ECA Academy
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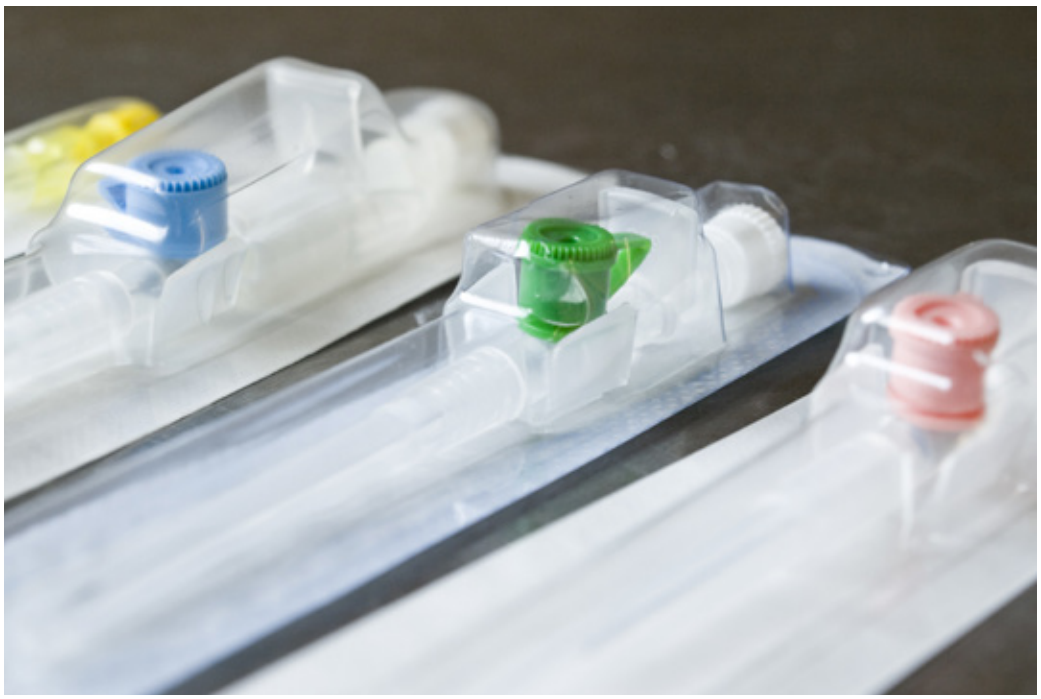
GMP Webinar
Consequences of the Postponement of the Medical Device Regulation

Date:
Thursday, 16 July 2020, 14.00 – 15.30 h (CEST)

Speaker:
Dr Gerhard Bauer-Lewerenz, Bauer-Lewerenz Consulting, Bad Homburg, Germany



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

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Background
Since the 1990s, Medical Devices (classical Medical Devices, active Medical Devices and IVDs) have been regulated under the three EU Directives (90/385/EWG/90, 93/42/EWG and 98/79/EG). Triggered by different implementations in the Member States and some incidents with Medical Devices, the new Regulation 2017/745/EU (Medical Device Regulation, MDR) was published. It contains a number of tightenings (e. g. UDI, market surveillance, new classification rules, etc.) and originally should have come into operation on 26 May 2020 after a three-year transition period. Once it has come into force, it will be directly binding for all Member States. There are transitional periods for Medical Devices which were placed on the market under the „old" Medical Devices Directives.

Due to the corona pandemic, however, the EU has decided to postpone the deadline for one year to 26 May 2021. What does this mean for the concerned companies? What are the consequences? Those who have already done all their "homework" can check everything again in a calmer manner. Those who were "just about to do it" will be given time to complete it. The notification of the Notified Bodies was behind schedule, there were "too few Notified Bodies for MDR". This can now be caught up.

Educational Objectives
This webinar informs about the chances the industry (and Notified Bodies) gets due to the postponement of the Medical Device Regulation. What are the main topics of the MDR? How can the additional time be used?
- Do a complete check
- Update the Technical Documentation
- Bring the risk analysis up to date (especially regarding missing or incomplete literature/preparing for the new ISO 14971)
- More Notified Bodies will get the necessary notification for the MDR; this will also give companies the necessary security
- Update Post-Market Surveillance (collection/evaluation of data)
- Finalise UDI issues
- Simplify forms and complete literature data
- Prepare for the next audits in a calmer manner

Target Audience
This webinar addresses people from the Medical Device Industry or those involved with Combination Products who are affected by the changes in the Medical Device Regulation.

Speaker

Dr Gerhard Bauer-Lewerenz, Bauer-Lewerenz Consulting, Bad Homburg, Germany
Dr Bauer has more than 25 years of professional experience in the Life Science Industry. He has experience as project manager, Head of Controlling, Head of Procurement, external and internal consulting (GMP Compliance), Audits of pharmaceuticals, medical devices, and API manufacturers in the EU, Asia, and the US.

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 € 211,65
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.

Organisation/Contact
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Do you have any questions?
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Registration for the Webinar "Consequences of the Postponement of the Medical Device Regulation"
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Speaker: Dr Gerhard Bauer-Lewerenz, Bauer-Lewerenz Consulting
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 15 July 2020

Title, First Name, Last Name

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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 %.
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