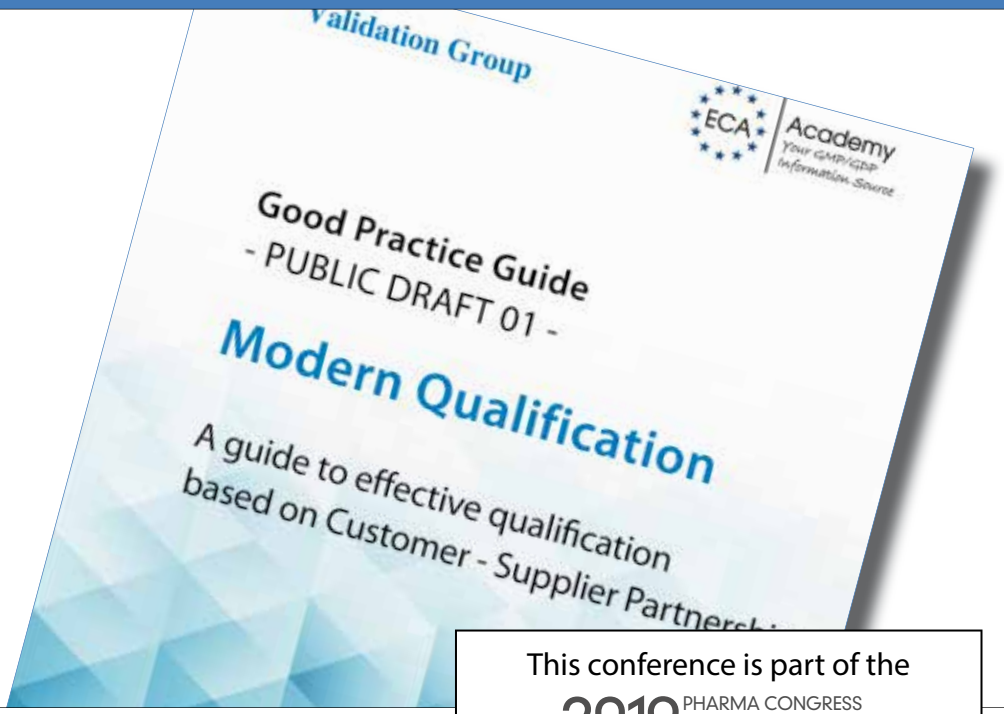
20 YEARS ECA Academy Your GMP/GDP Information Source

Modern Qualification



SPEAKERS


EVA-MARIA BAUMGARTNER
Syntacoll


DR BERTHOLD DÜTHORN
Robert Bosch Packaging Technology


KLAUS EICHMÜLLER
Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany


GERT MOELGAARD
ECA Validation Interest Group

This conference is part of the
2019 PHARMA CONGRESS Production & Technology
DÜSSELDORF, 9 - 10 APRIL 2019
www.pharma-congress.com

10 April 2019, Düsseldorf/Neuss, Germany

HIGHLIGHTS:

- Trends in Qualification and Validation
- Cost-effective Qualification and Validation
- European requirements for Qualification and Validation from an inspector's point of view
- Using the Modern Qualification Guide from a customer's point of view
- Integrated Qualification – how to leverage suppliers?

Modern Qualification 10 April 2019

Objectives

Pharmaceutical professionals and suppliers of equipment, systems and engineering to the pharmaceutical industry will get an overview of the "Modern Qualification" approach and the templates and examples for use in projects in the future. The course includes

- User Requirement Specifications
- Critical Aspects of manufacturing systems
- Good Engineering Practice and its influence to leverage qualification activities
- Cost-effective cooperation between suppliers and their pharmaceutical customers

Background

For pharmaceutical companies and suppliers to the pharmaceutical industry a good partnership on Testing, Qualification and Validation is increasingly important.

Project time and cost can be saved if the pharmaceutical requirements on Good Engineering Practices, Qualification and Validation are well known. Therefore ECA has developed a Good Practice Guide for "Modern Qualification" - a guide to effective qualification based on Customer-Supplier partnership.

The guide has been developed in partnership between pharmaceutical companies and suppliers of equipment, systems and engineering to the pharmaceutical industry. The first draft was made public at a conference in Berlin in September 2018 with participation from both European regulators and US FDA. This conference included a regulatory presentation on the Qualification and Validation expectations in Europe.

Qualification and validation have been mandatory activities for many years in the pharmaceutical industry. But new international regulations based on quality risk management principles can enable a better and more cost-effective approach to design, testing and documentation of supplier activities - in partnership with pharmaceutical customers.

You will get a free copy of ECA Good Practice Guide: "Modern Qualification – A guide to cost effective qualification based on Customer--Supplier Partnership.

Target Audience

Managers from the pharmaceutical industry and especially their suppliers of pharmaceutical equipment and services 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 projects

Moderator

GERT MOELGAARD, *ECA Validation Intrerest Group*

Programme

Congress Key Note

EU GMP Inspection in Sterile/ Aseptic Production

- Main focus areas of inspections
- Frequently detected findings
- Data Integrity issues – where are possible weak spots?
- Possible new areas due to the revision of Annex 1 and further regulatory changes

KLAUS EICHMÜLLER, *Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany – Head of Inspectorate*

Welcome and introduction to ECA Modern Qualification Guide

- ECA's Modern Qualification Guide
- Good cooperation between suppliers and customers - what works?
- What can a supplier do to enable cost-effective qualification projects?
- Trends in Qualification and Validation

GERT MOELGAARD, *ECA Validation Inrterest Group*

European requirements for qualification and validation

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

KLAUS EICHMÜLLER, *Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany – Head of Inspectorate*

Using ECA's Modern Qualification Guide as a pharmaceutical customer

- 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

EVA-MARIA BAUMGARTNER, *Syntacoll*

Integrated Qualification – Customer Supplier Collaboration as outlined in the new ECA Guideline

- Risk Assessment and Risk Management
- Specifications – task for both contractual partners
- Test documentation and execution
- Importance of Qualification Project Management
- Collaboration spirit as key success factor

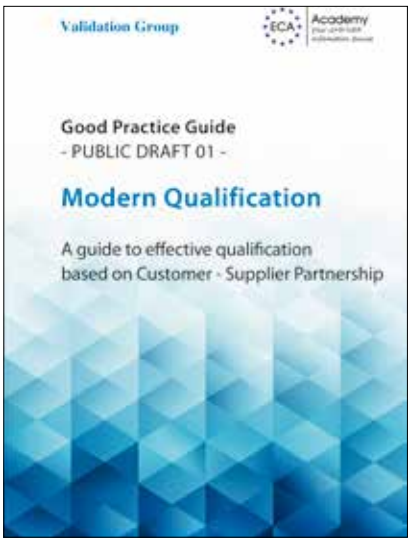
DR BERTHOLD DÜTHORN, *ECA Validation Interest Group*

Open discussion of ECA's Modern Qualification Guide and feedback to the next version

- The development of the Modern Qualification Guide
- Plans for a new Integrated Qualification and Validation guide
- ECA Conference with launch of the next version
- Feedback

GERT MOELGAARD, *ECA Validation Interest Group*

ECA Good Practice Guide: "Modern Qualification – A guide to cost effective qualification based on Customer--Supplier Partnership



Speakers

EVA-MARIA BAUMGARTNER, *Syntacoll*
She has been with Syntacoll GmbH since 2004 and has managed various and extensive qualification and validation projects for registrations of new medicinal products, medical devices and one combination product. In 2012, she was appointed validation manager and supports and leads projects for quality control, research & development and production. She has been a group member of the ECA task group "Modern Qualification" since 2017.

DR BERTHOLD DÜTHORN, *Robert Bosch Packaging Technology*
Vice President within the Robert Bosch Packaging Technology GmbH with global responsibility for Validation and Compliance Services, Integrated Solutions

KLAUS EICHMÜLLER, *Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany*
He was Deputy Head of the Central Authority for Supervision of Medicinal Products in Bavaria as long as it existed and has now been Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hesse since March 2014.

GERT MOELGAARD, *Chairman, ECA Validation Interest Group and Moelgaard Consulting*
Gert Moelgaard 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. Since 2015 he is Consultant. He is chairman of the ECA's Validation Group.

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.pharma-congress.com

Date
Tuesday, 9 April 2019, 09.00 – 17.45 h
Wednesday, 10 April 2019, 09.00 – 17.00 h
(Registration: Monday, 8 April 2019, 19.00 – 20.00 h,
Tuesday, 9 April 2019 & Wednesday, 10 April 2019, 08.00 – 09.00 h)

Venue
Crowne Plaza Düsseldorf / Neuss
Rheinallee 1
D-41460 Neuss, Germany
Phone: +49 (0) 2131 77 - 00
E-mail: emailus.neu02@gchhotelgroup.com

Fee
EUR 690.- per delegate and day plus VAT (EUR 1,380.- for both days) (due to the special congress fees, ECA membership discounts are not applicable, and participation does not entail ECA membership).
The conference fee is payable in advance after receipt of invoice and includes lunch on that day/both days, beverages during the event and during breaks as well as the Social Event on 9 April. VAT is reclaimable.

Your registration also entitles you to participate in all other Pharma Congress conferences on either day of your registration. For the other conferences on both days please visit www.pharma-congress.com.

Registration
Via the reservation form below, by e-mail or by fax message. Or you register online at www.pharma-congress.com.

PLEASE NOTE
Please note that there will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.

Please further note that there will be no room reservations via Concept Heidelberg. Please book your **hotel room directly with the reservation form** which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

Organisation & Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Phone: +49 (0) 62 21/84 44-0 | Fax: +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Andreas Mangel (Operations Director) at +49-6221/84 44 41, or per e-mail at mangel@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at +49-6221/84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

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

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

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

+49 6221 84 44 34

Modern Qualification (10 April 2019)
Part of the Pharma Congress Production & Technology 2019
Düsseldorf/Neuss, Germany, 9-10 April 2019

PLEASE NOTE:
Please book your hotel room directly with the reservation form which you will receive together with your confirmation/ invoice!

I register for:
☐ Modern Qualification (10 April 2019 – € 690)
☐ Both days (9-10 April 2019 – € 1,380)*

☐ Yes, I would also like to participate in the Social Event on 9 April.

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Please indicate the Purchase Order Number, if applicable

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-Mail (Please fill in)

* Please see www.pharma-congress.com for an overview of all conferences.

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 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)!
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.

wh/05022019