ECA Academy
Your GMP/GDP Information Source

Speakers

Aurélie Di Giovanni-Charpy
OM Pharma

Ralf Gengenbach
gempex

Rafael de Souza
Pharmaplan

Dr Alexander Sterchi
IE Industrial Engineering

Sebastian Zeller
Canexis Pharma

Lean Equipment Qualification

How to use ECA´s Equipment Qualification Guide for an efficient qualification

Live Online Training on 13 December 2022

Learn more about ECA´s Equipment Qualification Guide for an efficient qualification.

Highlights

- ECA´s Good Practice Guide Integrated Qualification and Validation
- Cooperation between customers and suppliers on Integrated Qualification and Validation
- ECA Q&V Guide and tools: Risk-based qualification from from URS to PQ
- ECA Q&V Case Study: Fast and effective project execution with suppliers

Case studies for the use of ECA´s Integrated Qualification and Validation guide

Objective

A team out of pharmaceutical companies, engineering companies and suppliers have developed ECA´s Integrated Qualification and Validation Good Practice Guide (GPG) over 4 years. Version 2.2 is published in autumn 2022. The key for a successful equipment qualification project is the "hand-in-hand" work from suppliers and customers together. With the integration of Good Engineering Practice (GEP) into qualification activities GEP-tests can be used also for the qualification phases – without repeated testing. This is one of the core concepts in the guide and benefit for the industry. With this course the practical "how to do" will be explained with "real-life" case studies.

Background

Thirty years after the coming into force of the EU GMP Guide in 1992 equipment qualification is still often a miracle. Qualification projects overrun scheduled time limits. Failures are discovered in the IQ and OQ exercises. To fix this and the deviation reports the time limits again have been extended. A non-harmonized terminology causes one of the main problems, especially when it comes to the integration of good engineering practice into qualification. But on the other side is the integration of good engineering practice activities a key factor for qualification in fast-track projects. How can this come together? This is the content of ECA´s Integrated Qualification and Validation Guide.

Target Audience

Everyone who may be influenced by the Annex 15 of the EU GMP Guide and FDA Process Validation Guidance regarding equipment qualification activities and want to see how the guide can be implemented in practice.

Moderator

Ralf Gengenbach, Head of ECA´s Validation Group, Germany

Integrated Qualification and Validation Guide

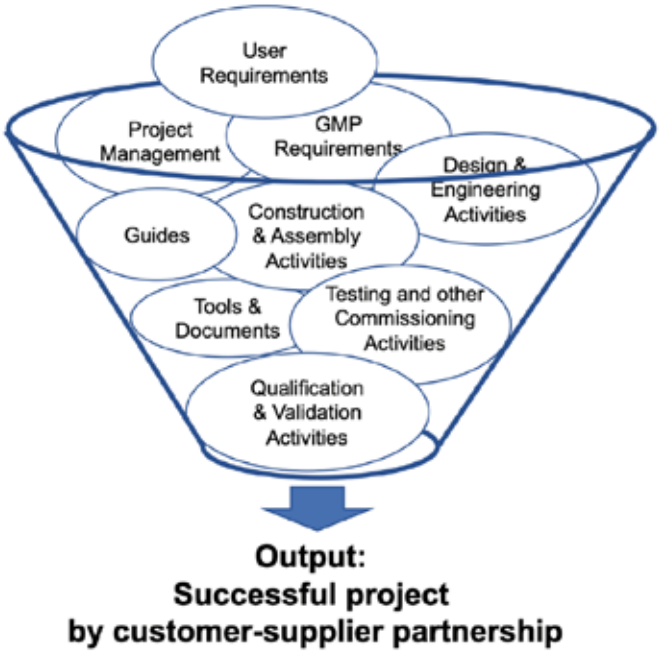
All participants of this course can download the new version 2.2 of the guide free of charge.

Programme

Overview: Integrated Qualification and Validation: Good Practice Guide from ECA

Ralf Gengenbach

- History of Qualification
- Why a new guideline?
- Main content and structure
- Comparison to other qualification guides
- The team behind



OM Pharma: Harvest Tank Case Study

Rafael de Souza & Aurélie Di Giovanni-Charpy

- Project introduction
- Lifecycle documents (QRA and URS)
- Cooperation supplier – customer
- Pros and Challenges
- Next steps

Case Study Canexis Pharma: Risk-based Lean Facility Qualification for a Cannabis Production Building

Dr Alexander Sterchi & Sebastian Zeller

- Lean, risk-based and integrated facility qualification
- Efficient collaboration between operations, facility design/construction and qualification experts
- Holistic support for facility design, utilization and operations
- Controlled environments for Cannabis extraction and isolation of compounds
- Combination of GMP and GACP requirements in one common building

Speakers

Aurélie Di Giovanni-Charpy
OM Pharma, Switzerland

With a general background in life sciences (biochemistry, microbiology), Aurélie has significant knowledge in qualification, validation in a highly regulated environment (biotechnology, pharmaceutical processes). She has 18 years of experience in project management, capex management and team management in the Pharmaceutical industry. Responsible for engineering and qualification of process equipment, she works on improving verification processes based on risk-based approaches by implementing the ASTM E-2500 standard for example.

Ralf Gengenbach
gempex, Germany

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. He has published beside many technical articles a book about Qualification and Validation, published by Willey and still serving as a basic standard. Since 2022 he has taken the chair of ECA's Validation Group.

Rafael de Souza
Pharmaplan, Switzerland

Rafael is MSc in Analytical Chemistry and is PMP certified. During his more than 18 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).

Dr Alexander Sterchi
IE Industrial Engineering, Switzerland

Alexander Sterchi is an industrial pharmacist and project manager for Qualification, Hygiene and Cleanroom topics at IE Industrial Engineering in Zurich. For over 20 years he was with F. Hoffmann-La Roche Ltd. in different local and global functions in operations and quality. He was as user representative for logistics, building and utilities during the planning and construction of a parenteral facility at Roche Kaiseraugst.

Sebastian Zeller
Canexis Pharma AG, Switzerland

Sebastian Zeller received his Bachelor of Science from the ZHAW (academic award: Dean´s List). Currently he is Chairman of the Board, Managing Director and Founder of Canexis. Before that he worked as laboratory technician (analytics, quality control, research and development) at Zeochem AG.

Your Benefit

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.


CERTIFICATE

If the bill-to-address deviates from the specifications on the right, please fill out here:

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Lean Equipment Qualification
Live Online Training on 13 December 2022

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
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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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
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 January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Tuesday, 13 December 2022, 13.00 – 16.45 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 € 490
APIC Members € 590
Non-ECA Members € 690
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 will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg
Germany
Phone +49(0)6221/84 44 0
+49(0)6221/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Sven Pommeranz (Operations Director) at
+49(0)6221/84 44 47, or at
pommeranz@concept-heidelberg.de.

For questions regarding organisation please contact:
Mr Maximillian Bauer (Organisation Manager) at
+49(0)6221/84 44 25, or at
bauer@concept-heidelberg.de.