

2019 PDA Drug Delivery of Injectables

Impact of Digitalization on Pharmaceuticals, Manufacturing and Patient Care

12-13 November 2019 | Grand Victoria Hotel | Taipei City, Taiwan



TUESDAY, 12 NOVEMBER

08:00 – 18:00 | Registration Open

09:00 – 09:30 | Opening Remarks

Herbert Chung-Hsiun Wu, PhD, Co-Chair, *BPIPO*

Markus Bauss, Co-Chair, *SHL Connect*

09:30 – 10:30 | P1: Opening Plenary

This session highlights digitalization developments in pharmaceutical manufacturing and personalized patient care.

Moderator: Georg Roessling, PhD, Senior Consultant, Business Development Asia, *PDA*

09:30 | Future of packaging materials – reduce your footprint on the environment

Yves Steffen, *Novartis*

10:00 | Revolutionizing Personalized Patient Care through Digital Therapeutics: An Industry Perspective

Ed Deng, *Health2Sync*

10:30 – 11:00 | Refreshment Break in Exhibit Area

11:00 – 12:30 | P2: From Primary Packaging to Devices

The role and importance of primary packaging and drug delivery devices now and the trends for the future

Moderator: Robin Hwang, CEO and President, *ICP Consulting Corp.*

11:00 | A CDMO perspective on modern drug delivery: The journey from Drug Substance to Drug Product

Thomas Schoenknecht, *Lonza*

11:30 | Micropump device for continuous subcutaneous administration of drug formulations

Robert Kriftner, *Sensile Medical*

12:00 | Digital Design - a look at the future transformation of device design

Ron Forster, *Amgen*

12:30 – 13:30 | Networking Luncheon

13:30 – 15:00 | Concurrent Tracks

Track A1: Manufacturing: Modern concepts for facility and filling operations

The manufacturing environment and the machines are essential for the manufacturing of pharmaceutical products. This session gives examples of the best current practices.

Moderator: Georg Roessling, PhD, Senior Consultant, Business Development Asia, *PDA*

13:30 | Modern Pharmaceutical Manufacturing Site
Speaker from *EirGenix*

Track B1: Devices: Increase Product Value

In this session, new developments in injection devices are presented and the value of modern injection systems for improved patient acceptance is described.

Moderator: Markus Bauss, Managing Director, *SHL Connect*

13:30 | Drug Delivery meets Automotive – Device Platform Design

2019 PDA Drug Delivery of Injectables

Impact of Digitalization on Pharmaceuticals, Manufacturing and Patient Care

12-13 November 2019 | Grand Victoria Hotel | Taipei City, Taiwan



14:00 Small Batch Production Filling Line <i>Matthias Angelmaier, Bosch Packaging</i>	Thomas Mayer, Sonceboz
14:30 Smart Medical Device: Connected Health - Manufacturing perspective <i>Alexander Mayer & Christian Kollecker, Hoefliger</i>	14:00 Differentiating Drug Values in Market by Injection Devices <i>Edgar Yeh, CC Bio</i>
	14:30 Possible Improvements of Current PFS Safety Injection of Flu Vaccines <i>Lee Lin Lee, MedicalChain International Corp.</i>

15:00 – 15:30 | Refreshment Break in Exhibit Area

15:30 – 18:00 | Concurrent Tracks

Track A2: Digital Manufacturing In this session, the concept of digitalization in production is presented. Impact on process control, documentation, overall efficiency and product quality is discussed.	Track B2: Devices with Connectivity This session describes the change from devices to connected devices and what the advantages for patients in home care can be.
Moderator: Georg Roessling , PhD, Senior Consultant, Business Development Asia, PDA	Moderator: Markus Bauss , Managing Director, SHL Connect
15:30 Process Modeling and Digital Twins in Biologics Manufacturing <i>Sei Murakami, Hitachi</i>	15:30 The benefits of Aerosol Drug Delivery Device and its Digitalization <i>Jackie Tieng, MicroBase</i>
16:00 Digital Manufacturing increasing Production Efficiency while increasing Product Quality <i>Matsumoto Mamoru, Hitachi</i>	16:00 Design, development and value proposition of Connected Drug Delivery Technology <i>Christian Keller & Chelsea Williams, SHL</i>
16:45 IIoT Enables Pharmaceutical Safety by Realtime Cold Chain Management <i>David Yang, Advantech</i>	16:30 Successful implementation of connected drug delivery devices: Lessons learned from Diabetes <i>Arnaud Guillet, Biocorp</i>
17:15 Panel Discussion on Digital Manufacturing <ul style="list-style-type: none">- What are the elements for the digital manufacturing environment?- Simulation and virtual reality- Sensors and data collection- Data processing/trend analysis- The benefits	17:00 Driving better Patient Outcome with Connectivity <i>Adam Shain, Aptar Pharma</i>
	17:30 Questions & Answers/Discussion

18:00 – 19:30 | Networking Reception

2019 PDA Drug Delivery of Injectables

Impact of Digitalization on Pharmaceuticals, Manufacturing and Patient Care

12-13 November 2019 | Grand Victoria Hotel | Taipei City, Taiwan



WEDNESDAY, 13 NOVEMBER

08:30 – 17:30 | Registration Open

09:00 – 10:15 | Concurrent Tracks

Track A3: Manufacturing/Technology:

Role of Primary Packaging Components and Device/Track and Trace/Assembly

This session shows how primary packaging components can interact with the filling machines, document the process and ensure total quality control.

Track B3: Digital Health Applications enabling Personalized Patient Care

Connected devices help patients better manage their own health and care at home, which also contributes to better adherence. This session gives examples how this can be used for monitoring and diagnostic purposes but also how the internet of things can contribute for data exchange between patients at home and healthcare providers.

Moderator: Wayne Wu, President, *PDA Taiwan Chapter*

Moderator: Chi-Feng Chang, PhD, Deputy Director, *BPIPO*

09:00 | Unique identification of glass containers throughout the manufacturing process: the benefits of glass marking during the automatic inspection of filled containers

Andrea Sardella, *Stevanato-Group*

09:00 | Digital Mobile Diagnostic Devices facilitating Self-Management of Health and Diseases

Alan Tsai, *iXensor*

09:30 | Enhancing Patient Safety and Product Quality through Technology and Digitalization

Kwang Kok Li, *West Pharma*

09:30 | Medical IOT leading to Patient-Centric Services

Jerry Hsu, *Asus Life*

10:00 | Questions & Answers/Discussion

10:00 | Questions & Answers/Discussion

10:15 – 10:45 | Refreshment Break in Exhibit Area

10:45 – 12:30 | Concurrent Tracks

Track A4: Manufacturing/Technology

The final step of manufacturing a drug delivery device is the assembly of the primary packaging with the device. This is a crucial step and it only is successful in terms of quality if clear specification for the primary packaging components and the filling have been considered. This session describes the testing and manufacturing steps which are necessary.

Track B4: Special Device Applications

This session has presentations which deal with special topics. One is about handling of highly potent drugs and the other presentation covers the whole development process of a syringe for ophthalmic use. The very challenging quality requirements and their technical implementation are described. The session ends with a regulatory related topic addressing essential performance requirements and control strategy for combination products.

Moderator: Wayne Wu, President, *PDA Taiwan Chapter*

Moderator: Shih-Chong Tsai, PhD, Executive Director, Institute of Biologics, *Development Center for Biotechnology*

10:45 | Container Integrity Testing

Heinz Wolf, *PTI Packaging Technologies*

10:45 | Close System Transfer Device (CSTD) use with oncology drugs and biologics

Lana Shiu, *Amgen*

11:15 | Qualification of Test Methods: Leak Simulation and Flow Test

Henry Lu, *Optek*

2019 PDA Drug Delivery of Injectables

Impact of Digitalization on Pharmaceuticals, Manufacturing and Patient Care

12-13 November 2019 | Grand Victoria Hotel | Taipei City, Taiwan



11:45 | Optimization of material and process flow for production of auto injector sub-assemblies

Gilbert Fluetsch & Lucy Chung, SHL

12:15 | Questions & Answers/Discussion

11:15 | Visisure® from concept to approval:

A low volume high accuracy syringe

Marc Rohrschneider, Novartis

11:45 | Essential Performance Requirements and the Control Strategy for Combination Product (PFS) from Design to Manufacture

Shu-Chen Chen, Genentech

12:15 | Questions & Answers/Discussion

12:30 – 13:30 | Networking Luncheon

13:30 – 15:30 | P3: Digital Health

Healthcare costs are increasing, and people look for ways to reduce costs by integrating digital health technologies into current healthcare infrastructure. This session gives a broader and global perspective of digital health. Highlighting efforts of governments but also showing opportunities for the healthcare systems and advantages for patients.

Moderator: Ed Deng, Co-Founder & CEO, Health2Sync

13:30 | How do governments worldwide promote digital health?

Lily Wong, PwC Taiwan

14:00 | Investing in digital health: global perspective, local implications

Joseph Mocanu, Verge HealthTech Fund

14:30 | US regulatory perspectives of connective devices

Lening Shen & Lana Shiu, Amgen

15:00 | How Mobile Technologies are Transforming Healthcare?

Jessy Kang, Smart Ageing Tech

15:30 – 16:00 | Refreshment Break in Exhibit Area

16:00 – 17:30 | P4: Panel Discussion: Future of Drug Delivery and Digitalization in Health Care in Asia

In many Asian countries, the patients still receive their injectables from healthcare professionals and the home care treatment does not yet play a significant role. But healthcare costs and improved patient care will lead to developments where patients receive user friendly application systems, like autoinjectors, pens and wearables. In addition, concepts of microelectronics and digitalization in combination with the pharmaceutical product will play a role. There will be opportunities to directly receive data from the patient and have a direct access to therapy and diagnostic data from the patient. Actually, the technologies by itself are there and the potential advantages for patient management and health care costs are given or at least can be estimated. This panel discussion wants to address the dynamic of this process and the implications on patient and healthcare system. What are the real advantages? What is the impact on the health care system? What will be the drivers? What will the situation be in 10-30 years from today?

Moderators: Herbert Chung-Hsiun Wu, PhD, Co-Chair, BPIPO, Markus Bauss, Co-Chair, SHL Connect, Marc

2019 PDA Drug Delivery of Injectables

Impact of Digitalization on Pharmaceuticals, Manufacturing and Patient Care

12-13 November 2019 | Grand Victoria Hotel | Taipei City, Taiwan



Rohrschneider, *Novartis*

Panelists:

- **Ron Forster**, *Amgen*
- **Arnaud Guillet**, *Biocorp*
- **Lana Shiu**, *Amgen*
- **Lily Wong**, *PwC Taiwan*
- **Joseph Mocanu**, *Verge HealthTech Fund*
- **Anthony Jones**, *Sanofi*

17:30 | Closing Remark

Georg Roessling, PhD, Senior Consultant, Business Development Asia, *PDA*