ECA Academy
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GMP Webinar
Serialization - Status & Aide Memoires for Inspections

Date:
Tuesday, 19 May 2020, 14.00 - 15.30 h CEST

Speaker:
Dr Ulrich Kissel,
European QP Association, KisselPharmaConsulting, Germany

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

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Background
Since 9th of February 2019 the Commission Delegated Regulation 2016/161 applies in the EU. With it the detailed rules for safety features on the packaging of medicinal products for human use are in place and need to be followed. Frequently updated Question and Answer documents have been published in addition to provide guidance. Moreover two Aide Memoires have been published in 2019:

- GMP INSPECTION OF MANUFACTURERS, and
- GDP INSPECTION OF WHOLESALERS

COMPLIANCE WITH COMMISSION DELEGATED REGULATION (EU) 2016/161 FOR SAFETY FEATURES.

Several months into the operational phase of the EU Verification System a significant number of manufacturers and supply chain actors have not yet connected to the system.

In addition, the Industry is still fighting with false alerts and most of the member states are still in stabilization phases. The EMVO report says that approximatively 1,5 - 3% of all scans undertaken by supply chain actors lead to false alerts being generated due to various reasons.

This Webinar will inform about the latest developments regarding the compliance with the Falsified Medicines Directive 2011/62/EU and its Delegated Regulation EU 2016/161.

Educational Objectives
Serialization - discussion and training / experience exchange on

- Status on serialization in industry and across EU
- The QP involvement into regulation 2016/161
- Issues and experiences (e.g. complaints & false alerts)
- Questions and Answers (Q&As) on Safety Features for Medicinal Products for Human use – What needs to be considered?
- Aide Memoire on Serialization (GMP-Inspections) – How to be compliant?
- Aide Memoire on Distribution and Warehousing (GDP-Inspections) - How to deal with suspected and confirmed falsified medicines?
- Potential further development – What you need to know

Target Audience
All actors of the supply chain (e.g. manufacturers, pharmacies, hospitals, wholesalers, dispensing doctors), as well as IT and engineering staff, responsible for the implementation or operation of the new systems are the target group of this event. The topics provided are also of interest for QA personnel dealing with alerts and complaints, QPs, suppliers of packaging (and authentication technology), and GMP/GDP Inspectors.

Speaker

Dr Ulrich Kissel, European QP Association, KisselPharma-Consulting, Germany
Ulrich Kissel is Qualified Person and Chairman of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

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 EUR 211,15
11-20 Persons EUR 186,75
more than 20 Persons EUR 161,85

Registration
By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. 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 GMP Webinar "Serialization - Status & Aide Memoires for Inspections" on Tuesday, 19 May 2020, 14.00 - 15.30 h CEST, Speaker: Dr Ulrich Kissel
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 18 May 2020

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