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## SPEAKERS



ROLF BAUER  
*Robert Bosch*



DR CLEMENS  
BORKENSTEIN  
*ZETA*



PETER WERNER  
CHRISTENSEN  
*Cook Medical, Senior  
Engineer*



KLAUS EICHMÜLLER  
*EU Inspector*



RALF GENGENBACH  
*gempex*



PETER LARSSON  
*Novo Nordisk A/S*



GERT MOELGAARD  
*Moelgaard Consult-  
ing, Head of ECA's  
Validation Group*



DR THOMAS  
SCHNEPPE  
*Bayer Bitterfeld GmbH*



DR CHRISTOPHER  
WATTS  
*VoPal*

# Launch Conference - ECA's new Integrated Qualification and Validation Guide

Working with Suppliers towards modern  
Qualification and Validation

8/9 October 2019, Berlin, Germany

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

## HIGHLIGHTS:

- Regulatory perspective from EU and FDA
- Panel discussion regarding EU and FDA requirements
- 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
- JETT Consortium – how to deal with example forms
- Equipment Categorisation – one way to an effective qualification
- Good Engineering Practice: A key to leverage the quality system of a good pharma equipment supplier
- Qualification and Validation: An integrated approach
- **2 Case studies:**
  - **Current FAT**
  - NEW** - **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](http://www.gmp-certification.eu)

# Launch Conference - ECA's new Integrated Qualification and Validation Guide

8/9 October 2019, 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 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.

This conference is 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 last year. 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.**

**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 and with JETT Consortium practical documentation, 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, Denmark, Head of ECA's Validation Group

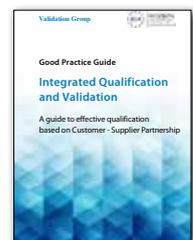
## Programme

### Introduction to Integrated Qualification and Validation

- Development of ECA's Integration and Validation guideline

### 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?



### Qualification and Validation requirements from a European inspector's view: Possibilities to integrate Qualification and Process Validation Activities

- Qualification and Validation requirements in EU Annex 15
- The importance of good cooperation between customers and suppliers
- Qualification observations from an inspector's view
- Possible problems in future?

### Introduction the ECA Guideline: Integrated Qualification and Validation - A guide to effective qualification based on Customer - Supplier Partnership

- Content of the guideline
- Application of the guide by suppliers and users
- Fit into the GMP regulations
- Benefit for involved parties

## Programme

### ISPE Commissioning & Qualification guides: From version 1 (2001) to version 2 (2019) - and other related guides

- What is ISPE?
- ISPE Baseline No 5 Commissioning and Qualification from 2001
- Bridging Baselines
- New ISPE Baseline No 5 Commissioning and Qualification, version 2 from 2019

### JETT Consortium – how to deal with example forms

- Origins of JETT
- Adoption of GAMP Guidance
- Initial Work
- URS Development Method
- Workers vs. Clingons
- Works Produce

### Equipment Categorisation - one way to efficient Qualification

- Equipment categorization helps to select an appropriate effort for qualification activities and helps to avoid excess work
- The perfect timing for equipment categorization during design phase in a customer supplier partnership
- Explanation of the 3 types of equipment categories for pharmaceutical industrial plants including practical examples
- Easy do-it-yourself categorization of pharma equipment depending on general quality risk impact), product and process critical aspects, technical, complexity of the process as well as supplier capabilities

### Good Engineering Practice – A key to leverage the quality system of a good pharma equipment supplier

- Key elements of GEP with relevance for GMP
- First approaches of ISPE and ASTM and their results
- How far suppliers are allowed to execute the qualification
- Some ideas how to integrate GEP documents best
- Why is there still a headache?



### Case Study: Current Factory Acceptance Test (FAT) – market approaches between tradition and state-of-the-art

- FAT requirements requested by User Requirement Specification
- Pre-requisites for FAT execution
- Implementation of FAT results into qualification
- FATs vs SATs
- Good practices for successful FATs

### Qualification and Validation: An integrated approach

- Process Qualification - 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)



### Case Study:

#### Transforming Novo Nordisk's qualification and validation concept to focus on GEP and supplier collaboration

### 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



### ROLF BAUER

*Robert Bosch, Head of department Qualification/Validation*

Rolf holds a Master Degree in Chemical Engineering. After 8 years working for the chemical and pharmaceutical industry he is since 2000 with Bosch working in project management and nowadays as head of the qualification department.



### DR CLEMENS BORKENSTEIN

*ZETA, Head of department Executive Quality*

Clemens Borkenstein has studied Food and Biotechnology at the University of Natural Resources and Life Sciences in Vienna, Austria (Universität für Bodenkultur Wien) and made his PhD in industrial biotechnology at the Max Planck Institute for Marine Microbiology in Bremen, Germany. 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.



### PETER WERNER CHRISTENSEN

*Cook Medical, Senior Engineer*

Peter Werner Christensen is actually a Senior Engineer at Cook Medical. As a specialist he is responsible for the Risk Management. He has an in-depth knowledge and understanding of the Medical Device and the whole pharmaceutical industry from more than 23 years in the field among Novo Nordisk and Cook Medicals. He is a worldwide speaker within the field of Pharmaceutical Engineering



### KLAUS EICHMÜLLER

*EU Inspector, Wolnzach c/o Regional Council Darmstadt, GMP Inspectorate, Germany*

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 is now Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hessen since March 2014.



### 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.



### PETER LARSSON

*Novo Nordisk A/S, Head of Engineering Management*

Peter Larsson is currently Head of Engineering Management in Novo Nordisk and the lead on implementing an integrated CQV model based on ASTM E2500. He has a background as Operations Manager, Project Manager, Engineering Manager and Project Engineer within 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.



### DR THOMAS SCHNEPPE

*Bayer Bitterfeld GmbH, GMP Projects*

Thomas has more than 30 years GMP experience in Pharmaceutical Industry: Qualified Person, Mgmt. Training, GMP Projects, Operational Excellence in different functions at Klöckner Pentapack, Schering AG, Asche AG, Bayer AG and actually Bayer Bitterfeld GmbH.



### DR CHRISTOPHER WATTS

*VoPal USA, Principle Consultant*

Chris Watts is a principal consultant within quality and regulatory, having gained experience both from industry and FDA. Chris was part of the team at the FDA that developed the Agency's modern approach to quality and compliance. These included the science and risk-based approach to cGMP inspection and CMC application review, including the recent ICH Quality guidelines and the FDA guidance on Process Validation.

## 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](http://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](mailto: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.

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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, 08 October 2019,  
09.30 – 17.30 h  
(Registration and coffee  
09.00 - 09.30 h)  
Wednesday, 09 October 2019,  
08.30 – 16.30 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](http://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](mailto: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](mailto:grimmer@concept-heidelberg.de).

### 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  
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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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