ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Packaging Manager

Speakers

Tobias Beer
EMVO, Belgium

Christian Jertrum
Hospitals Pharmacy Region Midtjylland (midt) Denmark

Dr Ulrich Kissel
EQPA, Germany

Dr Laura Ribeiro
OCP, Portugal

Dr Stephan Schwarze
Bayer, Germany

Steven De Strycker
Federal Agency for Medicines and Health Products, fagg, Belgium

Serialization – What's on

11/12 November 2020 | Hamburg, Germany

Highlights

- Delegated Regulation – Serialization & Anti-Tampering Device – Impact for the Pharmaceutical Industry & all Supply Chain Actors
- Regulatory Expectations
- The QP Involvement
- Experience on the Wholesaler and Hospital Pharmacy Scope
- View & Experiences of the EMVO
- Round Tables
  - Sharing of Practical Experience
  - Handling of Alerts / Deviations / Complaints/ Falsifications

How to comply with the Detailed Rules for Safety Features in Practice

Objective

It is the course's goal to inform about the latest developments regarding the compliance with the Falsified Medicines Directive 2011/62/EU and its Delegated Regulation EU 2016/161. Best practice examples will demonstrate how the requirements on verification of the authenticity of each single medicinal product can be fulfilled and false alerts can be managed efficiently. In addition, round table discussions will provide space for discussing open questions and sharing experience.

Background

Since 9th of February 2019 the Commission Delegated Regulation applies. 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. Data provided by the European Medicines Verification Organisation (EMVO) estimate that 40% of (theoretical) manufacturers as well as 25% of other supply chain actors (e.g. pharmacies, hospitals, wholesalers, dispensing doctors) have not yet connected to the medicines verification 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 3% of all scans undertaken by supply chain actors lead to false alerts being generated due to various reasons, such as:

- Missing data upload into the European Hub,
- Incorrect data upload,
- Incorrect scanner configuration of end-users,
- Pharmacy / hospital software systems not updated,
- Procedural reasons,
- System not used properly.

The training course will support you in collecting, sorting and proper understanding of the relevant requirements related to the defined safety features.
Practical examples will be presented and further discussed in corresponding workshops during this training course dealing with questions like:

- What are the challenges of the delegated regulation for safety features the supply chain actors are currently facing?
- What are the weak points of the current End-to-End verification system?
- How could a best practice process of suspected falsified medicines handling may look like?
- Do we need a new alert management system or will we use established quality systems?
- Is a modification of deviation management required?
- What to do if real falsification is the most likely conclusion?

Target Audience

Executive and operational managers of 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.

Moderator

Dr Stephan Schwarze

Programme

Delegated Regulation – Serialization & Anti-Tampering Device – What's in?

- Overview and context
- Requirements as defined in the Delegated Regulation
- What can be expected next?

Serialization - The Inspector's View

- Regulatory expectations
- Roles and responsibilities for implementation, maintenance, data upload & release
- Current issues: connections, false alerts

Serialization – Industry's Perspective

- Implementation challenges
- Reality check following February 9, 2019
- Current status
- Expectations from the industry's point of view

Serialization – The Perspective of the Qualified Person

- The QP involvement into regulation 2016/161
- Impact of safety features and serialization on certification
- Impact of Questions and Answers documents on serialization
- Data, data management and QPs
- QPs facing too many alerts
- The QP´s wish list on serialization

Serialization - Experience on the Wholesaler Scope

- How to deal with suspected and confirmed falsified medicines
- Who should manage communication with the end users
- Current issues

Experience with Serialization / FMD at the Hospital Pharmacy

- Alerts: When and how to approach the investigation of a suspected pack
- What should the end user do with the pack
- Current issues

View & Experiences of the EMVO

- Readiness and lessons learned of the European supply chain stakeholders
- Development of (false) alerts
- Stabilization periods across Europe
- Enforcement and inspections by National Competent Authorities

Round Tables

Some of the most important topics of this course will be further discussed.

Round Table(s) I
Sharing of Practical Experience

- Challenges at the packaging line
- Criminals taking advantage of the current situation?
- Alert handling process

Moderator: Dr Stephan Schwarze

Round Table(s) II
Handling of Alerts / Deviations / Complaints/ Falsifications

- Do we need a new alert management system or will we use established quality systems?
- Is a modification of deviation management required?
- Safety features and Serialization: How do they impact our complaint management systems?
- What to do if real falsification is the most likely conclusion?

Moderator: Dr Ulrich Kissel

Speakers

Tobias Beer, European Medicines Verification Organisation (EMVO), Belgium

Tobias has many years of experience in the pharmaceutical industry and has held various positions and roles. As Chief Operating Officer (COO) he is tasked with overseeing the day-to-day administrative and operational functions of the EMVO. In his previous positions at Boehringer Ingelheim and Germany's National Medicines Verifications Organisation (NMVO) Tobias was responsible for the development of business areas and the implementation of Directive 2011/62/EU.

Christian Jertrum, Hospitals Pharmacy Region Midtjylland (midt), Denmark

Christian is working as pharmaconomist in the purchasing department at Hospitals Pharmacy Region Midtjylland. He has got a lot of experience with Serialization / FMD at the Hospital Pharmacy at Central Denmark Region and he is a central person at the start-up both at midt and in national working groups where they planned the start in February 2019 for Hospital Pharmacies.

Dr Ulrich Kissel, European QP Association, KisselPharmaConsulting, Germany

Ulrich 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.

Dr Laura Ribeiro, OCP, Portugal

Laura is Head of Quality and Regulatory Affairs, managing a team of Responsible Persons and being responsible for the quality management system and continuous improvement of the company. She is also a member of the Board of Directors of the European GDP Association.

Dr. Stephan Schwarze, Bayer AG, Germany

Stephan is serving as Lead Counterfeit Protection at Bayer AG. Following his PhD in Pharmaceutical Technology he worked in several different areas of R&D and production at increasing management levels in the pharmaceutical industry. In 2005 he started to establish and constantly develop the function Counterfeit Protection Management for Schering and then Bayer. He is engaged in several working groups at international (e.g. PSI), European (e.g. efpia) and national level (e.g. DIN) collaborating in issues connected to anti-counterfeiting activities.

Steven De Strycker, Federal Agency for Medicines and Health Products, FAGG, Belgium

Steven is GMP Inspector at FAGG - Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten since 2014. Before that he worked in sterile manufacturing at MSD – Schering-Plough Labo nv in Belgium.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Serialization – What's on, 11/12 November 2020, Hamburg, Germany

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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Date
Wednesday, 11 November 2020, 09.00 to approx. 17.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 12 November 2020, 08.30 to approx. 15.00 h

Venue
Barcelo Hamburg
Ferdinandstr. 15
20095 Hamburg, Germany
Phone +49 (0) 40 22 63 62 0
Email hamburg@barcelo.com

Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch on both days and dinner on the first day and all refreshments. VAT is reclaimable

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Social Event
At the end of the first course day you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Conference language
The official conference language will be English.

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

For questions regarding content please contact:
Dr Andrea Kühn-Hebecker (Operations Director) at
+49(0)62 21/84 44 35, or at
kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Julia Grimmer (Organisation Manager) at
+49(0)62 21/84 44 44, or at
grimmer@concept-heidelberg.de.