

SPEAKERS



NILS DICKFELD

Meliscout



MAREN GÖPFERT

*Boehringer Ingelheim
Pharma*



BUKET HEKIMAN

PharmaVision



DR HILTRUD HORN

*HORN Pharmaceutical
Consulting*



**DR CHRISTIAN
MAURER**

AbbVie



KONRAD STOECKLI

F. Hoffmann-La Roche



DR RENKE WILKEN

*Managing Director of
FFPI*

Serialisation & Authentication

Verification of the Authenticity of medicinal products according to Directive 2011/62/EC

14-15 April 2015, Berlin, Germany

HIGHLIGHTS:

- Current status and developments of the Regulations in EU and the Rest of the World
- Technology & Packaging Line issues
 - Requirements for online coding, printing & reading
 - System-Integration into packaging lines
 - Limitations for online printing
- Qualification / Validation of authentication systems
- Case Study Boehringer Ingelheim: Implementation in the packaging plant
- Case Study AbbVie: Routine Operation & the SecurPharm Project
- Case Study F. Hoffmann-La Roche: Implementation into the existing IT environment
- Case Study PharmaVision Five years of experience in Turkey
- Regulatory impact of the 2D barcode implementation: how to proceed in practice

Serialisation & Authentication

14-15 April 2015, Berlin, Germany

Objectives

It is the conference's goal to inform about the latest developments in serialisation & authentication coming from the EU directive 2011/62/EC. 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

The European Commission brought into force Directive 2011/62/EC already in 2011. The main goal is the fight against counterfeit medicines. Yet, it took several years - until the mid of 2014 - to define the technical characteristics of the unique identifier delivering the possibility of verification of the authenticity of single folding boxes in the delegated acts. Now, the unique identifier (UI) contains information on the:

- Manufacturer product code
- Serial Number
- National reimbursement number, if present
- Batch Number
- Expiry Date

The 2D barcode (data matrix) has been set as carrier of the unique identifier, a decision which did not come unexpected but quite late. As the new requirements will become active in 2018, it is high time to start equipping production/packaging lines with the necessary devices.

Several steps are necessary to implement a system compliant with the European requirements:

- Installation of a real-time coding, printing & reading (verifying) equipment to packaging lines
- Installation of a software system to supply and store completely unique product codes for each folding box
- Integration of local systems/databases with a centralised database on a national or European level

Several other countries have also started to run national or international systems. From their experiences can be learnt how to select and how to install the necessary equipment and how to overcome obstacles in the implementation and early operation phases.

The conference will cover the process of implementation and case studies with practical examples will be presented, dealing with questions like:

- What are the pre-requisites before starting to equip lines with coding equipment?
- What are the requirements of the IT infrastructure, the online-printing and the inspection equipment?
- How to implement these systems in a pharmaceutical environment?
- What can the IT architecture look like with regard to local and centralised databases?
- How have these systems to be qualified and validated?
- What has to be considered regarding the packaging material? Printability and regulatory impact of changing the imprint?

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.

Programm

Fundamentals and Regulatory Requirements

Serialisation & Track and Trace (T&T)

- Some history in Pharma-Track and Trace.
- Basics: Serialisation of cartons.
- Aggregation of cartons, bundles, cases, pallets
- EU regulations: the delegated acts
- Germany: Securfarm - GSI initiatives
- T&T updated position of the EU community
- T&T initiatives worldwide f.i. USA, China, Korea, Brazil etc
- Overview of suppliers for hard- and software

Regulatory Aspects for changing the Secondary Packaging (Barcode, Safety features)

- Regulatory Challenges for changes of packaging materials (EU/US)
- Update on relevant variations guidelines
- Strategies for internal & external implementation
- Process: Change Control vs. Variations
- Affected CTD parts
- Timelines
- Typical Examples

Technology: Packaging line issues

Pre-requisites for starting line upgrades for serialization

- Regulatory requirements
- Technical requirements
- Material requirements
- IT requirements

Printing codes and limitations for printing on folding boxes

A couple of years ago FFPI elaborated a specification for cardboard intended to be used for pharmaceutical boxes. Beside others the specification defined the preconditions that must be fulfilled by cardboard if codes mainly for serialization purposes have to be printed by means of water based ink-jet or laser-ablation in fast running cartoners. Several different cardboard grades are tested since that time on codability. It was found that about 25 % of all grades cannot be coded neither by water based ink-jet nor by laser-ablation. Only about 1 % of all grades are codable with both, water based ink-jet and laser-ablation. UV-curable ink-jet was tested as well. Limiting factor with this process is surface energy of the surface to be coded. The findings will be presented in detail and the reasons for poor codability will be discussed.

Case Study F. Hoffmann-La Roche

Integration of the new Serialization functionality into existing IT systems

- MDMS
- EAI
- Packaging Line
- Barcode readers
- Delivery chain network

Best Practice Examples – Case Studies

Case Study F. Hoffmann-La Roche

Qualification and Validation of Serialisation systems

- Governance for functional implementation and roll-out
- Delivery and cross-system validation
- Ownership of Validation deliverables

Case Study Boehringer Ingelheim

Product serialization and authentication – How to implement the new technology?

- Necessity of serialization & coding
- Our approach
- Challenges during implementation
- Dos and Don'ts

Case Study AbbVie

Implementation of the serialization concept in the routine operation

- Equipment used
- Involvement of AbbVie in the SecurPharm Project
- Learning from the SecurPharm Project
- Special Challenges in the routine operation

Case Study PharmaVision

Five years of experience with serialization and authentication in Turkey

- Scope and main characteristics of Track & Trace System in Turkey
- Regulatory aspects and timeline for implementation in phases
- Case study: Implementation at PharmaVision
- Frequently faced problems & Facts as of 2015
- Management assessment: Challenges & Proposed solutions

Speakers



Nils Dickfeld

Meliscout

Nils Dickfeld studied Optical Technology and Image Processing. He has been working for PCE as development engineer and headed the department for Printing Verification. In 2012 he founded Melibokus Startup Scout (Meliscout) focusing on image processing for the chemical and pharmaceutical industry.



Maren Göpfert

Boehringer Ingelheim Pharma GmbH & Co. KG

Maren Göpfert is a chemical engineer. She is Head of packaging solid forms at Boehringer Ingelheim GmbH & Co. KG at Ingelheim site. She was previously Head of the Industrial Engineering Team 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.



Buket Hekiman

PharmaVision San. ve Tic. A.S.

Ms. Hekiman studied Pharmacy and received her Executive MBA degree from Bogazici University. Her responsibilities at PharmaVision include Business Development and Product Transfers. She is the Secretary General of ISPE Turkey Affiliate since 2011 and is also Chair of ISPE European Affiliate Council for 2013-2014.



Dr Hiltrud Horn

HORN Pharmaceutical Consulting, Germany

Dr Hiltrud Horn is managing director of HORN Pharmaceutical Consulting. From 1990 to 1997, she was employed by Hoffmann-La Roche in QA/QC. From 1997 to 1999, she dealt with medical writing in the 'International Drug Regulatory Affaires' department of Roche. In 1999, she joined Knoll AG as head of the departments 'Regulatory Compliance and CMC Documentation' for international drug registration.



Dr Christian Maurer

AbbVie GmbH & Co. KG

Christian Maurer is a pharmacist and has been Product Manager QA and Group Leader of the TechCenter, Manufacturing Science & Technology at Abbott in Ludwigshafen. Today he is deputy operations manager of packaging at AbbVie (former Abbott).



Konrad Stoeckli

F. Hoffmann-La Roche

Konrad Stoeckli works for Roche since 2001. He has been Validation leader for SAP R/3 and was also responsible for the Consolidation Project of over 20 ERP systems in EMEA. Since 2011 he is in the Business Quality unit and responsible for almost all SAP systems of Roche Pharma: ECC, Aii/OER, BPM, MDM.



Dr Renke Wilken

Managing Director of FFPI

Dr Wilken began to work for PTS (Papiertechnische Stiftung) in 1979. He has been responsible for the paper processing technology, research and development, consulting and training. He prepared numerous experts opinions and directed a lot of advanced training events. More than 80 publications are the outcome of these activities. Dr Wilken retired in 2010. Since that time he is a freelancing consultant. He is still managing director of FFPI (Forschungsgemeinschaft Faltschachteln für die Pharmaindustrie).

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?



By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge.

More information about ECA Academy can be obtained on the Website <http://www.gmp-compliance.org>

What Are the Benefits of ECA?

During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

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- ECA Biotech Manager
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Easy Registration



Reservation Form:
CONCEPT HEIDELBERG
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69007 Heidelberg
Germany



Reservation Form:
+ 49 6221 84 44 34



e-mail:
info@concept-heidelberg.de



Internet:
www.gmp-compliance.org

Date

Tuesday, 14 April 2015,
10.00 to approx. 18.00 h
(Registration and coffee 09.30 – 10.00 h)
Wednesday, 15 April 2015,
08.30 to approx. 14.45 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Fax +49 (0)30 212 7-117



Fees (per delegate plus VAT)

ECA Members € 1,490
Non-ECA Members € 1,690
APIC Members € 1,590
EU GMP Inspectorates € 845
The conference fee is payable in advance
after receipt of invoice and includes con-
ference 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
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For questions regarding content:

Dr Robert Eicher (Operations Director) at
+49-(0)6221/84 44 12 or per e-mail at
eicher@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Marion Grimm (Organisation Manager)
at +49-62 21/84 44 18, or per e-mail at
grimm@concept-heidelberg.de.



Social Event

On 14 April, you are cordially invited to a
social event in Berlin. This is an excellent
opportunity to share your experiences with
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laxed atmosphere.

If the bill-to-address deviates from the
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Serialisation & Authentication

14-15 April 2015, Berlin, Germany

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Title, first name, surname

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