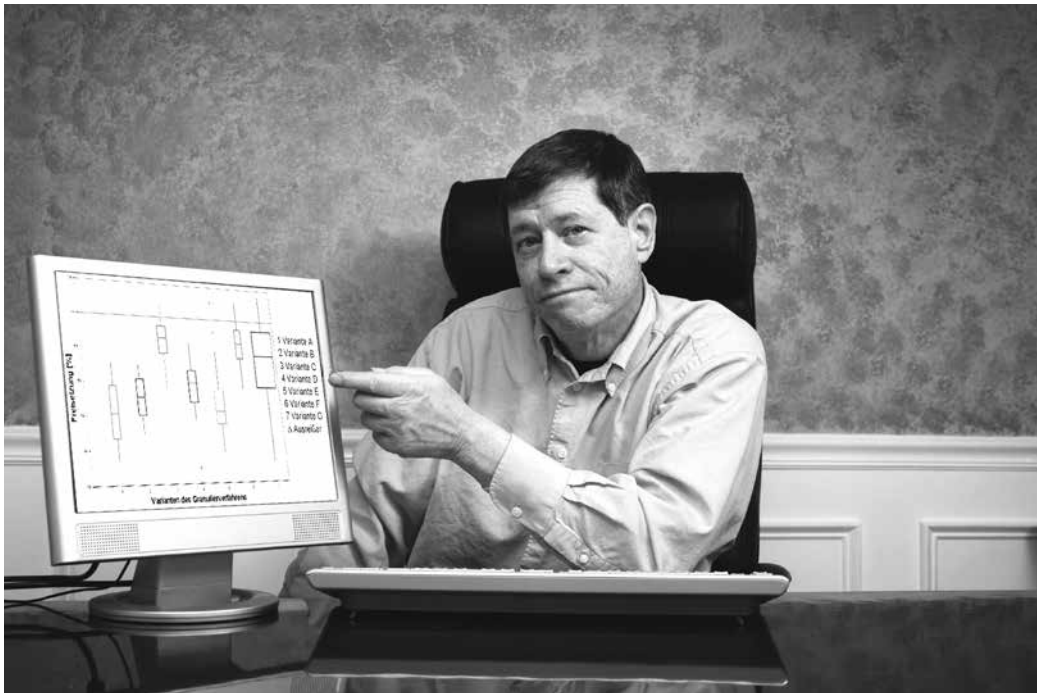
ECA Academy
Your GMP/GDP Information Source

GMP Webinar
Ongoing/Continued Process Verification

How to Implement it in Small and Medium-sized Companies

Date:
Wednesday, 3 June 2020, 14.00 -16.00 h CEST

Speaker:
Timur Güvercinci, Merck Healthcare KGaA, Darmstadt and self-employed GMP Trainer and Consultant



ECA has entrusted CONCEPT HEIDELBERG with the organisation of this webinar.

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de

Background
With the change of FDA´s process validation guideline from 1987 and the Annex 15 of EU GMP Guide, a validation life cycle entered the validation world. The development, the validation of the manufacturing process/ Process Performance Qualification (PPQ) and the Ongoing/Continued Process Verification are now the current validation stages. Especially the requirement for a stage 3 is a challenge for enterprises as this stage is new and did not exist before the validation life cycle. The Ongoing/ Continued Process Verification will substitute revalidation in most cases. It supplements the Product Quality Review (PQR) or Annual Product Review (APR), which is usually written in the USA every year. The FDA Process Validation Guidance requires statistically sounded data evaluated from a statistically trained person. Both in Europa and in the USA, this stage 3 is intended to show that the process is in "control of state". This applies to the single batches (intra-batch-variabilities) and to the comparison of single batches with each other (inter-batch-variabilities).This gives rise to a number of questions. Which data of a manufacturing process should be evaluated in an Ongoing/Continued Process Verification according to a rationale? How is the statistical sampling in this context? What statistical indicators are required? How can the requirements be implemented in small and medium-sized companies in a pragmatic way?

Educational Objectives
The following issues will be discussed:

- The Validation Life Cycle – FDA and Annex 15 requirements
- Specific characteristics of stage 3 Ongoing/Continued Process Verification
- What data have to be monitored?
- How to set up a statistical sampling plan?
- Statistical indicators for stage 3
- Proposals for implementaton for small and medium-sized enterprises
- Examples of FDA findings (Warning Letters)

Target Audience
Employees from companies, who are involved in pharmaceutical process validation activities (developers, QM, manufacturing, heads of validation departments, etc.) especially regarding stage 3 ongoing/continued process verification, are addressed. Of course consultants in this field, who want to get information from the view of the medicinal product manufacturers, are addressed too.

Speaker

Timur Güvercinci, Merck Healthcare KGaA, Darmstadt and self-employed GMP Trainer and Consultant
Timur Güvercinci is a pharmaceutical engineer by profession and has been working for more than 10 years in different quality functions for pharmaceutical and medical device companies. He is also a self-employed GMP Trainer and Consultant. Currently, he heads the QA Chemical Pharmaceutical Development at Merck.

Fees (plus VAT)
Single participation: € 199.- for ECA Members
Single participation: € 249,- for non-ECA Members
(This fee does not include the ECA Membership. You will find more about the ECA Membership at https://www.gmp-compliance.org/about-the-academy).

Participation of a Group
You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):
3-10 Persons € 211,15
11-20 Persons € 186,75
more than 20 Persons € 161,85

Registration
By mail, fax, e-mail or online on the Internet at https://www.gmp-compliance.org/. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

Technical Requirements
For our 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 email 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.

Presentation/Certificate
The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Do you have any questions?
For questions regarding content please contact:
Mr Sven Pommeranz,
phone +49(0)62 21 - 84 44 47,
Email: pommeranz@concept-heidelberg.de.

For questions regarding technical aspects please contact:
Ms Julia Grimmer,
phone +49(0)62 21 - 84 44 44,
email: grimmerconcept-heidelberg.de

Registration for the Webinar: "Ongoing/Continued Process Verification " on Wednesday, 3 June 2020, 14.00 -16.00 h CEST
Speaker: Timur Güvercinci, Merck Healthcare KGaA
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
☐ **Single Participation**
☐ **Group Participation**
  ☐ 3-10 Persons
  ☐ 11-20 Persons
  ☐ more than 20 Persons

Important: Deadline is 12 noon on 2 June 2020

Title, First Name, Last Name

Company | Department | VAT ID No. (mandatory)

Street | Postal Code/City

Phone | Fax

E-Mail (mandatory for your registration)

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 week 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.
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)!