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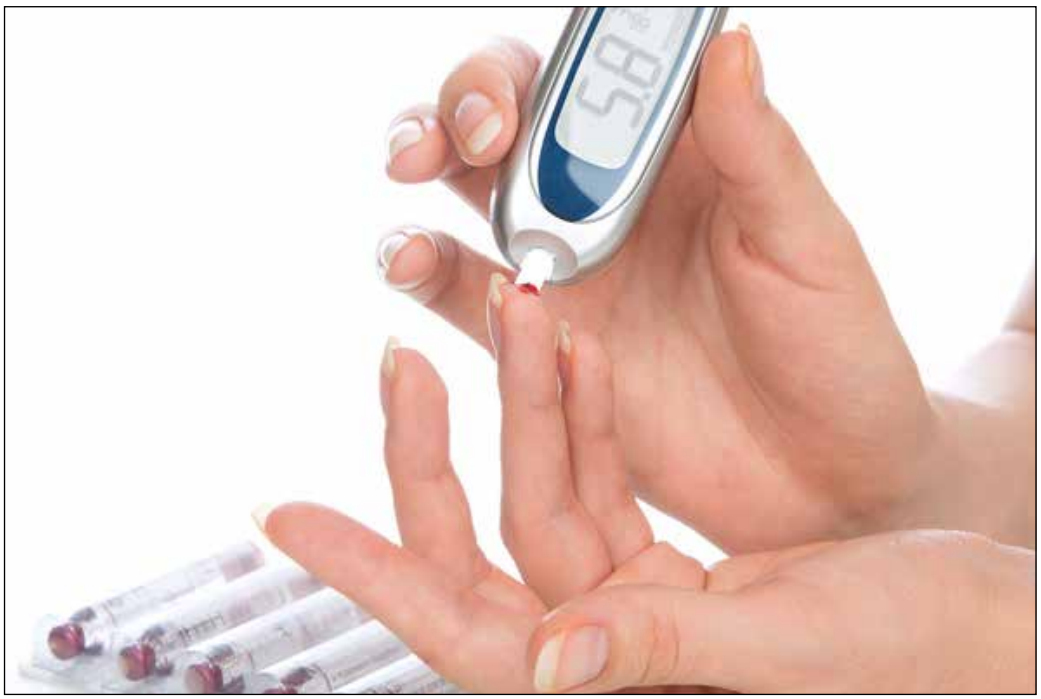
GMP Webinar
Process Validation regarding Medical Devices

Date:
Wednesday, 27 May 2020, 14.00 – 16.00 Uhr 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.

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Background
To show that a manufacturing process is reproducible is not only state of the art for medicinal products but also for medical devices. The regulatory requirements for process validation regarding medical devices are not as clear as those for medicinal products. There are very general requirements coming from ISO 13485 and from an old Global Harmonisation Task Force (GHTF) guideline dated 2004. Medical devices which are exported to the USA have to fulfil the process validation requirements from 21 CFR 820.75. But how to proceed process validaton in the medical devices industry today according to the state of the art that all requirements are met? Who is responsible for the process validation of medical devices? What documentation is necessary; what statistical indicators are helpful? Are there differences between medical devices and medicinal products? These questions will be discussed during the webinar. Additionally, warning letter findings due to process validation will be presented.

Educational Objectives
The following issues will be discussed:
- Overview regulations: ISO 13485, GHTF Guideline Process Validation, 21 CFR 820.75
- What manufacturing types have to be validated (decision tree)?
- Who is responsible for process validation?
- Appropriate risk management techniques
- Validation protocol, record, report
- Statistical indicators
- Similarities and differences regarding medicinal product requirements
  - Validation Life Cycle
  - Revalidation vs Ongoing/Continued Process Verification
- Examples of FDA Warning Letter findings

Target Audience
Employees from companies, who are involved in medical devices process validation activities (developers, QM, manufacturing, Regulatory Affairs, etc.) are addressed. Of course, pharmaceutical companies which use medical devices as part of a combination product are addressed too as well as consultants in this field, who want to get information from the view of the medical device industry.

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
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Group Participation (fee per person):
3-10 Persons € 211,15
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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.

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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.

Organisation/Contact
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Do you have any questions?
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Registration for the Webinar "Process Validation regarding Medical Devices" on Wednesday, 27 May 2020, 14.00 – 16.00 Uhr 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.

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Important: Deadline is 12 noon on 26 May 2020

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