ECA Academy
Your GMP/GDP Information Source

SPEAKERS

EVA BAUMGARTNER
Syntacoll

DR CLEMENS BORKENSTEIN
ZETA

FRANCO CASINELLI
Johnson and Johnson

DR BERTHOLD DÜTHORN
Syntegon

RALF GENGENBACH
gempex

DR RAINER GNIBL
GMP Inspector

PETER LARSSON
Novo Nordisk A/S

GERT MOELGAARD
Moelgaard Consulting, Head of ECA's Validation Group

ALICE REDMOND
Commissioning Agents

THOMAS RÜCKER
Letzner

Launch Conference

Final version: ECA's Integrated Qualification and Validation Guide

Working with Suppliers towards modern Qualification and Validation

All delegates receive the final Guide with a lot of examples and templates.

27/28 October 2020 in Berlin, Germany
or broadcasted live to your desk!

HIGHLIGHTS:

- Regulatory perspective from EU: view on Annex 15 and the integrated approach
- Customer and Supplier Cooperation: Integrated Qualification
- New ISPE Commissioning &Qualification guides: From version 1 (2001) to version 2 (2019) - and other related guides
- Panel Discussion ECA´s Integrated Qualification Guide vs ISPE GEP Guide
- Qualification terms (commissioning, verification…)– are Babylonian times back?
- Equipment Categorisation – one way to an effective qualification
- Qualification and Validation: An integrated approach
- 4 Case Studies
  - **How to Benefit from the Supplier and Customer/User Collaboration when proofing Equipment´s Fitness for Use**
  - **Water Systems**
  - **Risk Managed Qualification in Capital Projects**
  - **Update Transforming Novo Nordisk´s qualification and validation concept to focus on GEP and supplier collaboration**

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

Launch Conference – Final version: ECA's Integrated Qualification and Validation Guide

27/28 October 2020, Berlin, Germany

Welcome

This year is a special year and will be remembered for a long time. The **Covid-19 pandemic** is shaping our professional environment as well as our private lives. But life goes on.

Therefore the ECA has decided to offer this conference also as a Live Online Conference. All lectures and sessions of the conference will be held consecutively and can be attended by all participants - either directly on site in Berlin or live online at your screen.

Best regards,
Gert Moelgaard
Chairman of the Validation Group

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 become a regulatory expectation since years. Also many companies have very little integration between their activities, so the overall qualification and validation effort is complicated, expensive and time consuming. Only few companies have leverage 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. 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 conference.

The Conference 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 have further developed ECA`s Good Practice Guide "Modern Qualification" from the last years feedbacks from regulators, the pharmaceutical industry and suppliers are now integrated to improve the document to more needs of the users.. The revised guide "Integrated Qualification and Validation – a guide to effective qualification based on Customer – Supplier Partnership! will be presented in the final version.

The team behind the draft guideline will be present. Participants will have the **opportunity to review and discuss the contents** and technical aspects of the guidance document, its scope and practical application and to discuss. All delegates will receive a copy of the 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 Integrated Qualification.

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.

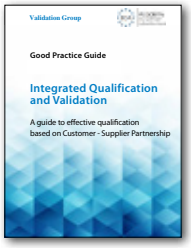
Moderator

Gert Moelgaard, Head of ECA´s Validation Group, Denmark

Programme

Introduction to Integrated Qualification and Validation

- Development of ECA's Integration and Validation guideline



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

- Qualification Life Cycle (Overview)
- Boundaries & Possibilities of Annex 15
- What is a must, what is a nice to have?
- Linking of Qualification & Validation possible?

A Qualification Case using elements of the new ECA´s Good Practice

- Content of the guideline
- about necessary activities and explanations/interpretations
- how to establish the basis for understanding of involved parties
- the success and the areas for impromvent in the future

ISPE Commissoning & Qualification Guide Version 2 (2019)

- Why to change the Baseline vers 1
- Key Aspects of the ISPE Guide
- How do they relate to each other

Case Study: Water System

- Risk workshop
- DQ the central qualification element
- GEP
- ECA-Guideline

Equipment Categorisation – one way to streamline Qualification

- Equipment categorization helps to select an appropriate effort for qualification activities and helps to avoid excess work
- What is the perfect timing for equipment categorization? during design phase in a customer supplier partnership
- Categorisation of Manufacturing Systems
- Questionnaire for a categorisation

Qualification terms – are Babylonian times back?

- What activities are required in qualification?
- What are the terms used for it (EU, US)?
- How are the different terms (FAT, SAT, Testing, Qualification, Verification) related?
- How to solve the problem in daily projects?
- The framework: Good Documentation Practice /Good Engineering Practice

Case Study: Risk Managed Qualification in Capital Projects

- Why does capital project delivery need to change
- What are the key principles of a project delivery
- How risk managed qualification is embedded in the Capital projects and what are the steps and relevant content (from requirement to release)
- How supplier can create value

Qualification and Validation: An integrated approach

- Process Qualification - the „marriage“ of qualification and process validation
- Development as basis
- Integration of critical process parameters into qualification
- The real goal is Process Validation/PPQ
- Key performance indicators

Case Study: Update – Transforming Novo Nordisk´s qualification and validation concept to focus on GEP and supplier collaboration

- The transition from Traditional qualification to a Science-and Risk-based integrated CQV process
- What is good quality in qualification and validation
- Core priniciples of Novo Nordisk
- Tailor-made project execution based on risk

Electronic Documentation in Qualification projects – first ideas

- Scanned classical paper qualification documentation vs. tests being prepared, excecuted and documentated in electronic format
- Requirements for electronic documentation in qualification

Feedback to the Integrated Qualification and Validation Guide

- Open questions
- Outlook

Panel Discussions
Panel discussions with regulatory authority and pharmaceutical industry ensure the transfer from theory into practice.

Speakers

EVA BAUMGARTNER
Syntacoll, Validation Manager
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 CLEMENS BORKENSTEIN
ZETA, Head of department Executive Quality
Clemens holds a PhD in industrial biotechnology. He has over 8 years of experience in pharma engineering, and is head of the department Executive Quality at the ZETA Group, responsible for Quality Assurance and Qualification.

FRANCO CASINELLI
Johnson and Johnson, Senior Manager Qualification
Franco Casinelli is Senior Manager Commissioning & Qualification, Johnson and Johnson - Engineering & Property Service Euro Platform. Franco is an electrical engineer and has 40 years experience in different pharmaceutical engineering contests. He was responsible in main projects as C&Q matter expert in EMEA and APAC.

DR BERTHOLD DÜTHORN
Syntegon, Vice-President Pagaging Technology
The pharmacist Berthold Düthorn currently serves as Vice President within Syntegon with global responsibility for Validation and Compliance Services, Integrated Solutions, Connected Industry Services 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, Managing Director
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.

DR RAINER GNIBL
GMP Inspector, District Government of Upper Bavaria, Germany, EU Inspector
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.

PETER LARSSON
Novo Nordisk A/S, Head of Engineering Management
Peter Larsson has a background as Operations Manager, Project Manager, Engineering Manager and Project Engineer within several companies in the pharmaceutical industry.

GERT MOELGAARD

Moelgaard Consulting, Head of ECA's Validation Group

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.

ALICE REDMOND

Commissioning Agents, Vice President Europe Operations at Commissioning Agents

Alice Redmond, has more than 29 years' experience in lifecycle management of pharma facilities inclusive of regulatory compliance, facility & process design, technology transfer, commissioning, qualification, and validation. Ms. Redmond worked for Sandoz/Novartis in Basel, Kundl and Ireland in the areas of quality, validation and technical operations. Alice holds a PhD in Cell Culture from Dublin City University.

THOMAS RÜCKER

Letzner, CEO

Thomas Rücker, born 1980 in Ludwigsburg, completed his master's degree in industrial engineering in 2005. In 2007, Mr. Rücker moved to Letzner Pharmawasseraufbereitung GmbH as project manager, where he switched internally to sales in 2010. Mr. Rücker became a managing partner in 2015.

SOCIAL EVENT

In the evening of the first conference day, 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.

GMP/GDP CERTIFICATION PROGRAMME

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

ECA Certified Validation Manager
ECA Certified QA Manager
ECA Certified API Production Manager
ECA Certified Quality Control Manager
ECA Certified Technical Operations Manager
ECA Certified Computer Validation Manager
ECA Certified Regulatory Affairs Manager
ECA Certified Microbiological Laboratory Manager
ECA Certified Sterile Production Manager
ECA Certified Biotech Manager
ECA Certified Pharmaceutical Development Manager
ECA Certified GMP Auditor
ECA Certified GDP Compliance Manager
ECA Certified Packaging Manager
ECA Certified Data Integrity Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Easy Registration

Reservation Form:
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69007 Heidelberg
Germany

Reservation Form:
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e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Tuesday, 27 October 2020,
09.30 – 17.30 h
(Registration and coffee
09.00 - 09.30 h)
Wednesday, 28 October 2020,
08.30 – 17.00 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Email berlin@steigenberger.de

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 all 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.

Conference language
The official conference language will be English.

For questions regarding content please contact:
Mr Sven Pommeranz
(Operations Director)
at +49-62 21/84 44 47,
or per e-mail at
pommeranz@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Julia Grimmer
(Organisation Manager)
at +49-62 21/84 44 44,
or per e-mail at
grimmer@concept-heidelberg.de.

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

CONCEPT HEIDELBERG
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D-69007 Heidelberg, Germany
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I will

- ☐ participate on-site in Berlin
- ☐ participate live online
- ☐ decide later

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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.

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