

NEW ECA DRAFT GUIDE



All delegates receive a first public draft of ECA's Modern Qualification Guide "Qualification – A guide to cost effective qualification based on Customer-Supplier Partnership" with a lot of templates.

SPEAKERS FROM EU AND FDA INSPECTORATE



DR RAINER GNIBL
District Government of Upper Bavaria,



GRACE MCNALLY
FDA, Senior Policy Advisor

INDUSTRY SPEAKERS



DR CLEMENS BORKENSTEIN
ZETA



FRANCO CASINELLI
Johnson and Johnson



DR BERTHOLD DÜTHORN
Robert Bosch Packaging Technology



MAREILE FUSS
Boehringer Ingelheim



MATHIEU MARROT
UCB



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



DR THOMAS SCHNEPPE
Bayer AG



STÉPHANIE SÉNÉCHAL
NNE



JESSICA WAGNER
GEA



SION WYN
Conformity Ltd

ECA Guide Launch Conference



Academy
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Information Source*

MODERN QUALIFICATION & VALIDATION

An effective, integrated approach to equipment qualification and process validation

11-12 September 2018, Berlin, Germany

HIGHLIGHTS:

- Regulatory perspective from an EU Inspector and FDA
- **Panel discussion with EU and FDA inspector**
- Cost-effective Modern Qualification
- Partnership between customer and supplier on qualification activities
- ECA's Good Practice Guide Modern Qualification: First Draft
- Integrating qualification into validation
- The URS as the key to successful Pharmaceutical Projects
- 3 Case studies on fast track execution projects
- **Workshop: The role of "Critical Aspects"**



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

Modern Qualification & Validation

11-12 September 2018, Berlin, Germany

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. 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 successfully integrated their qualification and validation programs, as the EU Annex 15 and the FDA Process Validation guide enables.

This Modern Qualification and Validation conference is about cost-effective and time saving integrated qualification and validation. Suppliers of equipment, facilities, engineering etc. can be an important factor in this.

A team of pharmaceutical companies and suppliers have developed a new ECA Good Practice Guide: "Modern Qualification – A guide to cost effective qualification based on Customer - Supplier Partnership". The first public draft of this guide will be presented.

The team behind the draft guideline will be present and there will be participants from regulatory authorities from EU and USA. 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. **Three case studies** regarding **fast track qualification projects and inspector's expectations** on such projects will also be presented.

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 developed a Good Practice Guide on Modern Qualification – A guide to cost effective qualification based on User-Supplier Partnership. This guide is supposed to assist pharmaceutical companies and suppliers with how to qualify in fast track projects. Like in the GAMP-Guide practical documentation, examples build the core of this Good Practice 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 an integrated approach to qualification and validation can enable successful fast-track.

Moderator

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

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.



Programme

Introducing the ECA Guideline: Modern Qualification - A guide to cost effective qualification based on Customer - Supplier Partnership

- Development of ECA's Modern Qualification guideline
- Content of the guideline
- Application of the guide by suppliers and users
- Fit into the GMP regulations
- Benefit for involved parties
- Outlook

Modern 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?

Modern Qualification and Validation from an FDA perspective

- FDA's Process Validation guide
- Process Validation as a life-cycle approach
- Lessons learned from the FDA Process Validation guide
- International harmonization of process validation?

Supplier Guidelines: The history of the GAMP Guide and its impact

- The need for guidance – objectives and drivers
- The Long and Winding Road
- Lessons learnt, and what the future holds...

Overview of current industry guidelines on Qualification and Validation

- ISPE Guides on C&Q, risk-based qualification and process validation
- GAMP® 5 guide on Computerised Systems
- PDA guides on process validation
- ECA guide on process validation

Qualification and Validation: An integrated approach

- PQ the „marriage“ of qualification and process validation
- Integration of critical process parameters into qualification
- The real goal is PPQ
- Key performance indicators in qualification and validation (Cm, CmK, Cp, CpK, Pp, PpK)

The role of the User Requirement Specification (URS) for successful pharmaceutical equipment projects

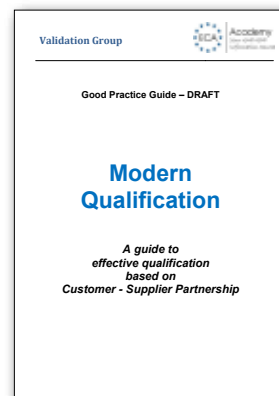
- Requirements for a successful URS
- The process from URS to approved design documents
- Important players during creation of URS and design documents
- Case study Octapharma Vienna

Good Engineering Practice – leverage the quality system of a good pharma equipment supplier

- What is GEP?
- GEP guidelines
- Commissioning vs Qualification
- GEP in the GMP environment

Case Study: Science and risk-based Commissioning and Qualification – J&J Pharmaceutical Plant in Xiang

- Project Overview – risk-based approach
- PPURS and URS
- Risk assessment
- Test matrices
- Commissioning
- Outcomes in numbers



Case Study: Verification approach as enabler of Fast track execution

- Risk-based approach
- Risk assessment defined for module
- Modularisation/bigger packages – less suppliers to audit
- No IQ/OQ performed – switch directly from SAT to PQ after verification
- Lessons learnt and room for improvement

Case Study: Fast track project executions

- Presentation of outline data and boundary conditions for fast track projects
- Important milestones in the project
- Objective for fast track project and determinations
- Success factors and challenges in the project

Workshop/Panel Discussion

A tutorial workshop about “Quality Risk Assessment and Critical Aspects” and a panel discussion with an EU Inspector and a FDA representative ensure the transfer from theory into practice.



Speakers



DR CLEMENS BORKENSTEIN
ZETA, Head of department Executive Quality



FRANCO CASINELLI
Johnson and Johnson, Senior Manager Commissioning & Qualification - Engineering & Property Service Euro Platform



DR BERTHOLD DÜTHORN
Robert Bosch Packaging Technology, Vice President Robert Bosch Packaging Technology



MAREILE FUSS
Boehringer Ingelheim, Head of Business Process Excellence/Strategic Projects



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GMP Inspector, District Government of Upper Bavaria, Germany



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GRACE MCNALLY
FDA, Senior Policy Advisor



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



DR THOMAS SCHNEPPE
Bayer AG, Corporate Function Process & Knowledge Management



STÉPHANIE SÉNÉCHAL
NNE, Office Manager & Senior Project Manager for Verification projects



JESSICA WAGNER
GEA Germany, Responsible for maintaining cGMP compliance of freeze dryers



SION WYN
Director, Conformity Ltd

WHAT ARE THE ECA FOUNDATION AND THE ECA ACADEMY?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website <http://www.gmp-compliance.org>

What Are the Benefits of ECA?

During the membership, you enjoy

- free access to the members' area where you always find the latest update of the "GMP Guideline Manager" online version – allowing you to access a GMP tree with guidelines sorted by topics or by authority. It lets you find relevant guidelines quick and easy. And as member you can also get to this detailed tree with the GMP WebApp on your smartphone or tablet PC.
- a 200,- Euro rebate for any ECA course and conference, plus the opportunity to complete the GMP Certification Programme with an internationally recognised certificate.

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.

LUFTHANSA IS MOBILITY PARTNER FOR ALL ECA EVENTS




As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!


*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

Easy Registration

 **Reservation Form:**
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

 **Reservation Form:**
+ 49 6221 84 44 34

 **e-mail:**
info@concept-heidelberg.de

 **Internet:**
www.gmp-compliance.org

Date

Tuesday, 11 September 2018,
09.30 - 18.00 h
(Registration and coffee 09.00 - 09.30 h)
Wednesday, 12 September 2018,
08.30 - 16.30 h

Venue

Steigenberger Hotel am
Kanzleramt Berlin
Ella-Trebe-Str. 5
10557 Berlin, Germany
Phone +49 (0)30 7407 43 - 0
kanzleramt-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.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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For questions regarding content please contact:


Mr Sven Pommeranz
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For questions regarding reservation, hotel, organisation etc. please contact:

Ms Susanne Ludwig
(Organisation Manager)
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ludwig@concept-heidelberg.de.

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

Reservation Form (Please complete in full)

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Modern Qualification & Validation

11-12 September 2018, Berlin, Germany

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

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 %
- until 1 weeks prior to the conference 50 %
- 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 HEIDELBERG will 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.

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