Equipment Qualification Forum

Release of ECA´s Qualification and Validation Guide - Version 3.0

05 - 06 November 2024, Heidelberg, Germany

All delegates will receive the current version 3.0 of ECA´s Qualification and Validation Guide

Highlights

- EU Regulatory Perspective
- Comparision of Equipment Qualification Guidelines
- Update CARA chapter
- Update Video assisted FAT/SAT
- Update Equipment Categories
- Overvies Electronic Documentation in Equipment Qualification
- Tutorial workshop Artificial Intelligence in Equipment Qualification"
- Strategies to plan qualification activities in Life Sciences Projects
- Audit and Inspection Findings regarding Equipment Qualification
- Case Studies

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 on 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 development of this revision the ECA has decided to offer this forum this year as an on-site event.

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 although a risk-based approach has been a regulatory expectation for years. Also many companies have very little integration between their activities and supplier´s 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 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 3.0 version, there are new examples to make the process on "how-to-do" ***the critical aspects risk assessments (CARA) easier to understand, improvements on illustration of video-assisted FAT/SAT, as well as some new aspects in equipment categorization. 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 and 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 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 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
Chairman of the Validation Group

Programme

Welcome and Introduction to Qualification and Validation
Ralf Gengenbach
- Development of ECA´s Integration and Validation guideline since version 2.2
- What is new?

Modern Qualification and Validation from an EU Inspector's View on Current Approach
Klaus Eichmüller
- Overview regulatory requirements
- Changes in Annex 15 for qualification activities
- In between: Cleaning Validation
- Process validation: Expections and weakness
- Perspective

Comparison of Equipment Qualification Guidelines – which one for which Purposes?
Ralf Gengenbach
- What is on the market regarding equipment qualification?
- What is mandatory and what is optional?
- How far are those guidelines and standards harmonized?
- Are there different guidelines for different purposes?

Update Critical Aspects Risk Assessment (CARA) Chapter
Rafael de Souza
- The CARA concept in the equipment qualification life cycle
- Comparison between Quality Risk Management and CARA

Video-assisted FAT/SAT – The Update in the Guide
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
- What is new in this chapter

Update 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
- What is new in the guide?

Electronic Documentation in Qualification Projects
Igor Krasula
- Requirements for electronic documentation in qualification
- Requirements related to Data Integrity
- The ALCOA principle
- Case study

Strategies to plan Qualification Activities in Life Science Projects
Pia Loris
- Qualification requirements in project plans
- GMP Qualification Requirements in Life Science Projects
- Potential Sources of Error during GMP Qualification
- Optimization of GMP Qualification Activities
- Examples

Audit and Inspection Findings regarding Equipment Qualification
Dominik Unglaub
- How deep is inspector's diving into the qualification topic?
- Which basic logic do they follow and which guidelines?
- Overview about some real inspection findings

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

Tutorial Workshop
Panel discussions about the possibilities of Artificial Intelligence 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 has been working in biotech industry since 2007. He joined ZETA in 2012 and presently holds the function of Corporate Head of Quality Assurance and Qualification.

Klaus Eichmüller

Hessian Office for Health and Care

After working in the pharmaceutical Industry Klaus Eichmüller joined the District Government of Upper Bavaria in Munich. Since 1996 he is working in the field of GMP Inspections of manufacturer of medicinal products and importers. He was Deputy Head of the Central Authority for Supervision of Medicinal Products in Bavaria" as long as it existed and has been Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hesse since March 2014.

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.

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.

Pia Loris

Drees & Sommer SE

Pia Loris has a degree in Chemical Engineering. She has a long-time experience (since 2007) with GMP projects regarding compliance, quality management and qualification activities for facilities, equipment, and rooms with Boehringer Ingelheim and Fresenius Medical Care Deutschland GmbH. She is a senior consultant working for Drees & Sommer since 2023.

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).

Dominik Unglaub

gempex

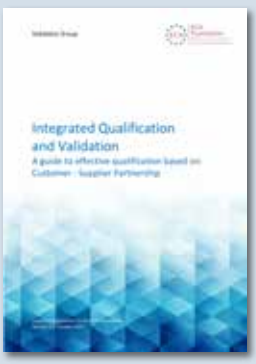
Dominik Unglaub is a trained pharmaceutical technician and “Industriemeister” He is with gempex in Switzerland since two 2 years. Dominik has been involved in the field of qualification dayly within his consulting activities He had the special opportunity to defend his qualification programs and concepts as part of various inspections.

Social Event

On 05 November 2024, 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.

Good Practice Guide

All delegates will receive the new version 3.0 of ECA´s Qualification and Validation Guide.



Date of the Conference
Tuesday, 05 November 2024,
09.00 - 16.30 h
(Registration and coffee 08.30 - 09.00 h)
Wednesday, 06 November 2024,
08.30 - 16.30 h

All times mentioned are CET.

Venue
Leonardo Hotel Heidelberg
Pleikartsförster Straße 101
69124 Heidelberg

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Email: info.heidelbergkirchheim@leonardo-hotels.com

Fees (per delegate plus VAT)
ECA Members € 1,690
APIC Members € 1,790
EU GMP Inspectorates € 945
Non-ECA Members € 1,890
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 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 – or search and register directly at www.gmp-compliance.org under the number 21670.

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 Manager)
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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)

Equipment Qualification Forum 2024
05 - 06 November 2024, Heidelberg, Germany

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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:
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- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
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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.

Privacy Policy: By registering for this event,
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