Qualification and Validation Forum

Release of ECA´s new Integrated Qualification and Validation Guide - Version 2.2

15-16 November 2022, Heidelberg, Germany

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

Highlights

- EU Regulatory Perspective
- ISPE Commissioning and Qualification Guide Parallels and Differences to ECA´s Guide
- How Suppliers work: GEP in Qualification
- Remote FAT/SAT
- Update Equipment Qualification according Categories
- Case Study Customer Supplier Cooperation – A Project Example from Merck Healthcare KGaA
- Update Electronic Documentation in Equipment Qualification
- Tutorial workshop on Trends in "Electronic Q&V Documentation"
- 3 C-Management
- Six essential Mistakes in Qualification

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

ECA Academy
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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 although a risk-based approach has been a regulatory expectation for years. Also, many companies have very little integration between their activities and suppliers' activities, so the overall qualification and validation effort is complicated, expensive and time-consuming. Only few companies have leveraged their qualification and validation programs to a fully integrated approach, as the EU Annex 15 and the FDA Process Validation guide emphasizes.

This Forum is about time saving integrated qualification and validation activities, where suppliers are an important factor in this modern approach.

A team of pharmaceutical companies, engineering companies and suppliers have developed and further optimized ECA`s Good Practice Guide "Integrated Qualification and Validation – a guide to effective qualification and validation based on Customer – Supplier Partnership". The guide considers feedbacks from regulators, the pharmaceutical industry and suppliers as well as practical experiences from real project cases. In this updated 2.2 version there are new aspects of data integrity when working with electronic documents, new examples to make the process on "how-to-do" ***the critical aspects risk assessments (CARA) easier to understand, improvements on illustration of remote FAT/SAT, as well as some new aspects in equipment categorization and setting-up a contract between pharmaceutical customers and suppliers. It is the endeavor of the expert team to keep the guide always up to date with the latest knowledge through newly gained experiences.***

The experts working on this guide will be present so participants will have the **opportunity to hear first-hand and to discuss the contents** and technical aspects of the guidance document, its scope and practical application. **Case studies** are presented to help better understand the content of the guide and its implementation. All delegates will receive the possibility to download the current guide free of charge . 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 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. Also addressed are pharmaceutical companies, API and excipients manufacturer and of course equipment suppliers and engineering companies.

Moderator

Ralf Gengenbach
Head of ECA´s Validation Group, Germany

Programme

Introduction to Integrated Qualification and Validation

Ralf Gengenbach

- Development of ECA´s Integration and Validation guideline until version 2.2
- What is new?

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

Dr Rainer Gnibl

- 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 Commissioning & Qualification Guide Version 2 (2019)

Jörg Zimmermann

- 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
- GAMP 5 2nd version

How Suppliers work: Good Engineering Practice in Qualification

Ralf Gengenbach

- 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?

Remote FAT/SAT

Rolf Bauer & Dr Clemens Borkenstein

- Definition, considerations and limits regarding remote testing
- Collaboration and alignment of equipment manufacturer and customer
- Checklist for preparations before / during and after a remote FAT
- Documentation of results and handling of deviations
- Show case project for remote test execution including "best of" video sequences

Equipment Categorisation – a Tool to streamline Qualification

Maik Guttzeit

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

Case Study Customer Supplier Cooperation – A Project Example from Merck Healthcare KGaA

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

Update Electronic Documentation in Qualification Projects

Igor Krasula

- Requirements for electronic documentation in qualification
- Requirements related to Data Integrity
- The ALCOA principle
- Case study

3 C-Management

Axel Heueis

- What does 3 C-Management mean?
- When to start with GMP?
- Ideal project course
- GMP-Doc´s interfaces
- Commissioning management slides

Overview about the Updates of the Working Groups

Speaker to be announced

- Contract group
- CARA group

Six essential Mistakes in Qualification

Ralf Gengenbach

Feedback to the Integrated Qualification and Validation Guide

Ralf Gengenbach

- Open questions
- Outlook

Tutorial Workshop

Panel discussions about the way to electronic documentation in qualification projects.

Speakers

Rolf Bauer

Syntegon

Rolf holds a degree in Chemical Engineering. After 8 years of working in the chemical and pharmaceutical industry, he joined Bosch (now Syntegon) in 2000, working in project management and eventually becoming head of the qualification/validation department.

Dr Clemens Borkenstein

Zeta

Clemens Borkenstein finished studies with a PhD in industrial biotechnology and is working in biotech industry since 2007. 2012 he joined ZETA and presently holds the function of Corporate Head of Quality Assurance and Qualification.

Holger Frey

Merck

Dipl.-Ing. Holger Frey studied chemical engineering He is working for Merck KGaA in different positions (consultant for validations, GMP project) since 2003. Since 2020, he has taken over the leadership of the qualification group within Pharma Technology as Head of Qualification.

Ralf Gengenbach

Gempex

Ralf Gengenbach is a chemical engineer with more than 30 years of practical experience in GMP and especially in the field of qualification and validation. He is founder and managing director of gempex GmbH, a global acting GMP consulting company. He is president of the VIP3000, an association for suppliers to the pharmaceutical industry. He was active for the development of technology as well as qualification relevant standards in different organisations, among others DIN UA2 (Board for standards 'biotechnology'), DECHEMA, and VCI. Besides many technical articles he has published a book about Qualification and Validation, published by Wiley and still serving as a basic standard. Since 2022 he has been the Chair of ECA's Validation Group.

Dr Rainer Gnibl

District Government of Upper Bavaria

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

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.

Axel Heueis

Drees & Sommer SE

Architect, Dipl.-Ing. Building Economics and Dipl.-Ing. Design (FH) is since 2001 with Drees & Sommer. He has worked in the Core Team Life Sciences and has become an Associate Partner since 2020. For more than 12 years he has experience in the project management of pharma production and lab building projects.

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.

Jörg Zimmermann

Vetter Pharma-Fertigung

Since November 2019, Jörg Zimmermann is Vice President, Vetter Development Service, External Affairs.

Social Event

On 15 November 2022, 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.

Date
Tuesday, 15 November 2022,
09.00 - 17.15 h
(Registration and coffee 08.30 - 09.00 h)
Wednesday, 16 November 2022,
08.30 - 16.30 h

All times mentioned are CET.

Venue
NH Heidelberg
Bergheimer Straße 91
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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, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

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.

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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