ECA Academy
Your GMP/GDP Information Source

Speakers

Eva Baumgartner
Syntacoll

Dr Berthold Düthorn
Syntegon

Ralf Gengenbach
gempex

Gert Moelgaard
Moelgaard Consulting

Rafael de Souza
Pharmaplan

Effective Equipment Qualification according to Annex 15

by cooperation between pharmaceutical companies and suppliers

Live Online Training on 08 June 2021

All participants receive the ECA´s Integrated Qualification and Validation guide

Highlights

- ECA´s GPG Integrated Qualification and Validation
- How suppliers work: Good Engineering Practice in Qualification
- 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 of pharmaceutical companies, engineering companies and suppliers have developed ECA´s Integrated Qualification and Validation Guide over 3 years. Since autumn 2020 the version 1.0 is available. The key for a successful 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 retesting. This is one of the core concepts in the guide . With this course the practical "how to do" will be explained with "real-life" case studies.

Background

Almost 30 years after the coming into force oft he 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 extend the time limits again. 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 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 revision and FDA Process Validation Guidance regarding Qualification/Verification and Process Validation activities and want to see how the guide can be implemented in practice.

Programme

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

- Development of ECA´s Integration and Validation guideline
- Main content
- Comparision to other qualification guides

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

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

Speakers

Eva Baumgartner
Syntacoll

Eva-Maria Baumgartner studied biotechnology at the University of Applied
Sciences Weihenstephan-Triesdorf and has been with Syntacoll GmbH since 2004. She has managed various qualification and validation projects for the registration of new medicinal products, medical devices and combination products.

Dr Berthold Düthorn
Syntegon

The pharmacist Berthold Düthorn currently serves as Vice President within Syntegon with global responsibility for Validation and Compliance Services, Integrated SolutionsDigitalization Solutions and as General Manager of Valicare GmbH. He published several articles on isolation technology.For more than 20 years he is active in the area of clean room standardisation (ISO TC 209) .

Ralf Gengenbach
gempex

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.

Gert Moelgaard
Moelgaard Consulting

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.

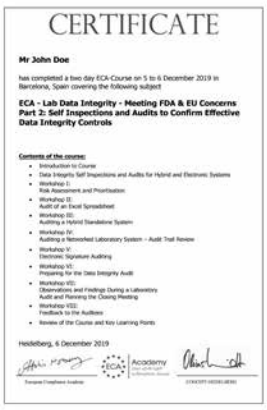
Rafael de Souza
Pharmaplan

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).

Your Benefits

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

Mr John Doe

has completed a two day ECA-Course on 5 to 6 December 2019 in Barcelona, Spain covering the following subject

ECA - Lab Data Integrity - Meeting FDA & EU Concerns Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

Contents of the course:

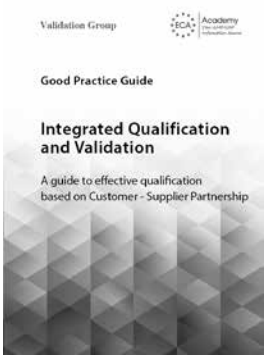
- Introduction to Course
- Data Integrity Self Inspections and Audits for Hybrid and Electronic Systems
- Workshop I: Risk Assessment and Prioritisation
- Workshop II: Audit of an Excel Spreadsheet
- Workshop III: Auditing a Hybrid Standalone System
- Workshop IV: Auditing a Networked Laboratory System – Audit Trail Review
- Workshop V: Electronic Signature Auditing
- Workshop VI: Preparing for the Data Integrity Audit
- Workshop VII: Observations and Findings During a Laboratory Audit and Planning the Closing Meeting
- Workshop VIII: Feedback to the Auditees
- Review of the Course and Key Learning Points

Heidelberg, 6 December 2019

ECA Academy

Guide to Integrated Qualification and Validation

All delegates receive the version 1.0 of ECA´s Integrated Qualification and Validation Guide– A guide to effective qualification based on Customer-Supplier Partnership with a lot of templates.



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CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Live Online Training: Effective Equipment Qualification according to Annex 15 by cooperation between pharmaceutical companies and suppliers on 08 June 2021

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:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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, 8 June 2021,09.00 – 17.15
All times mentioned are CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer 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 EUR 790,-
APIC Members EUR 890,-
Non-ECA Members EUR 990,-
For EU GMP Inspectorates, the participation is free of charge.
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.

Ordering a Recording

Independent from the Live Online Training Courses, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

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

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