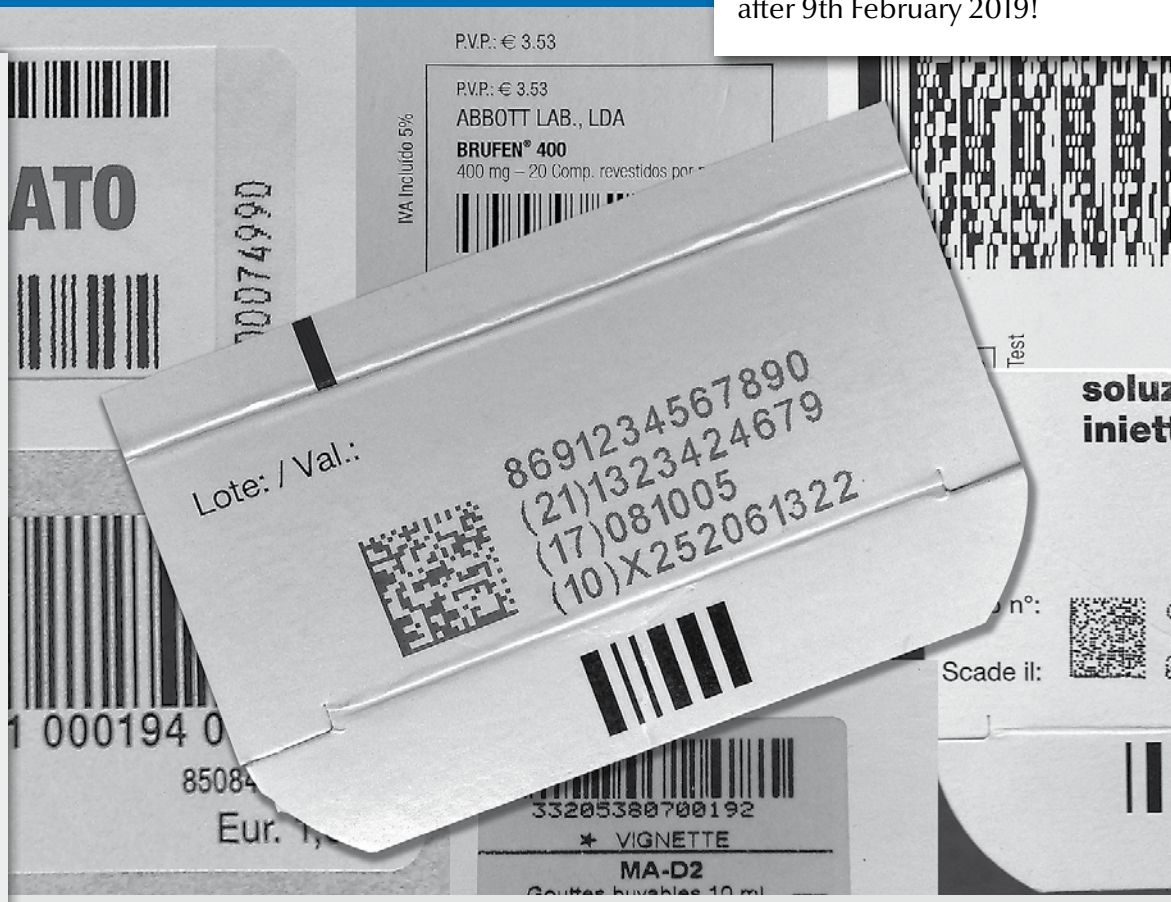
20 YEARS ECA Academy Your GMP/GDP Information Source

Track & Trace
Training Course

The Implementation Phase after 9th February 2019!



SPEAKERS:

Thomas Brückner
BPI Berlin

Maren Göpfert
Boehringer Ingelheim Pharma

Dieter Mößner
Edelmann GmbH

Dr Stephan Schwarze
Bayer AG

Wilfried Weigelt
REA Elektronik GmbH

Coding & Serialization: How to comply with the Detailed Rules of the Delegated Act for the Safety Features in Practice

26/27 September 2019, Prague, Czech Republic

PROGRAMME:

- Delegated Act for the Safety Features – Impact Assessment for the Pharmaceutical Industry
- Print Quality of Bar and 2D Matrixcodes
- Case Study: Implementation of Serialization and Aggregation – Challenges in Packaging and Supply Chain
- Case Study: Implementation of Serialization – Quality Relevant Aspects
- FMD and Delegated Regulation on Safety Features - Implementation in Europe and in the securPharm System
- DIN EN 16679 "Tamper Verification Features for Medicinal Product Packaging" – Practical Implementation including – Qualification
- ISO 21976 "Tamper Verification Features for Medicinal Product Packaging"

This education course is recognised for the ECA GMP Certification Programme „Certified Packaging Manager".
Please find details at www.gmp-certification.eu

Track & Trace Training Course

26/27 September 2019, Prague, Czech Republic

Objectives

It is the course's goal to inform about the latest developments in serialization & authentication coming from the EU directive 2011/62/EC and the corresponding Delegated Regulation as published in the Official Journal of the European Union. Best practice examples will demonstrate how the new European requirements on verification of the authenticity of each single medicinal product can be put into practice.

Background

Since **9th of February 2019 the Commission Delegated Regulation applies. Since then 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 to provide guidance.

Like many of such regulationS it is burdensome to read through these documents and sometimes it is also challenging to capture the relevant content. Key for a successful implementation of the applicable regulation is the understanding of what is really in there for you and what is actually relevant.

The training course will support you in collecting, sorting and proper understanding of the relevant contained information related to the defined safety features, which are

- a unique identifier and
- tamper evident closures

within the EU.

Practical examples will be presented and further discussed in corresponding workshops during this training course dealing with questions like:

- What is the impact of the delegated regulations for the safety features in the EU on the pharmaceutical industry?
- What does coding and serialization means for manufactures of printed packaging material?
- How is the code quality defined and how to test the appropriate code quality?
- Which kind of technical challenges have to be considered during the implementation of a serialization system?
- What are the relevant aspects to be addressed from a quality point of view?
- What are the challenges for manufactures since 9th February 2019?

Moderator

Dr Stephan Schwarze, Bayer AG, Berlin, Germany

Target Audience

Executive and operational managers of pharmaceutical companies, especially from packaging operations, as well as IT and engineering staff, responsible for the implementation or operation of the new systems are the target group of this event. Suppliers of packaging and authentication technology and pharmaceutical packaging companies are also welcome.

Programme

Delegated Act for the Safety Features – Impact Assessment for the Pharmaceutical Industry

- Which are the most relevant aspects?
- Consequences for the Pharmaceutical Industry – What are the experiences so far?
- Outlook – What else can be expected in this context?

Technical and Organisational Serialization Possibilities for the Pharmaceutical Manufacturer

- Serialization at the manufacturer of printed packaging materials
- Artwork changes, verification and approval
- Barcode specification and secure data transmission
- Inprocess controls and quality assurance
- Case Studies China, Korea, USA, EU, Russia
- End of line serialization at the pharmaceutical manufacturer
- Serialization at the contract manufacturer
- Experiences in implementation of the Delegated Act for Safety Features since 9th February

Print Quality of Bar and 2D Matrix Codes

- What does the EC Delegated act contain regarding Bar- and 2D Codes
- ISO Symbology and print quality standards (Bar- and 2D-Codes)
- What is GS1 Data Matrix, GTIN, NTIN, PPN?
- Testing of codes – why measure a code and not just scan?
- Meaning of measuring results
- China Code
- Experiences in implementation of the Delegated Act for Safety Features since 9th February

Case Study: Implementation of Serialization and Aggregation – Challenges in Packaging and Supply Chain

- Areas to be addressed: IT system – carton – processes
- Challenges in the implementation phase
- Equipment qualification/ process validation
- Packaging material management
- Impact on the Supply Chain

Case Study: Implementation of Serialization – Quality Relevant Aspects

- Data Handling – What is relevant, e.g. related to master data, CMOs, packaging, post release?
- In-Process-Control steps – Adaption necessary?
- Transparency and visibility of processes/behaviour – Any consequences?

FMD and Delegated Regulation on Safety Features - Implementation in Europe and in the securPharm System

- Current status of the implementation in Europe
- State and technical development of the "securPharm World" – news and background information
- Next steps and challenges in 2018 and beyond

DIN EN 16679 and ISO 21976 "Tamper Verification Features for Medicinal Product Packaging" – Practical Implementation

- Which safety features does the EU falsified medicines directive require?
- Which tamper verification guidelines / "standards" are available?
- Structure and contents of the European standard EN 16679 / technical characteristics of tamper verification features
- ISO 21976 "Tamper Verification Features for Medicinal Product Packaging"
- Conclusions / Recommendations for the Practical Implementation
- Qualification and Validation of tamper verification features

Discussion Forum
In addition, there will be a Discussion Forum at the end of day one where all delegates will have the opportunity to ask specific questions to benefit from the speakers' experiences in this field.

Topics that could be addressed are:

- Experiences with the FMD so far
- Alternative approaches / Backup plan: What should be done to secure the supply chain

Workshops
Some of the most important topics of this course will be further discussed in workshops or in interactive discussions.

Workshop I
Compliance with the requirements for Serialization – Quality Relevant Aspects
In this workshop participants will discuss the following topics:

- Serialization and Packaging Process – Which are the determining factors to maintain quality in course of packaging processes?
- Serialization and Quality – Which are the most important SOPs to be implemented immediately?
- Serialization and Complaints – How should a complaint handling concept look like to address serialization aspects appropriately?

Workshop II
Print Quality of Bar Codes and 2D Matrixcodes
The aim of this workshop is to evaluate how to measure the print quality:

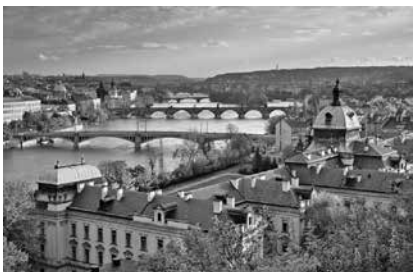
- What is the influence of properties of different print technologies to the code print quality?
- How to evaluate the ISO Data Structures (GS1, PPN, HIBC) used in Bar and 2D Codes?

Workshop III
Handling of Alarms

Participants will be able to attend all these three Workshops.

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.



Speakers

Thomas Brückner, *BPI (German Pharmaceutical Industry Association), Berlin, Germany*
Thomas Brückner [Dipl.-Pharm and pharmacist, health-care economist (ebs)] studied pharmacy at the Martin Luther University of Halle-Wittenberg. Since 2003 Head of "Pharmaceutical Affairs, Medical Devices, Pharmacopoeial Matters and Standardization" at BPI e.V., member in various DIN, CEN and ISO committees, the Board of Trustees of the Foundation for the Promotion of Standardization in the field of medicine, Member of the German Pharmacopoeia Commission, Chairman of the Board and the Executive Board of "securPharm e.V.".

Maren Göpfert, *Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany*
Maren Göpfert is a chemical engineer. She is Head of Product and Process Technology including packaging and device technology at Boehringer Ingelheim GmbH & Co. KG at Ingelheim site. She was previously Head of packaging solid forms at the Pharma Production Department. She also used to work in the automotive and aerospace industry at various positions including Production and Project Management and Engineering.

Dieter Mößner, *Edelmann GmbH, Heidenheim, Germany*
Since 22 years Dieter Mößner is working at Edelmann GmbH as technical project manager in PrePress and technical services. He is working with customers on artwork creation, serialization of folding boxes, tamper evidence and anti counterfeiting. He is leading national and European working groups in standardisation and is Chairman of the Packaging Standards Committee NAVp (www.navp.din.de) at the German Standards Institute DIN (www.din.de).

Dr Stephan Schwarze, *Bayer AG, Berlin, Germany*
Stephan Schwarze is Head of Counterfeit Protection Management at Bayer AG. The function belongs to Corporate Quality – Process and Knowledge Management. 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 had actively worked in WHO's IMPACT Technology Subgroup and served several years as technical advisor to the Board of PSI. Furthermore he is engaged in several working groups at international (e.g. Rx360), European (e.g. efpia) and national level (e.g. DIN) collaborating in issues connected to anti-counterfeiting activities.

Wilfried Weigelt, *REA Elektronik GmbH, Mühltal, Germany*
Wilfried Weigelt studied electrical engineering at the University of applied Sciences Wilhelmshaven. He is Head of the department REA Verifier at REA Elektronik GmbH, and has 20 year of experience in the business of automatic identification and data capture technologies, Excellent expertise about bar and 2D codes their print quality and data structures, Member of the securPharm workgroup coding to specify the PPN Code, Member of the DIN standardization gremium NA 043-01-31 AA, Member of the AIM ORM Workgroup and Member of the GS1 working group AutoID.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date

Thursday, 26 September 2019, 09.00 to approx. 16.45 h
(Registration and coffee 08.30 – 09.00 h)
Friday, 27 September 2019, 08.30 to approx. 16.00 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 (261) 191 111
email prague@corinthia.com

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845

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 with all further information when you have registered for the event. 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.

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
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Gerhard Becker (Operations Director) at
+49(0) 62 21 / 84 44 65, or per e-mail at
becker@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 per e-mail at
grimmer@concept-heidelberg.de.

Lufthansa is Mobility Partner for all ECA Events

Lufthansa Mobility Partner

As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – otherwise the booking platform window will not open.

If the bill-to-address deviates from the specifications on the right, please fill out here:

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Track & Trace Training Course
26/27 September 2019, Prague, Czech Republic

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number, if applicable**

Street/P.O. Box

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

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
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.