Pharma iQ
a division of IQPC

Pharmaceutical Serialisation & Traceability 2012

13 - 15 November, 2012, Geneva, Switzerland

Take away essential learning points for the next 6-12 months of your serialisation strategy implementation:

- **Start implementing your serialisation strategy across your manufacturing sites** - practical, operational case studies from **Teva, Novartis, Roche, Merck Serono** and **Boehringer-Ingelheim**
- **Assemble and coordinate your internal, cross-functional stake holder team** with insights from Jyrki Syvaeri, Corporate Director Supply Chain Integrity, **Boehringer Ingelheim**
- Updates and key take-homes on the pan-**European Stakeholder Model** from **EFPIA**
- **Prepare for the German securPharm project** with an overview from **Stephan Schwarze**, Head of Counterfeit Protection Management, **Bayer Healthcare**
- Hear from all the key stakeholders - manufacturers **(EFPIA)**, wholesalers **(GIRP)**, pharmacies **(PGEU)**, standards **(GS1)** and patients **(EAHP)**

"Good insights from industry and regulatory aspects. Serialisation implementation experiences invaluable! Will definitely be back"
GlaxoSmithKline

16+ International Expert Speakers, Including:

- **Ezri Deshen,** Senior Director Solid Operations, Global Operations, **Teva**
- **Christoph Krähenbühl,** **EFPIA Representative** (and Project Lead, Global Serialisation System, **AstraZeneca**)
- **Hugh Pullen,** Associate Director, European Government Affairs, **Eli Lilly**
- **Stephan Schwarze,** Head of Counterfeit Protection Management, **Bayer Healthcare**
- **Walter Bisson,** Global Program Manager, **Novartis**
- **Mathieu Aman,** Program Manager, Coding, Serialisation and Track & Trace, **F. Hoffmann-La Roche Ltd, Basel**
- **Sébastien Mauel,** Head of Product Security, **Merck Serono**
- **Jyrki Syvaeri,** Corporate Director Supply Chain Integrity, **Boehringer Ingelheim**

Exclusive New Interactive Sessions for 2012!

- Breakfast Briefing on partner selection and qualification
- Brand new interactive workshop – a step-by-step walkthrough on designing and implementing the best serialisation strategy

Special offer for Government, Academic and Regulator Representatives, see details on page 10

www.pharmaserialisation.com

ABOUT THE EVENT

Deadlines are right around the corner. Medicines must be serialised in Europe by 2016/17, and in some countries even sooner than that. You need to act now – before it is too late.

Well we have passed this point in time for the Who estimation, but how much is the cost of counterfeit product affecting the drug sales of your business? It is clear that counterfeit products, and particularly drug products, are on the rise and that the one stop shop solution doesn't really seem to exist, but how are you ensuring that your very latest strategies and technologies are up to date and combating the counterfeiters in the best way possible?

Key industry professionals are meeting alongside **EFPIA**, **GS1**, **GIRP, EAHP** and the **PGEU** at this meeting to discuss these exact issues and much more at the **Pharma IQ Serialisation and Traceability** meeting in November in Switzerland.

Bringing together all the key stakeholders – manufacturers, pharmacists and wholesalers – this year's meeting aims to ensure effective implementation of **the right** tools at **the right time** and **throughout the whole supply chain**.

I look forward to meeting you there.

Arran Oakes
Event Director
Pharmaceutical Serialisation & Traceability 2012

16+ Confirmed Speakers include:

- **Ezri Deshen**, Senior Director Solid Operations, Global Operations, **Teva**
- **Tanvi Goel**, Project Manager for Serialisation, **Mylan**
- **Christoph Krähenbühl**, **EFPIA Representative** (and Project Lead, Global Serialisation System, **AstraZeneca**)
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- **Sébastien Mauel**, Head of Product Security, **Merck Serono**
- **Jyrki Syvaeri**, Corporate Director Supply Chain Integrity, **Boehringer Ingelheim**
- **Martin Fitzgerald**, Deputy Director, **GIRP**
- **Jūratė Švarcaitė**, Pharmaceutical & Professional Affairs, **PGEU**
- Representative, **GS1 Global Office**
- **Richard Price**, Policy and Advocacy Officer, **European Association of Hospital Pharmacists (EAHP)**
- **Andrew Love**, Vice President, **Be4ward** (former Director Global Pack Management, **GlaxoSmithKline**)
- **Mark Davison**, Managing Partner, **BlueSphereHealth**

Day One, 13th November 2012

08.15 **Registration & Networking Coffee**

09.00 **Chairman's Opening Remarks**

PEOPLE & CULTURE: STRATEGIES TO ENSURE EFFECTIVE COMMUNICATION

09.10 **Building the Momentum and Support for Serialisation**

- Building a local campaign to ensure support
- Gaining buy-in from the right people
- Getting the message across, internally and externally
- Lessons learned from experience – common hurdles to overcome

Hugh Pullen, Associate Director, European Government Affairs, **Eli Lilly**

09.50 **Panel Discussion: Global Strategy – Planning for International Serialisation**

INTERACTIVE

- Key considerations
- Local regulations and support
- Stakeholder involvement – gaining internal buy-in
- Impact on third parties and partners

Panellists:

Walter Bisson, Global Program Manager, **Novartis**
Hugh Pullen, Associate Director, European Government Affairs, **Eli Lilly**
Mathieu Aman, Program Manager, Coding, Serialisation and Track & Trace, **F. Hoffmann-La Roche Ltd, Basel**

10.30 **SecurPharm – German Example for the EU Stakeholder Model**

- Regulatory background
- Project structure and principles
- Coding requirements
- IT- and organizational topology of the system

Stephan Schwarze, Head of Counterfeit Protection Management, **Bayer Healthcare**

11.10 **Speed Networking**

11.30 **Networking Coffee Break**

STAKEHOLDER INVOLVEMENT

12.00 **Patient Safety – Bar-Coding Medicines to the Single Unit Administered in Hospitals: Why is it Important and Necessary?**

CASE STUDY

- The evidence that demonstrates bar coding medicines to the single unit improves patient safety by reducing medication errors in hospitals at the point of administration
- Case studies of bar coding medicines to the single unit. How has it worked elsewhere and what we have learned?
- The wider arguments for bar coding to the single unit: medicines recalls, data management, reimbursement, and an ageing society
- We know it has great benefit, so why is bar coding to the single unit not already introduced as a standard, and how do we get there? Next steps

Richard Price, Policy and Advocacy Officer, **European Association of Hospital Pharmacists (EAHP)**

12.40 **The Pharmacy Perspective: Patient Safety, Serialisation, Real Life Experience – How Serialisation Impacts the Pharmacy**

- Explaining the pharmacists' needs regarding implementation of serialisation in day-to-day practice
- Evaluating the authentication system presently operational in pharmacies
- Exploring fits and misfits with regulators, wholesalers, industry and other stakeholder perspectives

Jūratė Švarcaitė, Pharmaceutical & Professional Affairs, **PGEU**

13.20 **Networking Lunch**

14.30 **Enabling Traceability Through Serialisation with GS1 Standards**

- The case for global supply chain standards
- Enabling regulatory compliance, e.g. EU Falsified Medicines Directive
- Improving Patient Safety by enabling Traceability (Track and Trace, Pedigree, Authentication, Recall)
- The momentum of implementation gathering pace…

Representative, **GS1 Global Office**

15.10 **The Wholesaler Perspective: How Serialisation Impacts Wholesalers – and How That Impacts You!**

- How wholesalers will impact your serialisation strategy – what should you consider?
- Evaluating the role wholesalers play in pharmaceutical traceability
- Keeping all stakeholders involved in decisions that affect them as well as yourself

Martin Fitzgerald, Deputy Director-General, **GIRP**

15.50 **Networking Coffee Break**

SERIALISATION STRATEGY

16.20 **Panel Discussion: A Harmonised Approach: Tackling Mass Serialisation Together – With All Stakeholders Involved**

INTERACTIVE

- How stakeholders can help each other to plan for serialisation
- Evaluating methodologies and approaches that work best for everyone involved
- Coordinating a rollout/implementation between stakeholders

Panellists: **GS1**, **PGEU**, **GIRP** and **EFPIA**

17.00 **Serialisation, Track & Trace and e-Pedigree for Pharma**

CASE STUDY

- Current challenges relating to detecting counterfeit drugs in the supply chain
- Preventing counterfeiting at the pharmacy
- Strategies for successful authentication of pharmaceutical products
- Secured distribution systems in the USA
- Benefits and pitfalls of the e-pedigree approach

Sébastien Mauel, Head of Product Security, **Merck Serono**

17.40 **Chairman's Summary and Close of Day One**

Day Two, November 14th 2012

07.30 – 09.00 Special Breakfast Briefing

Separate registration required. Includes a light breakfast

Implementing Serialisation: Get It Right First Time – Partner Selection, Management and Quality Control

Moving a serialisation project from plan to reality means managing a complex web of internal and external (vendor) resources whilst avoiding costly errors and delays. This session will catalyse a lively discussion with insights from both sides of the buyer / vendor relationship. Come and share your experiences and learn from others.

Key learning points:

- How to choose and manage serialisation technology suppliers
- Common pharma/vendor disconnects and how to avoid them
- Global partners or multi-local solutions: judging the best approach

Facilitated by:
Mark Davison, Managing Partner, **BlueSphereHealth**

08.30	**Registration**
09.00	**Chairman's Recap on Day 1**
09.10	**KEYNOTE: Getting Ready for the EU Falsified Medicines Directive** - Brief summary of the relevant FMD requirements and how they are likely to impact manufacturers - Example ESM (European Stakeholder Model) - what does the model look like? - What will participation mean for manufacturers? - Technical capabilities that manufacturers need to get into place - But readiness is wider than these technical capabilities - manufacturers need to ask themselves - Getting the internal organisation in place (IS and Business) to deal with exceptions? **Christoph Krähenbühl**, **EFPIA Representative** (and Project Lead, Global Serialisation System, **AstraZeneca**)
09.50	**Travtec Spotlight Session**
10.20	**Networking Coffee Break**
	OPERATIONAL CASE STUDIES: IMPLEMENTATION OF MASS SERIALISATION AT A MANUFACTURER
11.00	**Serialisation and Product Tracking - from Pilot to Full Scale Implementation at Novartis** CASE STUDY - Patient safety considerations - Complying to the regulatory framework - Developing an implementation roadmap - Management alignment - Multidimensional challenges **Walter Bisson**, Global Program Manager, **Novartis**

11.40 **Implementation of the Falsified Medicines Directive (FMD) in Roche**

CASE STUDY

- Fulfilling European regulation while meeting other worldwide regulations
- Impact on a globally operating company
- Pharma manufacturer readiness: an outlook 2010-2020
- What will the business impact (of the implementation of improved coding & serialization technologies) be on our operating model?

Mathieu Aman, Global Program Manager, "Coding, Serialization and Tracking & Tracing", **F. Hoffmann-La Roche Ltd, Basel**

12.20 **Networking Lunch**

During Lunch **Speaker "Genius" Bar** – Throughout lunch some of our expert speakers will be on-hand to help you with any specific, practical problems you may have. Bring your challenges with you and see if our experts can help!

13.40 **Translating Lessons from Pilot Projects to Implementation**

CASE STUDY

- Reporting key learning points from serialisation pilot projects
- Translating these key lessons from pilots into successful implementation in countries such as Turkey
- Overcoming the most significant barriers to serialisation
- Discussing different regulations and requirements around the world: an industry perspective

Jyrki Syväri, Global Integration Program Lead, Supply Chain Integrity, **Boehringer-Ingelheim**

SERIALISATION REQUIREMENTS AROUND THE WORLD

14.20 **Panel Discussion: An Overview – Serialisation Requirements Around the World**

INTERACTIVE

- Looking at which countries have different or unusual requirements
- Assessing these markets to put together a local strategy for serialisation
- Developing a global, flexible and integrated strategy that includes these markets

Panellists:

Walter Bisson, Global Program Manager, **Novartis**
Jyrki Syväri, Global Integration Program Lead, Supply Chain Integrity, **Boehringer-Ingelheim**
Mathieu Aman, Global Program Manager, "Coding, Serialization and Tracking & Tracing", **F. Hoffmann-La Roche Ltd, Basel**

15.00 **Networking Coffee Break**

15.30 **Interactive Roundtable Discussions**

INTERACTIVE

Roundtable A	Roundtable B	Roundtable C
Establishing a Cross-Functional Stakeholder Project Team – Gaining the Buy-In **Stephen McIndoe**, VP, **Be4ward**	Working with External Stakeholders to Deliver an Effective System **Tanvi Goel,** Project Manager for Serialisation, **Mylan**	Choosing the Right Technology Suppliers **Mark Davison**, Managing Partner, **Blue Sphere Health**

Roundtable D

Managing a Global, Multi-Requirement Serialisation Strategy

Jyrki Syvaeri, Corporate Director Supply Chain Integrity, **Boehringer Ingelheim**

16.10 **A Serial Issue: The Impact of Serialisation on Today's Pharmaceutical Manufacturers**

With serialisation deadlines looming just round the corner all over the world, do we truly appreciate the impact it will have on global pharmaceutical supply?

- A serialised world: how will pharmaceutical supply change with serialisation?
- Beyond security: serialisation can help functions beyond just supply chain security, including product recalls and reimbursement
- What are the financial, time and soft skill considerations when implementing your serialisation strategy?

Ezri Deshen, Senior Director Solid Operations, Global Operations, **Teva**

16.50 **Chairman's Closing Summary**

17.00 **Close of Conference**

Post-Conference Workshop, November 15th 2012

09.00-11.30

Setting up for Success in Serialisation – Beat the Deadlines!

This workshop will expand on the topics of the previous two days, providing attendees with the opportunity to think through their particular situation, identify gaps in their current plans and develop approaches to fill those gaps. The workshop will be interactive, with plenty of opportunity for Q&A and discussions amongst the attendees.

Key learning objectives:

- Defining all the impacts of the different serialisation models across a manufacturing organisation and it's supply chain partners
- Defining the appropriate governance, leadership and communication
- Understanding the options for defining and implementing solutions, globally and locally
- Understanding how to structure the people and suppliers to deliver the solutions
- Understanding how to build and manage a comprehensive plan to implement solutions

Facilitated by:

Stephen McIndoe, Vice President, **Be4ward**

Andrew Love, Vice President, **Be4ward**

Who Should Attend?

Senior Vice President, Vice President, Executive Director, Director, Associate Director, Head and Manager from departments including:

- Supply Chain
- Distribution
- Product Security
- Anti-Counterfeiting
- Logistics
- Quality Assurance
- Regulatory Affairs
- Serialisation

From companies including:

- Pharmaceutical Manufacturers
- Biotech
- Wholesalers
- Pharmacies
- Related government and regulatory officials

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Become a member here: www.pharma-iq.com/join.cfm

Maximise Your Involvement: Sponsorship and Exhibition Opportunities

Pharmaceutical Serialisation is attended by senior officials and decision-makers from industry, bringing together buyers and suppliers in one location.

Focused and high-level, the event will be an excellent platform to initiate new business relationships. With tailored networking, sponsors can achieve the face-to-face contact that overcrowded trade shows cannot deliver.

Exhibiting and Sponsorship options are extensive, and packages can be tailor-made to suit your individual company's needs. Most packages include complimentary entry passes, targeted marketing to industry officials and executives, and bespoke networking opportunities.

Other features of sponsorship include:

- Prominent exhibition space in the main conference networking area
- Participation in comprehensive pre-event marketing campaigns
- Tailored marketing strategies to suit your organisation's size, capabilities and individual requirement

For more information and to discuss the right opportunity, contact us on +44 (0)207 368 9300 or sponsorship@iqpc.co.uk

Sponsors & Exhibitors

SICPA is a Swiss company, founded in 1927, with headquarters in Lausanne, and is a leading global provider of integrated security and traceability solutions to both, governments and companies of various industry verticals.

The company employs more than 2'500 people and is established on 5 continents, with business activities in most countries worldwide.

In the pharmaceutical and healthcare sector, the customer specific solutions and services delivered by SICPA help companies enhance the visibility and the integrity of their supply chains, while providing value-adding business intelligence and ensuring product protection and regulatory compliance.

SICPA has successfully deployed and is operating product authentication and traceability systems on all continents.

Website: http://www.sicpa.com

Travtec Limited established 1995, design & manufacture specialist product handling systems for a wide range of industries. Our location is between Manchester and Liverpool in the northwest of England.

Our modern facilities utilise the latest development and production techniques, including computer aided design & manufacturing, control system design and build to customers specifications, include pneumatic, stepper, servo drive & PLC programming.

Our coding, marking & labelling product handling systems are designed to compliment Inkjet Printers, Labellers, Print/Apply & Thermal Transfer equipment. We work in partnership with OEM's to develop innovative new applications for products both existing and under development.

Website: http://www.travtec.co.uk

Pharmaceutical Serialisation & Traceability 2012

Main Conference: 13- 14 November 2012
Post-Conference Workshop: 15 November 2012
Geneva, Switzerland

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My registration code is PDFW

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Special offer:
Academic, government and regulator attendees to register for €699**, email enquired@iqpc.co.uk to get your pass today!

PHARMACEUTICAL MANUFACTURER PRICING		Register and pay by 10th August 2012*	Register and pay by 14 September 2012*	Register and pay by 12 October 2012*	Standard Price
Conference + Workshop	☐	SAVE €300 €2,248	SAVE €200 €2,348	SAVE €100 €2,448	€2,548
Conference Only	☐	SAVE €450 €1,449	SAVE €350 €1,549	SAVE €250 €1,649	€1,899
Workshop Only	☐	€649			
Breakfast Briefing	☐	To attend the breakfast workshop on Day Two, please tick the box (add €249)			
Conference Recordings	☐	For access to conference recordings, please tick the box (add €649)			

SOLUTION PROVIDER PRICING		Standard Price
Conference Only	☐	€2,599
Workshop Only	☐	€649
Breakfast Briefing	☐	To attend the breakfast workshop on Day Two, please add €249

*To qualify for discounts, payments must be received by the early booking deadline. Early booking discounts are not valid in conjunction with any other offer.

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Email: **enquire@iqpc.co.uk**

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Venue & Accommodation

VENUE: Geneva, Switzerland. Venue to be confirmed

ACCOMMODATION: Travel and accommodation are not included in the registration fee. For updates on the venue and accommodation information, please visit www.pharmaserialisation.com

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