



EUROPEAN COMPLIANCE
ACADEMY

**WITH 12 SPEAKERS
FROM AUTHORITIES
AND INDUSTRY**

DR MARTIN FRIEDRICH
Bayer Technology Services
GmbH, on behalf of EFPIA

TOR GRÅBERG
Medical Products Agency,
Sweden

GERHARD HECKMANN
Abbott

ROLAND LÄNGLE
Uhlmann Pac-Systeme

DR FRANCOIS-XAVIER LERY
EDQM - European Directorate
for the Quality of Medicines
and HealthCare

GARY NOON
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JÖRG PRETZEL
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BO RAATTAMAA
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FRANK SCHMID
IBM

TULU VEYISOGLU
PharmaVision

SIMONE VOLDRICH
SCHOTT forma vitrum

DR RENKE WILKEN
PTS - Paper Technology
Specialists



The EFPIA Project
in Sweden

2nd European Conference on

Tracking and Tracing

Mass Serialisation to combat counterfeit medicines

16-17 June 2010, Stockholm, Sweden

HIGHLIGHTS:

- Regulations & Drivers for Mass Serialisation
 - Global Overview
 - The EDQM Track & Trace service
 - EU legislation - current status and impact
- Prerequisites for an harmonized European System
- Technology & Packaging Line issues
 - Requirements for online coding, printing & reading
 - System-Integration into packaging lines
 - Limitations for online printing
 - Laser Coding on glass
- IT considerations
 - Integration in existing IT systems
 - Total Project Costing
- Case studies and actual experiences
 - Experiences from Turkey
 - The EFPIA Pilot Project
 - Implementation at Abbott

Objectives

It is the conference's goal to inform about the latest developments in using mass serialisation to fight counterfeit medicines: progress in Europe and the USA, necessary technology, costs and implementation.

Background

Counterfeit medicines are undoubtedly a threat to patients and to the health of our society. The European Commission reacted in 2008, proposing possible legislative actions, which are still under discussion.

It is clear by now, that safety features for each individual package will become mandatory. The Commission proposed the usage of the 2D-Datamatrix-Code in a mass serialisation system. The European Federation of Pharmaceutical Industries and Associations (EFPIA) reacted by starting a pilot project in Sweden in the second half of 2009. First results are available now and look promising. Further experiences are available in Turkey where the official mass serialisation system with usage of the 2D-Datamatrix Code was also launched in 2009.

Several steps are necessary to implement such a system:

- Installation of a real-time coding equipment to production/packaging lines
- Installation of a visual inspection system to verify readability of the imprint
- Installation of a software system to supply and store completely unique product codes for each folding box
- Implementation of a centralised database connecting industry and pharmacies
- Installation of vision equipment in pharmacies to verify authenticity and to write back the issue of the folding box to the database

Several other countries also started to run local solutions, so there are **experiences to learn from**: how to select and how to install the necessary equipment and how to overcome obstacles in the implementation and operation phases.

The conference will cover the process of implementation and deal with questions like:

- How will Mass Serialisation go on in Europe? How in the US?
- What are the requirements of the IT infrastructure, the online-printing and inspection equipment?
- How to implement these systems in a pharmaceutical environment?
- How can these data be handled in existing production software?
- What can the IT architecture look like with regard to local and centralised databases?

Target Audience

Executive and operational managers of pharmaceutical companies as well as IT and engineering staff;
Suppliers of packaging and authentication technology and pharmaceutical packaging companies;
Regulating agencies affected by the EU proposal for safety features.

Moderator

BO RAATTAMAA
CEO GSI Sweden and Chairman GSI in Europe

Social Event

On 16 June 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 Exhibition

The European Compliance Academy offers you the opportunity to present your company, your products and services to your target group almost without any scattering losses. The costs for an exhibition space at this event are € 1,490 plus VAT. As an exhibitor, you are granted a 50% discount on the registration fee (for one person). You will find details and a registration form on our website www.gmp-compliance.org. Just follow the link "Conferences" and "Exhibition & Sponsoring" on the homepage.

Vision becomes reality - visibility and integrity in the pharmaceutical supply chain

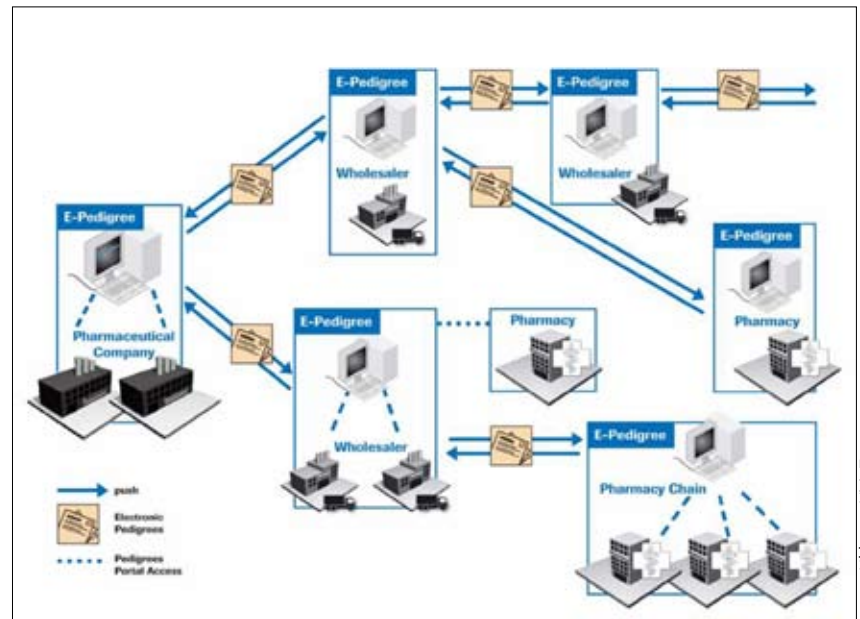
- Key Drivers for Tracking & Tracing
- Anti-counterfeiting – A serious / life-threatening problem
- GSI solutions and their values for traceability and anti-counterfeiting
- Global overview of the implementation of mass serialisation systems

EDQM Track and Trace service

- Existing systems in Europe: Different standards and issue of interoperability
- Definition of an Unique Medicine Identifier (UMI) per item
- Control function of EDQM
- Pack verification by query of UMI

Regulatory aspects regarding authentication and anti-tampering

- Impact to industry and retailers
- Current status for the EU legislative proposal



Technology: Packaging line issues

Practical aspects of track & trace: online coding, serialisation and product tracking

- Different requirements: online coding, serialisation, product tracking
- Solutions for integration into packaging lines
- Installation examples: Fully integrated from folding box to palletizing, manual operations, etc.
- Integration of tracking & tracing systems in MES and ERP

Limitations for printing on folding boxes

Online printing of folding boxes is an essential step in the implementation of a tracking & tracing system. It has to ensue fast and free of errors. But this is not possible for all available paper qualities of folding boxes. In this lecture the results of a study will be shown in which the online printability on different qualities has been investigated.

Laser Coding on Pharmaceutical Glass

- Goals and Challenges
- Coding Technology
- Reliable Identification
- Proof of Concept: a Case Study

Prerequisites for a harmonised European System

- Defining harmonised and non harmonised systems
- Is harmonisation necessary?
- Track and trace, traceability and authentication
- Prerequisites for successful harmonisation

Serial Track & Trace Solution - IT considerations and Total Project Costing

- Overview on standards, system architecture scenarios and required system components
- Integration with production line systems, i.e. MES, D2M-printing equipment
- Usage of the system and the data
- Overview on overall project costing



Best Practice Examples – Case Studies

Verification of Pharmaceutical Products at the Point of Dispensing - The EFPIA Concept

- The need for product verification
- EFPIA's approach to secure pharmaceutical products
- Results of EFPIA's pilot project
- Current developments

Case Study: Abbott

Implementation of a Tracking & Tracing System: Practical Aspects

- Track and Trace equipment for printing, verification and recording of serialized data
- Equipment and process for full automated lines and manual workplaces
- Reengineering of existing machines
- IT system: server, interfaces, network
- Validation and qualification aspects
- Impact on line performance, staff, OEE, set up and packaging material
- Lessons learnt

Tracking & Tracing Experience - Turkey

- Pharmaceuticals in Turkey – an Overview
- Regulatory Aspects and Timeline of Tracking & Tracing
- PharmaVision Track&Trace Application
- Reasons for Delay of System Application
- Actual Status – 2010
- PharmaVision's Response to Requests and Changing Conditions
- Management Assessment of the Situation

Speakers

DR MARTIN FRIEDRICH, *Bayer Technology Services GmbH*

Dr Friedrich studied control engineering and earned his PhD in the field of automation of chemical processes in 1993. He has held several positions within the Bayer Group, mainly in the fields of process operation and optimisation. At Bayer Technology Services, he leads a group that supplies solutions for the automation of intralogistics processes as well as Track & Trace applications. In 2009 and early 2010 he served as project manager for the EFPIA product verification pilot project.

TOR GRÄBERG, *Medical Products Agency Sweden*

Mr. Gräberg has been with the Medical Products Agency since 1996 as a Pharmaceutical Inspector with a focus on manufacturing of medicinal products both national and international. In 2004 he was appointed as Chief Pharmaceutical Inspector and Head of Drug Inspectorate. Mr. Gräberg is the Swedish representative within EMEA GMDP Inspection Working Group. Since January 2010 he is the Chairman of PIC/S (Pharmaceutical Inspection Co-operation Scheme). Before joining the MPA Mr. Gräberg was working as a production manager during 13 years in the pharmaceutical industry. He holds a M.Sc. degree in Pharmacy from the University of Uppsala, Faculty of Pharmacy.

Easy Registration



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Internet:
www.gmp-compliance.org

Date

Wednesday, 16 June 2010, 10.00 – 18.15 h
(Registration and coffee 09.30 – 10.00 h)
Thursday 17 June 2010, 08.30 – 15.45 h

Venue

Clarion Hotel Stockholm
Ringvägen 98, Box 20025
104 60 Stockholm, Sweden
Phone +46 8 462 10 00
Fax +46 8 462 10 99

Conference fees

Non-ECA Members € 1690.- per delegate plus VAT
ECA Members € 1520.- per delegate plus VAT
APIC Members € 1605.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates € 845.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days 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 when you have registered for the conference. Please use this form for your room reservation or be sure to

mention "VA 6465 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 14 May 2010. Early reservation is recommended.

Conference Language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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For questions regarding content:

Dr Robert Eicher (Operations Director) at +49-62 21/84 44 12 or per e-mail at eicher@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

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

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

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2nd European Conference on Tracking and Tracing

Stockholm, Sweden, 16-17 June 2010

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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 %

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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)!

Speakers (cont.)

GERHARD HECKMANN, *Abbott GmbH & Co. KG*

Gerhard Heckmann graduated in Electronics and has a degree in MBA. He joined BASF Pharma in 1988 and Abbott Global Pharmaceutical Operations in 2001. He is responsible for packaging engineering and maintenance at the manufacturing site in Ludwigshafen and leads the TPM group. Gerhard is core team member of the international Abbott Track and Trace program and managed the implementation in Germany.

ROLAND LÄNGLE, *Uhlmann Pac-Systeme GmbH & Co. KG*

Mr Längle studied Electrical Engineering with specialization in Automation Technologies. Since 2005 he works at Uhlmann Pac-Systems in Laupheim. He is head of the „Electrical Automation Projects“ department. Additionally he is the Product Manager of SCADA, BDE, Track&Trace Systems and customized software solutions for pharmaceutical packaging machinery.

DR FRANCOIS-XAVIER LERY, *EDQM - European Directorate for the Quality of Medicines and HealthCare*

Francois Lery is a pharmacist and holds a PhD from the University of Paris. He worked for the French Health Products Safety Agency and joined the European Directorate for the Quality of Medicines (EDQM) in 2001. He was seconded from the EDQM to the EMEA for the coordination of GMP inspections and also managing the collaboration between EU, US and Australia. Since 2009 he has joined back the EDQM with responsibilities for anti-counterfeiting projects i.e. Track & Trace of mass-serialised pharmaceutical items and API fingerprinting.

GARY NOON, *Aegate Ltd*

Gary Noon has 25 years' experience in the pharmaceutical industry, fulfilling a number of roles including senior positions in general management, marketing, business development and sales in the US and Europe. He has worked for many companies such as Roche, Bristol Myers Squibb, GlaxoWellcome and Warner Lambert and was President of IMS Health in the US. He has particular expertise in strategic marketing, supply chain management and product development and commercialisation. He now is CEO of Aegate Ltd.

JÖRG PRETZEL, *GSI Germany GmbH*

Jörg Pretzel graduated in Business Management at Munster university. Between 1981 and 1996 he held the post as CEO Central Europe and Vice President Sales at A.C. Nielsen. From 1997 to 2003 he worked as manager at Herlitz PBS AG and at Uvex GmbH. Since 2003 he is CEO of GSI Germany in Cologne.

BO RAATTAMAA, *GSI Sweden*

Bo has an education from Stockholm University and a background from food retailing and food service business in Sweden. He has had several high level positions in ICA, the leading food retailer in Sweden, as head of HR, head of IT, Head of Logistic development and CEO of ICA's food service company. Key experience are, how to manage and develop large IT and logistic systems. Today Bo is CEO, GSI Sweden. GSI Sweden has 9.000 customers in different sectors.

FRANK SCHMID, *IBM Deutschland GmbH*

Frank Schmid is Senior Managing Consultant at IBM Global Business Services. He is responsible as practice leader for Sensor Networks and Track & Trace Solutions. Since 2002 he is integrating solutions for different industries i.e. retail, pharma. For a German pharmaceutical manufacturer he designed and integrated a Serial Track & Trace System according to the requirements of the Turkish Ministry of Health

TULU VEYISOGLU, *PharmaVision San. ve Tic.A.S.*

Mr Veyisoglu studied chemical engineering in Istanbul and Leicester (UK). During his career he was Technical VP of Roche Istanbul and Technical Director of the Sandoz Plant in Istanbul. Since 2009 he is General Coordinator of PharmaVision. Mr Veyisoglu is founding member of the Turkish affiliate of ISPE.

SIMONE VOLDRICH, *SCHOTT forma vitrum ag*

Simone Voldrich is currently Projectmanager Product Development at SCHOTT forma vitrum responsible for Track and Trace solutions on pharmaceutical glasscontainers. Simone received her Bachelor in Evolutionary Biology in 2005 as well as her Master of Science specialized in Microbiology and has been with SCHOTT since 2008. Simone is responsible for a stable marking and identification processes combining quality requirements and glass relevant factors.

DR RENKE WILKEN, *PTS Paper Technology Specialists*

Dr Wilken is a jobs physicist and began to work for PTS in 1979. He is responsible for the paper processing technology, research and development, consulting and training. Moreover he is working in several German and European Committees for Standardization and gives lectures in the universities of Munich and Darmstadt