ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Packaging Manager

Speakers


Daniel Dangl
AMVS


Volker Ditscher
WIPOTEC


Dr Ulrich Kissel
EQPA


Markus Medved
Swedish Medical Products Agency


Dieter Mößner
Packaging Expert


Dr Laura Ribeiro
OCP


Emil Schwan
Swedish Medical Products Agency

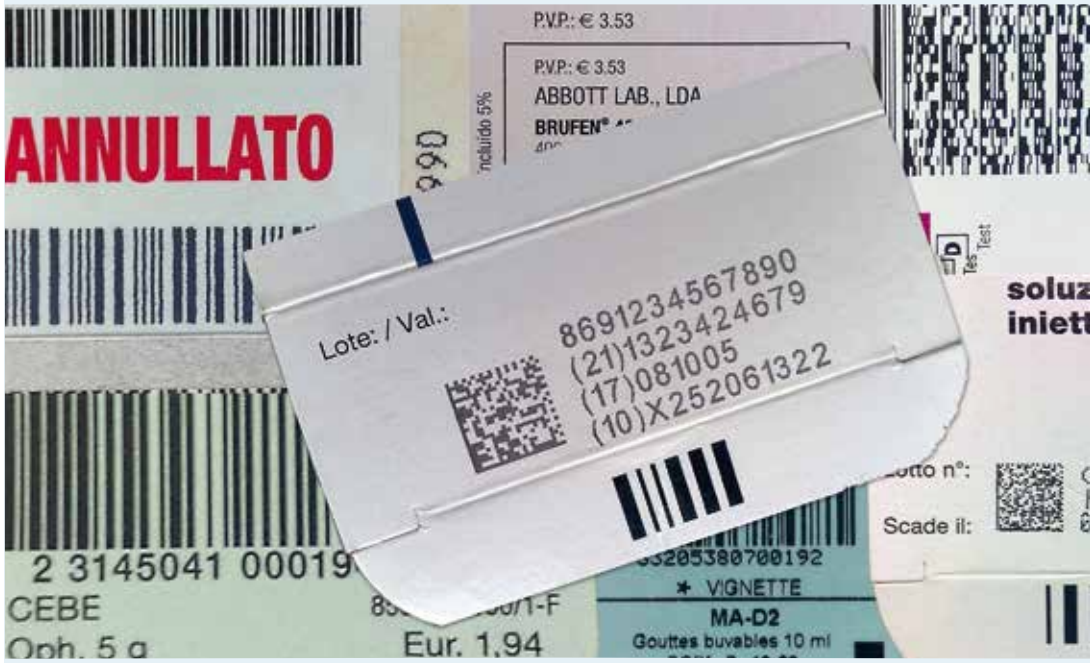

Dr Stephan Schwarze
Bayer


Wilfried Weigelt
REA Elektronik

Serialization/Aggregation

Requirements, Challenges & Solutions

Live Online Training on 23/24 October 2024



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

Highlights

- EU Delegated Regulation
- Regulatory Expectations
- The QP Involvement
- Experience & Challenges on the Wholesaler Scope
- View of an NMVO
- Coding: Practical Examples
- Track & Trace: Serialization & Aggregation
- Handling of Alerts / Deviations / Complaints/ Falsifications
- UDI Requirements for Medical Devices

With a view on the Requirements for Medical Devices

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 three Aide Memoires have been published for:

- GMP INSPECTIONS OF MANUFACTURERS,
- GDP INSPECTIONS OF WHOLESALERS,
- INSPECTION OF PHARMACIES

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

More than four years in the operational phase of the EU Verification System a significant number of manufacturers and supply chain actors have still not 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. Scans undertaken by supply chain actors often 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, 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?
- What are the requirements for Medical Devices?
- 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 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 devices, and GMP/GDP Inspectors.

Programme Day 1

EU FMD and Associated Regulations

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

Regulators' View

- GMP/GDP Regulatory expectations
- Approval of artwork and information
- Examples for "Artwork Errors" including not applying correct serialisation or uploading incorrectly

Q&A Session 1

Handling of Alerts: View of an NMVO

- Successful handling of alerts
- How the challenges regarding alerts are addressed
- How the stakeholders were brought on board
- How the number of alerts was brought under control

View of a Wholesaler

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

View of a QP

- 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?
- Impact of safety features and serialization on certification
- Data, data management and QPs
- The QP´s wish list on serialization

Q&A Session 2

Programme Day 2

Aggregation - Practical Examples: Aggregation with Folding boxes, Bundles, Outer Packaging, Pallets

- Selected regional requirements for Aggregation (e.g. Turkey, US, ...)
- Practical examples of Track & Trace Systems (from Folding Boxes to Pallets)

Coding: Practical Examples

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

View of a Pharma Company

- Implementation challenges (EU)
- Current status (EU)
- Expectations & Global Challenges

Serialization: Medical Devices

- Overview
- Requirements of the Medical Device Regulation (MDR)
- UDI (Unique Device Identification) and Eudamed Database
- Coding techniques for UDI
- Testing and verification of data

Q&A Session 3

Speakers

Daniel Dangl, AMVS, Austria
Daniel is working for Customer Management at the Austrian Medicines Verification System (AMVS). He is also Lector for Organic Chemistry at FH Campus Vienna (University of Applied Sciences). Previously he was Advisor GMP & Quality Operations at PHARMIG and Project Coordinator Production at MSD.

Volker Ditscher, WIPOTEC, Germany
Volker Ditscher has been working for the WIPOTEC Group since 2007. As a project manager, he has managed several hundreds of serialization and aggregation projects. Since 2011, Volker has been Business Unit Director and Director Global Sales Track & Trace for the corresponding product area at WIPOTEC worldwide.

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.

Markus Medved, Swedish Medical Products Agency, Sweden
Markus is currently working at the Swedish Medical Products Agency (MPA) as a case manager for exemption requests concerning exemptions from the requirements for labelling, safety features and package leaflet and also handling general questions that concern the product information of medicinal products. Prior to the MPA he was the senior quality responsible pharmacist for several pharmacies in the Uppsala region.

Dieter Mößner, Packaging Expert, 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.

Emil Schwan, Swedish Medical Products Agency, Sweden
Emil comes from the Swedish Medical Products Agency (MPA), where he spent eight years as a pharmaceutical inspector. As an inspector he inspected sites in Sweden and in countries outside EU, e.g. China, India, USA. He has GMP / GDP knowledge for both medicinal products and APIs. After working as a Senior Consultant for RegSmart Life Science AB, he returned as an inspector with the MPA in November 2021.

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 more than 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.

Participant comment:
„VERY wide and CLEAR PRESENTATIONS that cover all the main topics that we have to face."
Dr Annalisa Agnelli, IBSA Institut Biochimique SA, Switzerland - Live Online Training, October 2021

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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 – Requirements, Challenges & Solutions
Live Online Training on 23/24 October 2024

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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If you cannot attend the conference you have two options:
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- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Wednesday, 23 October 2024,
09.00 to approx. 17.00 h
Thursday, 24 October 2024,
09.00 to approx. 13.30 h
All times mentioned are CEST.

Technical Requirements

We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.
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 organisation please contact:
Ms Nicole Bach (Organisation Manager) at
+49(0)62 21/84 44 22, or at
nicole.bach@concept-heidelberg.de.

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