

The 4th University of Würzburg
Anti-Counterfeit Conference

Strategies against Falsified/ Counterfeit Medicines

How to Establish Anti-Counterfeit
Strategies in Pharmaceutical
Companies

26 - 27 May 2014,
Würzburg (near Frankfurt), Germany

SPEAKERS:

Frédéric Broise

EDQM, France

Brian Daleiden

TraceLink Inc., USA

Dr Martin Friedrich

Bayer Technology Services

Prof Dr Ulrike Holzgrabe

University of Würzburg, Germany

Patrik Merckell

Novartis Pharma AG, Switzerland

Jesus Rivas

Novartis Pharma AG, Switzerland

Johannes Schön

Boehringer Ingelheim

Dr Stephan Schwarze

Bayer Pharma AG, Germany

Lynda Scammell

MHRA, UK

Michael Wortmann

TAPA EMEA

HIGHLIGHTS:

- Current Challenges
- Setting up, Implementing and Running a Successful Global Anti-counterfeiting Program
- How to React when a Company Receives Information about Counterfeit Products
- Regulatory Perspective – MHRA
- EDQM Anti-counterfeiting Traceability Service for Medicines (eTACT)
- The European Stakeholder Model (ESM)
- Medicines Verification in Europe: Impact on Pharmaceutical Companies
- Implementing Machine Readable Codes on Primary Packaging Material and Devices
- How to Secure Final Dosage Form Transportation and Distribution
- Supply Chain Integrity for APIs and Excipients
- TAPA (Transported Asset Protection Association) – Benefits for Pharmaceutical Companies?
- FDA's Anti-Counterfeit Strategies – Update and Future Activities

Dear Colleagues,



It is a great pleasure for me to invite you to the 4th International Conference "Strategies against Falsified / Counterfeit Medicines" in Würzburg. After three successful conferences in November 2008, April 2010, and April

2012, this is the fourth conference on this topic supported by the University of Würzburg and the German Pharmaceutical Society.

Counterfeit APIs and medicines pose a growing threat to patients worldwide, with increasing numbers in Europe and the USA. Customs all over the world find more and more illegally produced drugs. And drugs are increasingly sold via the internet making it much easier to put counterfeits into circulation.

Thus, strategies against counterfeited medicines become more important. With this in mind, our this year's conference programme will focus on:

- The activities of the authorities to combat counterfeit medicine, for instance of the MHRA in UK
- Case studies for anti-counterfeiting strategies in pharmaceutical companies and how to react when a company receives information about counterfeit products
- Actual track&trace (T&T) developments in Europe: the European Stakeholder Model (ESM) and the EDQM traceability service eTACT
- Measures to secure transportation and distribution of pharmaceutical products
- FDA's anti-counterfeit strategies and current activities (FDA speaker invited)

The aim of this event is to provide a platform for interesting and interactive discussions with regulatory authority representatives, industry experts, university colleagues and delegates from suppliers of anti-counterfeiting products and systems to exchange experiences on the various aspects of anti-counterfeiting activities.

It will be a great pleasure for me to welcome you in Würzburg on behalf of the Institute of Pharmacy and Food Chemistry of our University.

Prof Dr Ulrike Holzgrabe
Chair of Pharmaceutical and Medicinal Chemistry
University of Würzburg

The University of Würzburg

With over 600 years of tradition, the Julius Maximilian University of Würzburg is today one of Germany's mid-sized universities. 400 professors in 10 faculties here teach roughly 24,000 students. The University of Würzburg is among the leading institutions of higher education in Germany; this has been confirmed by rankings carried out by national and international research organizations, international external assessment committees as well as by the German Federal and State Excellence Initiatives (founded in 2006). Internationally, the University of Würzburg is also one of the top-ranking academic institutions in many fields of research and study.

The German Pharmaceutical Society (Deutsche Pharmazeutische Gesellschaft)

The German Pharmaceutical Society (DPHG), founded in 1890 in Berlin, is one of the oldest German scientific societies (10.000 members). The aims of the DPhG are to promote the pharmaceutical sciences and interdisciplinary way of thinking, to encourage junior scientists within the pharmaceutical community, to maintain contact with foreign scientists and with foreign special societies, to facilitate transfer of new scientific knowledge into pharmacy practice, to advise legislative and administrative bodies on pharmaceutical matters and to establish position statements on pharmaceutical questions of public interest. <http://www.dphg.de>

The European QP Association

The European Qualified Person (QP) Association was founded in July 2006 by the European Compliance Academy's (ECA) Advisory Board Members. The European Qualified QP Association wants to provide QPs in Europe with a platform allowing them to exchange their experience, discuss the latest regulatory requirements, to identify and address difficulties and challenges and to support a harmonised European approach. <http://www.qp-association.eu/>

Media Partner

Anti-counterfeiting and supply chain security news from SecuringIndustry.com

 SecuringIndustry.com is a free-to-access information service that covers the issues surrounding supply chain and brand security. Our aim is to provide practical advice and intelligence to help manufacturers define and pursue their own strategies for tackling crime including counterfeiting, product diversion, adulteration and theft. We cover key developments in:

- coding and track-and-trace technologies;
- the evolution of data standards;
- overt, covert and forensic authentication systems;
- cargo thefts and shipment security;
- developments in the global regulatory environment;
- enforcement actions and case studies; and much more

The site incorporates breaking news and features, researched and written by specialist industry journalists and guest writers, as well as a regularly updated feed of external editorial from the world's press, a comprehensive and intuitive directory of security-related goods, technologies and services, plus the latest market research and events in supply chain security across multiple industrial sectors. Our editorial mission is to identify the most important and relevant information in supply chain security and bring it into one place for our community of readers, with the ultimate aim of helping to protect the rights and welfare of the public and the interests and reputations of commercial organisations. Website: www.securindustry.com

Strategies against Falsified/Counterfeit Medicines

26 - 27 May 2014, Würzburg, Germany

Objectives

The aim of this conference is to present both the regulatory authorities' activities and the pharmaceutical industry's activities to develop and establish appropriate counterfeit protection systems. The conference will focus on effective and affordable strategies, improve collaboration among regulators and pharmaceutical industry, and discuss actions in the global fight against counterfeit.

Background

According to the European Commission the risk that falsified medicines reach patients in the EU is growing every year. And also the EMA is aware of a remarkable increase in falsified medicines. Until recently, the most frequently falsified medicines in wealthy countries were expensive "lifestyle" medicines. Today, more and more medicines used to treat serious illness are now being falsified.

The EMA and the European Commission differentiate between falsified and counterfeit medicines. While **falsified medicines** are fake medicines that are designed to mimic real medicines including its ingredients, documentation and supply chain, **counterfeit medicines** are medicines that do not comply with intellectual-property rights or that infringe trademark law.

In the fight against counterfeit medicines the European Union published the **Directive 2011/62/EU about the prevention of the entry into the legal supply chain of falsified medicinal products** in July 2011. The aim of this Directive is to protect patients in the EU against falsified medicines. This includes:

- obligatory safety features on the outer packaging of the medicines (such as an individual code per pack)
- an EU-wide logo to identify legal online pharmacies
- stricter rules on the controls and inspection procedures of APIs and excipients (e.g. written confirmation since July 2013 for APIs)
- more stringent record-keeping requirements for wholesale distributors (see Good Distribution Practice Guideline, March 2013)
- obligation of the manufacturing authorization holder to immediately inform on any suspected falsified medicinal product

The related Delegated Act to this Directive with more specific technical details how to proceed related to the safety features is expected to be published in 2014.

In this context, the EFPIA has established a **European Stakeholder Model (ESM)**. The EMS is based on the concept that any medicinal product must be checked with its delivery (point of dispensing verification). The technical implementation is accomplished via the European Medicines Verification System (EMVS), which will enable the complete tracing of a medicinal product from the pharmaceutical manufacturer to the distributing pharmacy by means of using the 2 D Data Matrix Code.

In addition, an anti-counterfeiting traceability service proposal was launched in the EU by the European Directorate for the Quality of Medicines, **EDQM, known as "eTact"**.

Even though it is not sure which system will prevail, enough details are known now to get familiar with what is expected from pharmaceutical manufacturers to meet the requirements of the European Directive. And it is thus **the aim of this conference to highlight the requirements a pharmaceutical company has to fulfil today in order to be ready for the future European Verification System**.

Besides the European GDP Guideline requirements, more and more pharmaceutical companies are looking for new security standards for the transport of pharmaceutical goods. **TAPA's concept (Transported Asset Protection Association)** is one example, which will be addressed at the conference, too.

And also in the **US** the **"Drug Quality and Security Act"** was approved by the House of Representatives and by the Senate and President Obama signed the Act into law on November 2013. This act is supposed to protect consumers and improve security in the pharmaceutical supply chain and to prevent counterfeit medicines from reaching patients.

This conference intends to inform participants about the latest regulatory requirements in the EU and the US and about the measures the pharmaceutical industry has to take now to combat counterfeit medicines.

Target Audience

This conference is intended for people working in

- Packaging Development
- R&D
- Manufacturing / Packaging
- Quality Assurance / Quality Control (QPs)
- Purchasing and Materials Management
- Regulatory Affairs
- Counterfeit Protection Management

of pharmaceutical, biopharmaceutical and API manufacturing companies.

The conference is also intended for members of national or international authorities and for personnel working in Security Technology, and Packaging Components or Labelling companies.

Moderator

Prof Dr Ulrike Holzgrabe
University of Würzburg, Germany

Session 1 Introduction / Current Challenges

Introduction to the Conference

- Recent cases
- Current Challenges
- Drug Shortages

Prof Dr Ulrike Holzgrabe, University of Würzburg

Session 2 Track & Trace Implementation

EDQM Anti-counterfeiting Traceability Service for Medicines (eTACT)

- Traceability system
- European Directorate for the Quality of Medicines & HealthCare (EDQM)
- Interoperability
- Public governance
- Patient access
- EPCIS standards

Frédéric Broise, EDQM, France

Protecting Patients from counterfeited Medicines: The European Stakeholder Model (ESM)

- Stakeholders working together: Basic principles for cooperation
- Verification of medicines: Technology and system architecture
- Rights and responsibilities: Governance over the system
- Cost effectiveness: Drivers and estimates
- Status, timelines and outlook

Dr Martin Friedrich, Bayer Technology Services, Germany

Medicines Verification in Europe: Impact on Pharmaceutical Companies

- Global requirements for traceability of medicines
- To-Dos for commercial and manufacturing organisations
- Lessons learned: What can go wrong and how to avoid this

Dr Martin Friedrich, Bayer Technology Services, Germany

Reduction of Medicinal Errors by Implementing Machine Readable Codes on Primary Packaging Material and Devices

- Upcoming regulatory requirement: Korea, India, Belgium, USA, ... what is needed?
- Which technical solution fits best? Are static, variable or serialized code printing required? Unit of use?
- Which standards for datamatrix quality control should be followed? ISO 15415 vs. ISO TR 29158.

Patrik Merckell, Novartis Pharma AG, Switzerland

Session 3 Supply Chain Integrity Implementation

Supply Chain Integrity - Active Pharmaceutical Ingredients (APIs) and Excipients

- Regulatory Background
- Risk Assessment
- Supply Chain Qualification
- Monitoring and Control Processes

Jesus Rivas, Novartis Pharma AG, Switzerland

How to Secure Final Dosage Form Transportation and Distribution

- Assess your Risk: Theft - Diversion - Counterfeit
- Manage your Processes and your Logistical Service Providers
- Monitor the Situation: Information Sharing and Best Practice

Johannes Schön, Boehringer Ingelheim

TAPA Transported Asset Protection Association - How a Standardized Partnership between Supply Chain Stakeholders can Mitigate the Risk?!

- The current supply chain situation
- The Threat
- Some Examples
- Mission, Vision & Objectives
- Services & Certifiable Standards
- Achievements & Benefits for Members
- Outlook

Michael Wortmann, TAPA.EMEA

Session 4 Necessary Measures Implementation

Setting up, Implementing and Running a Successful Global Anticounterfeiting Program

- Justification
- Internal support and commitment
- Organizational set-up and involved functions
- Scope
- Processes

Dr Stephan Schwarze, Bayer Pharma AG, Germany

How to react when a Company receives Information about Counterfeit Products

- Receiving and routing of reports
- Single-point-of contact
- Case handling
- Case escalation
- Reporting requirements and obligations
- And then?

Dr Stephan Schwarze, Bayer Pharma AG, Germany

Session 5

Regulatory Perspective

Perspective from UK Medicines Regulator

- Enforcement Strategy
- Falsified Medicines Directive
- Operation Pangea
- Internet Pharmacies

Lynda Scammell, MHRA, UK

United States Drug Supply Chain Security Act: Preparing for Product Tracing, Verification and Serialization across the Supply Chain

- Drug Supply Chain Security Act overview
- DSCSA regulatory timelines for manufacturers, re-packagers, wholesale distributors and dispensers
- Detailed analysis of the core regulations (Tracing, Verification, Serialization)
- DSCSA interoperable data exchange requirements and industry responses (HDMA ASN, GSI EPCIS and more)
- FDA plans for DSCSA implementation and industry stakeholder engagement (guidance, workshops and more)
- Understanding the business process and operational issues for your company
- Preparing your business and network for 2015 DSCSA compliance

Brian Daleiden, Vice President of Marketing, TraceLink Inc., USA

Social Event



On the evening of the first conference day, you are cordially invited to a social event in the historical city of Würzburg. This is an excellent opportunity to share your experiences with colleagues from

other companies in a relaxed atmosphere.

Short Presentations by Selected Suppliers

Vendors are invited to present new anti-counterfeiting technologies or systems in scientific short presentations (10 min presentation and 5 min discussion).

Please send a short summary of your lecture to Günter Brendelberger at Concept Heidelberg (brendelberger@concept-heidelberg.de).

These short presentations have to be approved by the Steering Committee of the conference (Prof Holzgrabe / Dr Schwarze) in advance. As a prerequisite you need a regular registration for the conference or you may register for the conference exhibition.

The number of these short presentations is limited to max. 5 short presentations.

Conference Exhibition

During the two conference days, Security Technology Companies and Labelling/Packaging Component Companies are invited to exhibit their systems, products, and services in the foyer in the front of the conference room. Please contact Marion Weidemaier for further information on the opportunity to exhibit at the conference: Phone ++49(0)62 21-84 44 46, Fax ++49(0)62 21-84 44 34, e-mail: weidemaier@concept-heidelberg.de

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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.

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

Würzburg – Accessibility via Frankfurt Airport



The transfer from Frankfurt Rhein Main Airport to Würzburg is rather convenient:

1. By Bus Shuttle

There will be a bus shuttle free-of-charge from Frankfurt Airport to the Maritim Hotel Würzburg available on Sunday, 25 May 2014, at 20.00 h. Travelling time approx. 2 hours.

On Tuesday, 27 May 2014, buses will transfer for Frankfurt Airport directly after the end of the conference. Travelling time: approx. 2 h.

2. By Train

Alternatively, there is a direct 1 h 30 min train connection from Frankfurt Airport to Würzburg Main Station.



Frédéric Broise, Scientific Officer, EDQM, France

Frédéric Broise is a pharmacist. After more than 10 years working in the pharmaceutical industry mainly as a Quality Assurance Manager for Packaging, device and supply chain, he joined the European Directorate for the Quality of Medicines & HealthCare (EDQM) in July 2013 as eTACT project manager.

Brian Daleiden, Vice President of Marketing, TraceLink Inc., USA

Brian leads global marketing at TraceLink. In this capacity, Brian also guides the company's global regulatory analysis and market education programs that help industry stakeholders understand current and emerging regulatory, business and technical issues. In addition, Brian manages the TraceLink Cloud Community of thought leaders from across the global pharmaceutical supply network. Prior to co-founding TraceLink, Brian led product and corporate marketing at SupplyScape, a noted leader in supply chain security and integrity solution. In addition, Brian has held numerous marketing, business unit management and software development leadership roles focused on the global manufacturing and supply chain space at Catalyst International, Rockwell Automation and several startup companies.



Dr Martin Friedrich, Bayer Technology Services, Leverkusen, Germany

Dr. Martin Friedrich, Diploma in Technical Cybernetics Univ. Stuttgart, PhD in Automation of chemical processes. Working for Bayer since 1992. Currently Head of Track&Trace with Bayer

Technology Services, responsible for execution of coding & serialisation projects for pharma manufacturers. Project manager in EFPIA's design and implementation of European medicines verification system since 2008.



Prof Dr Ulrike Holzgrabe, University of Würzburg, Würzburg, Germany

Ulrike Holzgrabe holds a chair in Pharmaceutical and Medicinal Chemistry at the University of Würzburg and is a member of several national and international committees dealing with the

German and European Pharmacopoeia. Thus, she is interested in modern analytical methods for quality assurance of drugs and unravelling counterfeit drugs.



Patrik Merckell, Global Program Manager Packaging Technology Strategy, Novartis Pharma AG, Basel, Switzerland

Patrik Merckell has worked for Novartis Pharma AG for eleven years in the areas of Packaging Technology, Product Security (Tamper Evident

Packaging, Verification Features) and Artworks. He has a degree from the esig+ in Lausanne, the Swiss School for Engineers of the Graphical Industry.



Jesus Rivas, Novartis Pharma AG, Basel, Switzerland.

Jesus joined Novartis in 2011 as Global Sourcing QA Manager after 9 years within the pharmaceutical industry where he has held different positions with increased responsibility in

Qualification/Validation, Technical Support to Manufacturing Operations, and Quality Assurance where he worked as QA Responsible for Materials / Vendor Management and as Qualified Person (QP). He is pharmacist from Universidad Complutense de Madrid (UCM), Spain and holds post-graduate degree in Pharmaceutical Industry from CESIF Madrid, Spain. Jesus is also an active member of IPEC Europe being currently part of the GDP committee.



Lynda Scammell, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Lynda works as the Senior Policy Adviser on the Enforcement Group of the Medicines and Healthcare products Regulatory Agency (MHRA). The Enforcement Group within MHRA

has powers to carry out investigations relating to crime involving medicines and bring criminal prosecutions through the Criminal courts. Lynda deals with all policy and legislative developments that affect the group and its operational activity and Lynda is the MHRA's representative on the Council of Europe's Counterfeit Medicines Expert Working Group (C-Med) and has been involved in training events/awareness raising initiatives in the EU, Eastern Europe and Africa. She is part of the team responsible for the drafting of the Medcrime Convention from 2008 onwards.



Johannes Schön, Senior Manager Anti-Counterfeiting Supply Network Quality Management Boehringer Ingelheim GmbH & Co. KG

Johannes is responsible for Boehringer Ingelheim's global anti-counterfeiting program covering aspects of response, monitor and

prevention. He joined Boehringer Ingelheim in 2000 to head a QC laboratory for packaging materials and devices and a team performing validation and transfers of packaging processes. This was followed by assignments in BI's global operations network and global supply chain including performance management and benchmarking. Since February 2012 he is in his current responsibility within BI's Corporate Division Quality with a strong involvement in the global implementation of serialization.



Dr Stephan Schwarze, Bayer Pharma AG, Berlin, Germany

Stephan Schwarze is Head of Counterfeit Protection Management at Bayer HealthCare Pharmaceuticals. In 2005 he started to establish and develop this function. Before he had

worked in several different areas of R&D and production at increasing management levels. He is a member of EFPIA's TEDOC Packaging & Distribution Subgroup. 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 the working groups at national (DIN) and European (CEN) level related to norming activities on "Tamper Verification Features" compliant with the EU Falsified Medicines Directive".



Michael Wortmann, TAPA EMEA Board of Directors, Compass Transport Systeme, Düsseldorf, Germany

Michael Wortmann is working in international logistics and forwarding for more than 30 years.

Since 1997, Michael holds management positions in the Düsseldorf based ComPass group (a member of the Dutch VCK group) currently as Managing Director of ComPass Transport Systeme. ComPass joined the TAPA association in 2003 and is TAPA certified since 2004. Michael was elected into the TAPA EMEA Board of Directors in early 2011. In this voluntary role, Michael is responsible as membership lead for all membership related affairs.

Easy Registration



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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
www.counterfeit-conference.org

Date

Monday, 26 May 2014, 09.00 – 18.30 h
(Registration and coffee 08:00 – 09:00 h)

Tuesday, 27 May 2014, 08:30 – 16:00 h

Venue

Maritim Hotel Würzburg
Pleichertorstraße 5
97070 Würzburg, Germany
Phone + 49 / (0) 931 / 3053 – 0
Fax + 49 / (0) 931 / 3053 – 901

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the event hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

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 and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable

Registration

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

Conference language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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For questions regarding content:
Dr Günter Brendelberger
(Operations Director) at
+49-6221/84 44 40, or per e-mail at
brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier
(Organisation Manager) at
+49-6221/84 44 46, or per e-mail at
weidemaier@concept-heidelberg.de.

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

Reservation Form (Please complete in full)

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**4th University of Würzburg Anti-Counterfeit Conference:
Strategies Against Falsified/Counterfeit Medicines**
26-27 May 2014, Würzburg, Germany

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☐ I will make use of the Bus Shuttle from Würzburg to Frankfurt Airport on 27 May

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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)! (As of January 2012)