Feedback to the Integrated Qualification and Validation Guide

- Open questions
- Outlook

Speakers

EVA BAUMGARTNER

Syntacoll, Validation Manager

Eva-Maria Baumgartner studied biotechnology at the University of Applied Sciences Weihenstephan-Triesdorf and has been with Syntacoll GmbH since 2004. She has managed various qualification and validation projects for the registration of new medicinal products, medical devices and combination products.

DR CLEMENS BORKENSTEIN

ZETA, Head of department Executive Quality

Clemens holds a PhD in industrial biotechnology. He has over 8 years of experience in pharma engineering, and is head of the department Executive Quality at the ZETA Group, responsible for Quality Assurance and Qualification.

FRANCO CASINELLI

Johnson and Johnson, Senior Manager Qualification

Franco Casinelli is Senior Manager Commissioning & Qualification, Johnson and Johnson - Engineering & Property Service Euro Platform. Franco is an electrical engineer and has 40 years experience in different pharmaceutical engineering contests. He was responsible in main projects as C&Q matter expert in EMEA and APAC.

DR BERTHOLD DÜTHORN

Syntegon, Vice President

The pharmacist Berthold Düthorn currently serves as Vice President within Syntegon with global responsibility for Validation and Compliance Services, Integrated Solutions, Connected Industry Services and as General Manager of Valicare GmbH. He published several articles on isolation technology.For more than 20 years he is active in the area of clean room standardisation (ISO TC 209).

RALF GENGENBACH

gempex, Managing Director

Ralf Gengenbach is founder and managing director of gempex Co. Ltd., Germany. He is member of different organisations, among others DIN UA2 (Board for standards 'biotechnology'), of DECHEMA and ISPE. He is approved Quality Auditor according to DIN ISO 9000ff.

DR RAINER GNIBL

GMP Inspector, District Government of Upper Bavaria, Germany

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

PETER LARSSON

Novo Nordisk A/S, Head of Engineering Management

Peter Larsson has a background as Operations Manager, Project Manager, Engineering Manager and Project Engineer within several companies in the pharmaceutical industry.

GERT MOELGAARD

Moelgaard Consulting, Head of ECA's Validation Group

Gert Mølgaard has more than 25 years experience in the pharmaceutical and biotech industry, including several years of experience in process control, automation, computer systems validation and process validation as well as process engineering and consulting. He has previously worked in Novo Nordisk, Novo Nordisk Engineering and NNE Pharmaplan. From 2009-2012 Gert Mølgaard was been involved in training FDA's investigators at FDA's internal training on the 2011 Guidance on Process Validation and has contributed to several books and technical guidelines.

ALICE REDMOND

Commissioning Agents, Vice President Europe Operations

Alice Redmond has more than 29 years experience in lifecycle management of pharma facilities inclusive regulatory compliance, facility & process design, technology transfer, commissioning, qualification, and validation. Ms Redmond worked for Sandoz/Novartis in Basel, Kundl and Ireland in the areas of quality, validation and technical operations. Alice holds a PhD in Cell Culture from Dublin City University.

THOMAS RÜCKER

Letzner, CEO

Thomas Rücker, born 1980 in Ludwigsburg, completed his master's degree in industrial engineering in 2005. In 2007, Mr Rücker moved to Letzner Pharmawasseraufbereitung GmbH as project manager, where he switched internally to sales in 2010. Mr Rücker became a managing partner in 2015.

GMP/GDP CERTIFICATION PROGRAMME

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

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ECA Certified Microbiological Laboratory Manager
ECA Certified Sterile Production Manager
ECA Certified Biotech Manager
ECA Certified Pharmaceutical Development Manager
ECA Certified GMP Auditor
ECA Certified GDP Compliance Manager
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Easy Registration

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Date
Tuesday, 27 October 2020,
09.30 – 17.00 h
Wednesday, 28 October 2020,
08.30 – 16.15 h

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Fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
EU GMP Inspectorates € 895
Non-ECA Members € 1,790

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

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.

For questions regarding content please contact:
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Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

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Live Online Conference on 27/28 October 2020

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