Qualification and Validation Forum

Update 2023

Live Online Conference on 14-15 November 2023

All delegates receive the current Guide Version 2.2 with a lot of examples and templates.

Highlights

- Modern Qualification and Validation from a European inspector's view: ECA Good Practice Guide and the relation to EU GMP Annex 15
- Integrated Qualification and GMP Equipment Design: Two ECA guidelines in practice
- Equipment Categorization – a tool to streamline qualification
- Critical Aspects Risk Assessment (CARA) – new chapter to clarify risks
- Survey to develop the guide further on
- Case Study Customer Supplier Cooperation – A Project Example
- eValidation – How to overcome Challenges with Paper-Based CQV Approches
- Paperless Validation and Qualification System Implementation and Experiences

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

ECA Academy
Your GMP/GDP Information Source

Welcome

Dear Colleagues,

Last year the ECA has launched its Good Practice Guide Integrated Qualification and Validation in the version 2.2. This year the group is on the way for a bigger revision. As always are feedbacks from the industry and from regulators part to develop the guide further on.

To discuss the developments for a bigger revision the ECA has decided to offer this forum this year as a Live Online event Part of this forum is also a survey for the development.

Best regards,
Ralf Gengenbach
Chairman of the Validation Group

Overview

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 to prevent changing all procedures already set. Still many companies have very little integration between their activities, so the overall qualification and validation effort is complicated, expensive and time consuming. But some companies have leveraged 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 with qualification 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 forum.

The Forum 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 is currently developing further the version 2.2 of ECA`s Good Practice Guide "Integrated Qualification and Validation – a guide to effective qualification based on Customer – Supplier Partnership" to a bigger revision. Under discussion are again feedbacks from regulators, the pharmaceutical industry and suppliers to improve the version 2.2 from last year to more needs of the users. New aspects are introduced to Critical Aspects Risk Assessments (CARA) and about Equipment Categorization. Also, revisions in the in the main text are discussed.

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 sessions and a survey. All delegates will receive a copy of the current version 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 their Good Practice Guide 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 want to see how an integrated approach to qualification and validation can enable successful, lean projects.

Moderator

Ralf Gengenbach
Chairman of the Validation Group

Programme

Introduction to Integrated Qualification and Validation
Ralf Gengenbach
- Development of ECA´s Integration and Validation guideline

Modern Qualification and Validation from a European Inspector's point of view: ECA Good Practice Guide and the relation to EU GMP Annex 15
Dr Franz Schönfeld
- 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

Integrated Qualification and GMP Equipment Design: Two ECA guidelines in practice
Gert Moelgaard
- Quality Risk Management and Good Engineering Practice
- Qualification and Validation alternatives
- Supplier management challenges
- Qualification and Validation for the future

Equipment Categorisation – new chapter and appendix as a tool to streamline qualification
Maik Guttzeit
- Regulatory possibilities for using qualification approaches, which are adapted to relate risk
- On the way: The revised categorization chapter, what is planned?
- Appendix: template equipment qualification

Critical Aspects Risk Assessment (CARA) – new chapter to clarify risks
Rafeal de Souza
- The CARA concept in the equipment qualification life cycle
- Comprarison between Quality Risk Management and CARA

Case Study Customer Supplier Cooperation – A Project Example
Holger Frey
- Project description (Capex project with integrated Qualification Activities together with the supplier)
- Project milestones
- Qualification project together with the supplier
- Validation and Start-up

eValidation – How to overcome Challenges with Paper-Based CQV Approches
Denis Dreher
- Experience and Challenges with Paper-Based CQV Processes
- Understanding the Concept of a Paperless Validation System
- Differences between electronic Document Management System and eValidation Systems
- Efficient implementation of an eValidation Tool – Strategies and Best Practices

Paperless Validation and Qualification System Implementation and Experiences
Saurabh Joshi and Alejandro Parisi
- Goal and Benefits
- Standardisation of business processes and templates
- Steps in order to choose the right system: from a User Requirement to a validated system
- Global rollout
- Practical examples

Feedback to the Integrated Qualification and Validation Guide
Ralf Gengenbach
- Open questions
- Outlook

Survey
Feedback from delegates on how to develop the Integrated Qualification and Validation Guide further on.

Speakers

Denis Dreher

Excyte

Denis Dreher (M. Sc. Informatics), Head of Department CSV Continental Europe at Exyte, has accumulated over 15 years of experience in national and international IT Compliance and CQV projects within the pharmaceutical and biotech industry. He is a PMI-certified project manager (PMP), a certified Information Systems Security Professional (CISSP) and a certified ISMS auditor according to ISO/IEC 27001.

Holger Frey

Roche Diagnostics

Dipl.-Ing. Holger Frey studied chemical engineering He was working for Merck KGaA in different positions (consultant for validations, GMP project, Head of Qualification) since 2003. Since 2023 he is senior qualification manager at Roche Diagnostics.

Ralf Gengenbach

Gempex

Ralf Gengenbach is founder and managing director of gempex Co. Ltd., Germany. He was active, among others in DIN UA2 (Board for standards 'biotechnology'), and DECHEMA. He is chairman of VIP3000 as well as of the ECA Validation Interest Group and has published many articles and a book about Qualification. He is still involved in many qualification projects for newly to build factories and active world-wide as 3rd party auditor.

Maik Guttzeit

Bayer

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, of ASME BPE Subcommittee on System Design and also of the ECA validation group. Since 2018 he is with Bayer AG, first as Global Technology Manager Aseptic and Sterile and in his current role as principal expert for C&Q concepts.

Gert Moelgaard

Moelgaard Consulting

Gert Moelgaard 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.

Alejandro Parisi

ROCHE Pharma Global

Alejandro Parisi is a chemical engineer and started his career in the Pharmaceutical Industry 25 years ago. He joined Roche Penzberg in 2004 as a qualification engineer and afterwards led the qualification & validation team for 7 years. Starting 2017 Alejandro moved to the global role “Validation Network Lead", responsible for the Roche Pharma validation and qualification activities including the introduction of a paperless software ("eVALRoche"). Now he is also the Business Process Owner for this system, representing all business processes and activities with the IT.

Saurabh Joshi

Valgenesis

Saurabh has over two decades of industry experience, he led quality in operations, qualifications-validations, QMS, centres of excellence, and consulting. Saurabh has studied pharmaceutical sciences and has worked with many renowned pharmaceutical companies. At ValGenesis, Saurabh uses his domain expertise to help customer and clients to unleash their true potential by going paperless and transition to Pharma 4.0 journey.

Dr Franz Schönfeld

District Government of Upper Franconia, Germany

Dr Franz Schönfeld is a GMP and GDP inspector at the local inspectorate for medicinal products and active substances of the District Government of Upper Franconia. He is head of the expert working group for APIs at the Central Authority of the Federal States for Health Protection.

Rafael de Souza

Pharmaplan

Rafael is MSc in Analytical Chemistry and is PMP certified. Since 2004, he has gained 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).

Good Practice Guide

All delegates receive the current Guide Version 2.2 with a lot of examples and templates.

Date of the Live Online Conference

Tuesday, 14 November 2023,
09.00 - 17.00 h
Wednesday, 15 November 2023,
08.30 - 12.30 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 € 1,590
APIC Members € 1,690
EU GMP Inspectorates € 895
Non-ECA Members € 1,790

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

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 for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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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Reservation Form (Please complete in full)

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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 July 2022).

German law shall apply. Court of jurisdiction is Heidelberg.

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