ECA Academy
Your GMP/GDP Information Source

SPEAKERS

DR BERTHOLD DÜTHORN
Syntegon

RALF GENGENBACH
gempex

DR RAINER GNIBL
GMP Inspector

MAIK GUTTZEIT
Bayer

DR MICHAEL JAHNKE
Octapharma

IGOR KRASULA
Valicare, a Syntegon Company

GRACE MCNALLY
Greenleaf Health

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

RAFAEL DE SOUZA
Pharmaplan

Launch Conference

New Version 2.0: ECA's Integrated Qualification and Validation Guide

Working with Suppliers towards modern Qualification and Validation

All delegates receive the new Guide Version 2.0 with a lot of examples and templates.

Live Online Conference
16/17 November 2021

HIGHLIGHTS:

- Integrated Qualification and Validation acc. EU GMP Annex 15: Inspector´s View
- Modern Qualification and Validation from an Ex-FDA perspective
- ISPE Commissoning & Qualification Guide Version 2 (2019)
- How suppliers work: Good Engineering Practice in Qualification
- Cooperation between customers and suppliers on Integrated Qualification and Validation
- Remote FAT/SAT – Tools possible not only in a pandemic situation
- ECA Q&V Guide and tools: Risk-based qualification from URS to PQ,
- ECA Q&V Case Study: Fast and effective project execution with suppliers
- Supplier Contracts during Qualification
- Case Study Influence of pharmaceutical QA during renovation and new buildings
- Electronic Documentation in Qualification projects – new Appendix
- Equipment Categorization – a tool to streamline qualification

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

Launch Conference – New Version 2.0: ECA's Integrated Qualification and Validation Guide

Live Online Conference, 16/17 November 2021

Welcome

This year, like the last, is bound to have a lasting impact on us all. The **Covid-19 pandemic** is still 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 once more.

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/commissioning activities. 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 version 1.0 of ECA`s Good Practice Guide "Integrated Qualification and Validation – a guide to effective qualification based on Customer – Supplier Partnership" to a 2.0 version. It now includes feedback from regulators, the pharmaceutical industry and suppliers to improve the version 1.0 from last year to better fit the needs of its users. The revised guide version 2.0 will contain new appendices about critical aspects risk assessments (CARA), remote FAT/SAT, equipment categorization and about contracting qualification activities. The electronic documentation appendix has been revised as well as the main text of the document.

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 version 2.0 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 and Validation.

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?
- What GMP rules are important for contracting (overview)?
- GMP rules for electronic documentation from supplier? (Overview)
- How about equipment categorization to leverage qualification activities

ISPE Commissoning & 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

Modern Qualification and Validation from an Ex-FDA perspective
- FDA's Process Validation guide
- Process Validation as a life-cycle approach
- Lessons learned from the FDA Process Validation guide
- International harmonization of process validation?

How suppliers work: Good Engineering Practice in Qualification
- Basic Engineering Workflows (CD, BD, DD – EPCMQ Projects)
- Process-, Equipment Engineers and more (the full picture)
- Key Documents in Engineering Processes
- FAT, SAT and Commissioning
- How a supplier can support qualification
- Typical pitfalls?

Cooperation between customers and suppliers on Integrated Qualification and Validation
- Importance of Project Quality Plan (PQP) as upfront clarification document
- Agreement of scope of supply and services – task for both contractual partners
- Technical documentation, Test documentation and execution - the effect of work-shops for common understanding and agreement
- Importance of Qualification Project Management - Collaboration spirit as key success factor

Remote FAT/SAT – Tools possible not only in a pandemic situation
- The new chapter in ECA´s Good Practice Guide
- How to organise remote FAT/SATs?
- Case studies

ECA Q&V Guide and tools: Risk-based qualification from URS to PQ
- Critical Aspects Risk Assessment (CARA) and its 3 steps
- Interface between Product and process requirements (PPURS) and URS
- CARA and the "red thread" of user requirements
- Support C&Q tools: Use of Test Matrix (TM) and Requirements Traceability Matrix (RTM) from DQ to PQ

ECA Q&V Case Study: Fast and effective project execution with suppliers
- International standard, common language with suppliers
- Using the best ideas in our company
- Categories of equipment: benefit during qualification
- What would we expect from our suppliers?
- Integrated Qualification and Validation from a pharma perspective: Case Study LAF

Supplier Contracts during Qualification
- Legal requirements on contracts
- What should be in a contract and what not
- How a contract can support the quality of cooperation
- New chapter contracting in ECA´s Good Practice Guide
- New Annex about contracting (checklist)

Case Study: Influence of pharmaceutical QA during renovation and new buildings

- How many QA is enough in technical projects?
- How to enhance a qualification project (implementation of FAT/SAT, equipment categorisation)
- URS: definitions regarding quality relevant and economic relevant requirements
- Complaints, deviations, changes during project life cycle
- Traceability of qualification activities during project life cycle
- Handover of an project to routine production

Electronic Documentation in Qualification projects – new Appendix

- Requirements for electronic documentation in qualification
- Case studies

Equipment Categorization – a tool to streamline qualification

- Regulatory possibilities for using qualification approaches, which are adapted to relate risk
- The revised categorization chapter, what is new?
- New appendix: template equipment qualification

Feedback to the Integrated Qualification and Validation Guide

- Open questions
- Outlook

Speakers

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, Digitalization Solutions and as General Manager of Valicare GmbH. He published several articles on isolation technology. For more than 20 years, he has been 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.

MAIK GUTTZEIT

Bayer, Global Technology Manager Aseptic and Sterile

Maik Guttzeit holds a Dipl.-Ing. degree in general process engineering. For almost 20 years Maik was Team Leader Validation at GEA which provides customized GMP Lyophilizer systems. He is member of the GAMP® D-A-CH committee and also member of ASME BPE Subcommittee on System Design. Since September 2018 he is working for Bayer as Global Technology Manager Aseptic and Sterile.

DR MICHAEL JAHNKE

Octapharma, Senior Quality Advisor

Michael Jahnke (PhD) is currently acting as Quality Advisor and QP at Octapharma. His main responsibilities are defined in the site and project management and the Quality Unit regarding GMP-questions. He has studied microbiology and more than 25 years experience in the EU- and FDA-regulated GMP environment.

IGOR KRASULA

Valicare, a Syntegon Company

Igor Krasula is an Electrical Engineer (BME- Biomedical Eng.).
Since 2007 worked as Validation Engineer qualifying Bosch/Syntegon Aseptic Filling Lines. Currently manages team of validation experts in the field of commissioning & qualification (CQ&V) of Inspection Systems, Medical Device Assembly Machines and Mixing and Granulation Systems for worldwide-located pharmaceutical manufacturers.

GRACE MCNALLY

Greenleaf Health Inc., Senior Vice President, Regulatory Affairs

Grace holds a BSc in physics and was over 33 years working for the US FDA. As Senior Policy Officer Grace chaired the workgoup, which has developed FDA´s General Principles and Process Validation Guidance. Since July 2021 she is with Greenleaf Health supporting pharmaceutical and medical technology companies in strengthening quality systems, developing compliance strategies, ensuring inspection readines and works as an (mock) auditor.

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 Moelgaard 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.

RAFAEL DE SOUZA

Pharmaplan, Project Quality Manager

Rafael is MSc in Analytical Chemistry and is PMP certified. During his more than 16 years of professional career, he has wide experience in good manufacturing practice (GMP), quality assurance and commissioning, qualification and validation (CQ&V) in the pharmaceutical and biotech industries from projects in Switzerland, Brazil, Denmark and France. He has been working on projects leading activities following traditional principles for Commissioning and Qualification as well as Risk and Science based principles (including projects based on ASTM E-2500).

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:

ECA Certified Validation Manager
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ECA Certified Quality Control Manager
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ECA Certified Regulatory Affairs Manager
ECA Certified Microbiological Laboratory Manager
ECA Certified Sterile Production Manager
ECA Certified Biotech Manager
ECA Certified Pharmaceutical Development Manager
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Date
Tuesday, 16 November 2021,
09.00 - 17.00 h
Wednesday, 17 November 2021,
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

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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.

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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 16/17 November 2021

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