ISPE Thailand 4th Seminar 2018

Track & Trace Serialization: Pharmaceutical Product Journey from Manufacturer to Patient

12 – 13 December 2018

At Convention Hall C-D Room, Ambassador Hotel,
Sukhumvit Soi 11, Bangkok, Thailand

Background

Falsified medicines and medication errors continue to cause health issues for patients worldwide. ***Track and Trace*** are playing an important role in ensuring safe drug distribution chains and instituting quality. It is one of the tools to help prevent counterfeit and falsified medicines from reaching patients whilst contributing to supply chain efficiencies and reducing cost.

Serialization is the assigning of a unique serial number to each saleable unit of each prescription product, which is linked to information about the product's origin, batch number and expiration date. The units can then be tracked through its entire supply chain — from production to retail distribution to the final dispensation to the patient. Serialization is a regulatory requirement in some countries such as USA, UK, Europe, Japan, Indonesia and etc., where a documented chain of custody is further established by requiring wholesalers and pharmacies to record shipments and receipts of serialized products.

Nowadays, hospitals are focused on gaining access to trusted product data – recognizing it as a vital asset for the health of their processes and patients. With ***Track & Trace Serialization***, product data is as important as the product itself. The quality of the product data is a direct reflection of the quality of the product and its manufacturer. It would help to deliver the right product at the right time, in the right place for physicians.

In this seminar on ***Track & Trace Serialization: Pharmaceutical Product Journey from Manufacturer to Patient***, you will

- **LEARN** from experts on what serialization is, the impact and benefits of serialization to industry, how to implement serialization system, and global standards (GS1)
- **HEAR** from local and international industry who will share their experiences on implementing serialization
- **DISCUSS** the regulatory requirements and Thai FDA point of view and trend on serialization
- **UNDERSTAND** why serialization has been discussed in healthcare *worldwide*
- **PREPARE** your system for *trace & track of your product* throughout its lifecycle

Get to know speaker

Bart Vansteenkiste

Bart Vansteenkiste has worked for Domino for over 17 years in different commercial roles. A master degree of Electromechanical Engineering and his former role as Pharmaceutical and OEM key account manager for Belgium gave him the perfect background to join the head quarters based FMD group in 2011. Within this group Bart has been focussing on the legislative and technical challenges facing the healthcare sector. Bart regularly attends and presents at conferences on behalf of Domino.

- Bart is fluent in Dutch, English, French and Spanish which is a big benefit in his current role, advising Domino's customers and sales channels on the implications of the legislative requirements and the implementation of 2D coding, serialisation, aggregation and Track & Trace projects. Bart works in close co-operation with a number of leading OEM partners in Germany and Italy and with trade associations like EFPIA and the EGA.
- Since February 2016 Bart has been appointed Global life sciences sector manager, taking the lead for developing Domino's Life Sciences business and strategy. Bart also liaises with Domino's pharma key accounts.

Boonrak Thawornrungroaj

Boonrak THAWORNRUNGROAJ, with 30 years of his career in pharmaceutical industry, medical devices and biological industry, Currently he is Managing Director for Government Pharmaceutical Organization – Merieux Biological Product (GPO-MBP) over 18 years in different roles including: Head of Manufacturing, Head of Site Quality Operataion, and Vaccine Advocacy & Partnerships. He has been responsible for several vaccine development projects.

GPO-MBP is the vaccine manufacturer and export Vaccine to UNICEF and 15 countries under marketing authorization holder of Sanofi Pasteur.

Professional Qualifications:

- Bachelor degree Pharmaceutical Science, Mahidol university (1984 – 1989)
- MBA, Marketing Ramkhumhaeng University (1997 – 2000)

Dr. Anuchit Sekthira

Dr. Anuchit Sekthira is associate director, validation global quality assurance Americas in leading pharmaceutical company in the USA with +30 years working experience in the qualification and validation.

Professional Qualifications:

- PhD Chemical Engineering (University of Mississippi, USA)
- MSc Chemical Engineering (University of Mississippi, USA)
- BSc Chemical Engineering (University of Florida, USA)
- BSc Chemistry (Chiang Mai University, Thailand)
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Shawn Chen

Shawn Chen is a GS1 Thailand's Section Manager, and taking care of four departments, Industry Engagement, Marketing, AIDC/Training, and Commercial Services. He has over 20 years experienced on consulting, researching, networking, sales, barcode and RFID territories, and including the eight- year experiences in GS1 community.

Shawn Joined Industrial Technology Research Institute of Taiwan, R.O.C (ITRI) in 2009 to hold Long Term Evolution (LTE) project for two years. In the end of 2010, Shawn was working for GS1 Taiwan as a project manager for handling projects that related to GS1 standards such as Barcodes, RFID, and the Internet of Things. Furthermore, he was responsible for providing the barcode and RFID solutions to supply chain, government and healthcare sector.

In GS1 Career, Shawn has assisted GS1 Global Office to build up barcode verification expert group. Due to his experiences, he recruited MCSE, MCDBA, MCSD, MCP and CCNA certificates.

Ms Manuh Pitasari

Ms Manuh Pitasari is Products and Services Manager of Factorytalk. She has more than 15 years' experience in multiple areas of Pharmaceutical manufacturing operations. She is a specialist in Sterile production and has been responsible to introduce new production lines and entire new facilities in ASEAN through to succesful European PIC/s GMP inspections (UK, Germany). She has a deep background in compliance, GMP computer systems, and is a highly active and practical GxP practitioner.

After undertaking projects with leading European Searlisation experts, including EMVO management members, Ms. Manuh has since been closely involved with the emerging serialization landscape in Indonesia over the last 2 years. She has become a regular speaker on the subject at events organized by ISPE and AllPack Indonesia, and provided trainings or consulting for a range of organisations including the Indonesian Pharmacists Association, Badan POM (The National Agency of Drug and Food Control of Republic of Indonesia), and various regional and Multi-National companies looking to meet the upcoming Indonesian serialization regulations.

Area of Expertise:

- Serialisation
- Sterile Manufacturing and Validation
- Commissioning and Qualification
- GxP Project Management
- Computer System Validation for production equipment and eQMS
- Quality Management System
- GMP Inspection
- Data Integrity
- electronic Quality Management System (eQMS)

Topic : Track & Trace Serialization: Pharmaceutical Product Journey from Manufacturer to Patient

Date : 12th – 13th December 2018
Venue : At Convention Hall C-D Room Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand

Wednesday 12th December, 2018 (Entitled to 5 CPE credits)

Day 1		Speaker
08.00-08.50	Registration	
08.50-09.00	Welcome and opening	*ISPE Thailand President*
09.00-10.30	**Worldwide legislations overview** **Serialization and aggregation,** what is it? how will it impact pharmaceutical manufacturing?	*Mr. Bart Vansteenkiste*
10.30-11.00	Coffee break	
11.00-12.00	**Sharing Experiences from Local Pharmaceutical Industry**	*Mr. Boonrak Thawornrungroaj*
12.00-13.30	Lunch	
13.30-15.00	**The importance of standards when serializing and aggregating** **How to Implement "Serialization System"**	*Mr. Bart Vansteenkiste*
15.00 -15.30	Coffee break	
15.30-16.30	**Get the benefit from your investment for Serialization**	*Mr. Bart Vansteenkiste*
16.30-17.00	Q&A	

Thursday 13th December, 2018 (Entitled to 5.5 CPE credits)

Day 2		Speaker
08.00-09.00	Registration	
09.00-10.30	**GS1 Standard:** What is it? What are these terms GS1, GTIN, SGTIN, EPCIS, Data Matrix barcode? **How to develop & implement global standards for patient safety & supply chain efficiencies**	*Mr. Shawn Chen*
10.30-11.00	Coffee break	
11.00-12.00	**Serialization in Thai Regulatory Perspective**	*Dr. Suchart Chongprasert or his representative*
12.00-13.30	Lunch	
13.30-15.00	**Sharing Experiences from USA Pharmaceutical Industry**	*Dr.Anuchit Sekthira*
15.00 -15.30	Coffee break	
15.30-17.00	**Challenges on Serialization Program in Indonesia**	*Ms. Manuh Pitasari*

Registration Fee

Seminar 12 - 13 December 2018	Registration Fee
ISPE/TIPA Member	4,000 Baht
Non-member	6,000 Baht

Note :

1. The registration fee is for 2 days seminar (12th - 13th October 2018)
2. Member applies to member of ISPE and TIPA only.
3. **GOING GREEN** in this seminar with electronic presentation handout i.e. handout will be made available before the seminar in downloadable PDF file

Hotel and Travel

Conference Hotel : Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand

http://ambassador.bangkokshotels.com/en/

Travel : http://www.amtel.co.th/location/

How to register

HOW TO REGISTER

1. **Online Registration** Browse website http://ispeth.org/EVENT-4_2018 , fill-in delegate details and click submit
2. **Confirmation** ISPE staff will confirm your registration status via email. If not receive email within 2 working days after submitted the form, please contact our staff.
3. **Payment** Make a payment to reserve your seats and capture/ scan transferred evident i.e. payslip to email REGISTER@ISPETH.ORG

REGISTRATION CLOSES ON 10 DECEMBER 2018 OR WHEN ALL SEATS ARE FULLY RESERVED.

FIND OUT MORE INFO & CONTACT US: WWW.ISPETH.ORG EMAIL: REGISTER@ISPETH.ORG
T: +6688-090-4664

PAYMENT

Payment must be received prior to the event otherwise the reservation will be cancelled. All payments should be made in Thai Baht.

BANK > KASIKORN BANK, LAD PRAO 67 BRANCH
ACCOUNT > ISPE FOUNDATION
NUMBER > 027-8-46566-7
SWIFT CODE > KASITHBK
BANK ADDRESS > 2347 LADPRAO 67, WANGTHONGLANG, BANGKOK, THAILAND 10310

TERMS AND CONDITIONS

All fees stated include luncheons, refreshments and documentation. It does not include the cost of accommodation and travel.

SUBSTITUTION / CANCELLATION

Substitute delegates are not allowed. Cancellations must be received in writing at least 10 business days before the start of the event.