ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Packaging Manager

Speakers

Dr Ulrich Kissel
EQPA, Germany

Martin Kühn
Meliscout, Germany

Emmanouela Nikolakopoulou
EMVO, Belgium

Dieter Mößner
Germany

Dr Laura Ribeiro
OCP, Portugal

Dr Franz Schönfeld
GMP Inspector, Germany

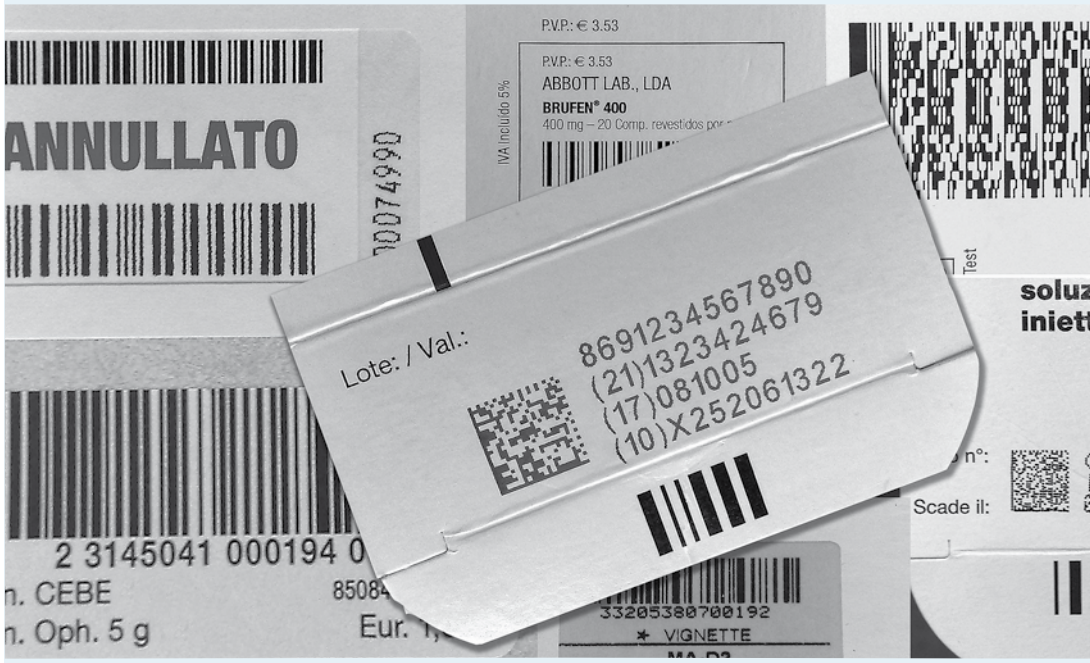
Dr Stephan Schwarze
Bayer, Germany

Wilfried Weigelt
REA Elektronik, Germany

Serialization/Aggregation –

Dealing with different global requirements

Live Online Training on 7/8 October 2021



Highlights

- EU: Delegated Regulation – Serialization & Anti-Tampering Device
- Regulatory Expectations
- The QP Involvement
- Experience & Challenges on the Wholesaler Scope
- Update of the EMVO
- Requirements in Russia and Brazil
- Coding: Russian KryptoCode / Japan & Others
- Track & Trace: Serialization & Aggregation
- Handling of Alerts / Deviations / Complaints/ Falsifications

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

Programme

Objectives

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, global aspects, like aggregation and the different types of coding will be covered.

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.

More than two years ago in 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 1,5 - 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.

This Live Online 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 Q&A sessions during this Live Online Training Course dealing with questions like:

- What are the challenges of the EU 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?
- Will aggregation soon be required in the EU?
- What are the requirements regarding serialization / aggregation on a global level?
- How to deal with the different global requirements in practice?
- 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?
- What to do if a 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.

Programme Day 1 - EU View

Provisional timetable, the actual schedule may vary depending on the situation

09.00 - 09.15 h Welcome/Introduction

09.15 - 10.15 h Delegated Regulation – Serialization & Anti-Tampering Device – What's in?

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

10.15 - 10.30 h Break

10.30 - 11.30 h Serialization - The Inspector's View

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

11.30 - 12.00 h Q&A Session 1

12.00 - 13.00 h Break

13.00 - 13.45 h Update 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

13.45 - 14.45 h 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

14.45 - 15.00 h Break

15.00 - 16.00 h 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

16.00 - 16.30 h Q&A Session 2

Programme Day 2 - Global View

09.00 - 10.00 h Track & Trace: Aggregation with Folding boxes, Bundles, Transport Packaging, Pallets

- Current requirements in Turkey, EU, France, Brazil etc.
- Practical examples of Track & Trace Systems (from Folding Boxes to Pallets)
- Case Study: Track & Trace Systems for Primary Packaging

10.00 – 11.00 h Coding: Russian KryptoCode/ Japan & Others

- Requirements & Practical Examples
- Printing, Coding & Control
- Scanning

11.00 - 11.15 h Break

11.15 - 12.15 h Serialization – Industry's Perspective

- Implementation challenges (EU)
- Current status (EU)
- Expectations & Global Challenges: Canada, Russia, Ecuador

12.15 - 12.45 h Q&A Session 3

12.45 - 13.45 h Break

13.45 - 14.45 h 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?

14.45 - 15.00 h Break

15.00 - 16.00 h Global View: Focus on Russia and Brazil

- Russian Serialization requirements
- Implementation and technical challenges
- Outlook on extension to additional products
- Brazilian Serialization requirements
- Serialization, aggregation and commissioning requirements
- Outlook – who's next?

16.00 - 16.30 h Q&A Session 4

Speakers

Emmanouela Nikolakopoulou, European Medicines Verification Organisation (EMVO), Belgium
Emmanouela is the Head of Legal and Partner Engagement and sole legal counsel of the EMVO. She is leading a dynamic team of young professionals focusing on business and project management activities as well as communications. She also provides senior management with legal advice, reviews and negotiates contractual and legal documentation and ensures EMVO's compliance with applicable legislation. Before joining EMVO in 2017, Emmanouela worked as legal counsel at SWIFT and the European Commission. She holds LL.M. degrees in Civil, Public and Competition law from universities in Athens, Aix en Provence and Brussels.

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.

Martin Kühn, Meliscout GmbH, Germany
Martin is currently Global Managing Director at Meliscout, where he is responsible for vision inspection solutions for the pharmaceutical industry. He has more than 15 years of experience with serialization/aggregation: starting with the first Bollini-applications in 2006, followed by installations in Turkey in 2010, to the nationwide roll-out in the US in 2017. During the last six years Martin was Managing Director for North America at Wipotec in Atlanta/USA.

Dieter Mößner, Essingen, Germany
Dieter is working as a Global Key Account Manager at a leading German manufacturer of packaging machines. Before that he was working as Project Engineer Pharma and Key Account Manager at a leading manufacturer of folding boxes and package leaflets for the pharmaceutical and cosmetics industries. Dieter had led projects in Braille application, serialization, tamper evidence and anti-counterfeiting of pharma and consumer goods packaging.

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 Franz Schönfeld, District Government of Upper Franconia, Germany
Franz Schönfeld is GMP Inspector and Head of the Expert Working Group for APIs and excipients at the German Central Authority of the Federal States for Health Protection (EFG 07/ ZLG).

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.

Wilfried Weigelt, REA Elektronik GmbH, Germany
Wilfried is Head of the department REA Verifier at REA Elektronik GmbH and has 20 years of experience in the business of automatic identification and data capture technologies. He has a strong expertise in bar and 2D codes, their print quality and data structures. Moreover, he is a member of the securPharm workgroup specifying the PPN Code as well as of the DIN standardization body NA 043-01-31 AA. He is also a member of the AIM ORM workgroup and of the GS1 working group AutoID.

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GERMANY

Reservation Form (Please complete in full)

Serialization – Dealing with different global requirements,
Live Online Training on 7/8 October 2021

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)

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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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)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Thursday, 7 October 2021, 09.00 to approx. 16.30 h
Friday, 8 October 2021, 09.00 to approx. 16.30 h

All times mentioned are CEST.

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At https://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.

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.

Registration

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

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.

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Your Benefit

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training...." This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

PE/23032021