Dear Colleagues,

The **2018 PDA Taiwan Drug Delivery of Injectables Conference** will kick off with an update on recent changes to regulations, focusing on the proposed revision to Annex 1 and other regulations relevant for parenteral packaging.

The Conference will concentrate on primary packaging components, devices, and fill-finish procedures. Relevant tests, such as visual inspection, container closure integrity, and extractables and leachables, will also be covered. A special session will address the use of electronics for pharmaceutical applications.

This Conference will go beyond the technical aspects of pharmaceutical manufacturing, with a special session devoted specifically to business-related aspects of the industry. In this session, critical considerations regarding such areas as marketing and the challenges of developing successful partnerships, especially for the manufacture of biotech/biosimilar products, and what needs to be in place for successful partnerships, will be addressed. And, hear directly from the experts how patient-friendly injection systems may impact market success.

The Conference agenda incorporates panel discussions and plenty of time for the presenters to answer your questions. An exhibition will highlight new products and services.

Plan to stay on after the Conference to take part in several training courses that will take a more in-depth look at some of the topics.

We are looking forward to seeing you in Taipei,

**Magnus Fastmarken**, Global Director Marketing, *SHL Group, Co-Chair*

**Robin Hwang**, Consultant, *ICP Consulting Corp., Co-Chair*

**The Scientific Organization Committee:**

**Magnus Fastmarken**, Global Director Marketing, *SHL Group, Co-Chair*

**Robin Hwang**, Consultant, *ICP Consulting Corp., Co-Chair*

**Markus Bauss**, Managing Director, *SHL Connect, SHL Group*

**Biotechnology & Pharmaceutical Industries Promotion Office (BPIPO), Ministry of Economic Affairs**

**Gabriele Peron**, Senior Marketing Advisor, *Stevanato Group*

**Mathias Romacker**, Senior Director, Device Strategy/Marketing, *Pfizer, Inc.*

**Wayne Wu**, PDA Chapter President Taiwan, *Intech Biopharm Corp.*

**Molly O’Neill Moir**, CMP, Vice President, Programs and Meetings, *PDA*

**Georg Roessling**, PhD, Senior Consultant, Business Development, *PDA*
## Tuesday, 6 November

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<tr>
<th>Time</th>
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<td>8:00 –</td>
<td>Registration Open</td>
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</table>
| 9:00 – 10:15 | P1: Opening Plenary  
**Moderator:** Georg Roessling, PhD, Senior Consultant, Business Development Asia, PDA |
| 9:00 – 9:15 | Welcome and Opening Remarks  
Wayne Wu, PDA Chapter President Taiwan, and Vice President, Intech Biopharm Corp.  
Mr. Jong-Chin Shen, Minister of Economic Affairs (MOEA)  
Mr. Shih-Chung Chen, Minister of Health and Welfare (MOHW) |
| 9:15 – 9:40 | The Evolving Pharma Outlook on Primary Containers and Injection Devices  
Mathias Romacker, Senior Director, Device Strategy, Pfizer, Inc. |
| 9:40 – 10:00 | Parenteral (Injectable) Drugs Differentiated by Injection Devices  
Robin Hwang, Consultant, ICP Consulting Corp. |
| 10:00 – 10:25 | The FDA's Perspectives on Regulation of Combination Products  
Lana Shiu, MD, Executive Director | Medical Device Regulatory Affairs, Amgen, Inc. |
| 10:25 – 10:55 | Refreshment Break in Exhibit Area |
| 10:55 – 12:30 | P2: Regulatory Updates, Part 1  
**Moderator:** Mathias Romacker, Senior Director, Device Strategy, Pfizer, Inc. |
| 10:55 – 11:20 | Activities of the Taiwan Inspectorate FDA Taiwan  
Ellen Ying-Hua Chen, GMP Inspector, FDA Taiwan |
| 11:20 – 11:45 | US FDA: Inspection Observations in Asia Pacific  
Alicia M. Mozzachio, MS, Senior Advisor, International Activities, CDER, U.S. FDA |
| 11:45 – 12:00 | Questions and Answers/Discussion |
| 12:00 – 13:00 | Networking Luncheon |

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*This opening plenary will set the stage for the conference and will describe the current trends for injectables in the pharmaceutical industry and the impact on primary packaging and devices. Special focus will be given to biosimilars with respect to market differentiation through patient friendly drug delivery devices.*

*This session will take place in two parts and will share activities and observations of GMP inspectors in Taiwan and the Asia Pacific area. Regulatory representatives will discuss inspection observations in Asia Pacific and industry representatives will address current hot topics on Annex1/filtration and data integrity issues. Finally, a presentation will describe a case study for a global registration strategy of an autoinjector.*
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<th>Time</th>
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<th>Speaker/Institution</th>
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<tr>
<td>13:00 – 13:30</td>
<td>P3: Regulatory Updates, Part 2</td>
<td>Moderator: Mathias Romacker, Senior Director, Device Strategy, Pfizer, Inc.</td>
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<tr>
<td>13:30 – 14:00</td>
<td>Data Integrity: How to Achieve Employee’s Compliance by the System and Awareness</td>
<td>Jianchen Xu, PhD, Quality Specialist, Novo Nordisk</td>
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<tr>
<td>14:00 – 14:30</td>
<td>Regulatory Strategy Considerations for a Novel Reusable Autoinjector: A Case Study for a Combination Product Registration</td>
<td>Julia Yeh, Director, Regulatory Affairs, Amgen, Inc.</td>
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**Track A: Primary Packaging Components**

**Moderator:** Gabriele Peron, Senior Marketing Advisor, Stevanato Group

**Track B: Manufacturing**

**Moderator:** Robin Hwang, Consultant, ICP Consulting Corp.

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<th>Time</th>
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<tbody>
<tr>
<td>15:00 – 18:00</td>
<td>Flexible and Modular Facilities</td>
<td>Dennis Powers, Director of Sales Engineering, G-CON Manufacturing</td>
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<tr>
<td>15:00 – 15:30</td>
<td>How to Mitigate and Control Biodrug Challenges for Glass Primary Packaging: A Manufacturing Approach</td>
<td>Alessandro Morandotti, Product Manager Syringes, OMPI</td>
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<tr>
<td>15:30 – 16:00</td>
<td>Considerations for Selection and Evaluation of Container Closure Systems</td>
<td>Kok Li Kwang, Technical Support Manager, West</td>
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<td>16:00 – 16:15</td>
<td>Questions and Answers/Discussion</td>
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<td>16:15 – 16:45</td>
<td>Innovations in Glass Container Design: A Manufacturer’s Perspective</td>
<td>Wenzel Novak, PhD, Global Senior Director Business Development Medical Systems, Gerresheimer</td>
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<td>17:15 – 17:45</td>
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<td>15:00 – 15:30</td>
<td>Changing Production Strategies in Sterile Filling</td>
<td>Kristian Slavik, Sales Director of Southeast Asia and Far East, Optima</td>
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<td>15:30 – 16:00</td>
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<td>17:30 – 18:00</td>
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Impact of Sterilization on Protein Aggregation and Degradation in a Polymer-Based Pre-Filled Syringe System
Katsuyuki Takeuchi, Associate Product Manager – Pharmaceutical Solutions, Terumo
17:45 – 18:00
Questions and Answers/Discussion

Wednesday, 7 November
8:00 – 15:15
Registration Open

8:30 – 10:00
Track A: Devices
Moderator: Magnus Fastmarken, Global Director Marketing, SHL Group

Devices like pens, autoinjectors and wearables are the drug delivery systems for patient-friendly medicines. This session will give an overview on the technologies and their advantages. With the progress of miniaturization of electronic parts, new devices are being developed which allow it to communicate with the patient and to also collect data on the patient and injection process. Some of the latest developments will be presented and potential advantages for patients, doctors, and pharma industry will be discussed.

8:30 – 9:00
Autoinjectors: The Gold Standard in Self-Treatment with Biologics
Thomas Schoenknecht, PhD, Executive Director, Business Development, SHL Group
9:00 – 9:30
Orfeo Niedermann, MBA, Business Development Director, Delivery Systems, Ypsomed
9:30 – 10:00
Questions and Answers/Discussion

8:30 – 10:00
Track B: Testing
Moderator: Georg Roessling, PhD, Senior Consultant, Business Development Asia, PDA

To guarantee the quality of pharmaceutical products, many data must be measured and assessed. This must happen during development but also in routine production. The right selection of primary packaging components is needed to ensure that no leachables affect the quality, but to also ensure container closure integrity. Besides the right fit of the primary packaging components, the suitability for assembling into devices has to be tested. The presentations in this session will describe the latest developments in regulations and technology on container closure, extractables and leachables, and device testing. For any injectable, the visual inspection of the primary container is mandatory. An industry perspective will share the latest on visual inspection.

8:30 – 9:00
Current Best Practice in Bioburden Control
James N. Polarine, Jr., MA, Senior Global Technical Service Manager, STERIS Corporation
9:00 – 9:30
Trends in Container Closure Integrity Testing
Lei Li, PhD, Associate Senior Consultant Engineer, Eli Lilly and Company
9:30 – 10:00
Questions and Answers/Discussion

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

10:30 – 12:00
Track A: Devices
Moderator: Magnus Fastmarken, Global Director Marketing, SHL Group

10:30 – 10:55
Connectivity: Adding Value beyond Drug Delivery
Markus Bauss, Managing Director, SHL Connect, SHL Group
10:55 – 11:20
Good Injection Device Can Add Values to Your Drugs
Edgar Yeh, Project Manager, CC Biotechnology Corporation

15:30 – 17:00
Track B: Testing
Moderator: Georg Roessling, PhD, Senior Consultant, Business Development Asia, PDA

10:30 – 11:00
Extractables and Leachables
Piet Christiaens, PhD, Scientific Director, Nelson Labs
11:00 – 11:30
Container and Device Testing
Erik Berndt, Industry Manager Medical/Pharmaceutical, Zwick
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<tr>
<td>11:20 – 12:00</td>
<td>Injection Device Assembly and Testing</td>
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<td>Gilbert Fluetsch, MBA, Director, Automation, SHL Group</td>
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<td>Lucy Chung, Director, Automation, SHL Group</td>
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<tr>
<td>11:30 – 12:00</td>
<td>Questions and Answers/Discussion</td>
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<td>12:00 – 13:00</td>
<td>Networking Luncheon</td>
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<td>13:00 – 14:30</td>
<td>P3: Lifecycle Management Approaches for a Successful Business</td>
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<td>Moderator: Robin Hwang, Consultant, ICP Consulting Corp.</td>
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<td>This session addresses the relevance of lifecycle management approaches for a successful business. Approaches might be changes in formulation or changes in the application system (e.g., change from vial to syringe).</td>
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<td>13:00 – 13:30</td>
<td>Lifecycle Management Strategy for Her2 Family on Biosimilars Development</td>
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<td>Dr. L-C Liu, CEO, EirGenix, Inc.</td>
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<td>13:30 – 14:00</td>
<td>Drug Delivery System Life Cycle Management (LCM): Factors to Consider</td>
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<td>Amy Wang, PhD, Director, Drug Delivery and Device Development, Alexion Pharmaceuticals, Inc.</td>
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<td>14:00 – 14:30</td>
<td>Polymeric Primary Containers for Mitigating Challenges in Therapeutic Protein Drug Products</td>
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<td>Bruce Eu, Engineering Director, Final Product Technology, Amgen, Inc.</td>
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<td>Risako Tanaka, Sales, Daikyo Seiko, Ltd.</td>
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<td>14:30 – 15:00</td>
<td>Refreshment Break in Exhibit Area</td>
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<td>15:00 – 17:30</td>
<td>P4: Electronics, Devices, and Pharma</td>
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<td>Moderators:</td>
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<td>Chung-Hsien Wu, PhD, Director, Biotechnology &amp; Pharmaceutical Industries Promotion Office, Ministry of Economic Affairs, Taiwan</td>
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<td>Markus Bauss, Managing Director, SHL Connect, SHL Group</td>
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<td>In the history of disease treatment, first there were pharmaceutical components only. With biological products, devices became increasingly important to improve convenience for patients. Recently there are approaches to make devices “intelligent” by integrating electronic features into them. This will potentially improve patients’ treatments by allowing the device to directly interact with the patient.</td>
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<td>This session will address the future in the interdisciplinary field of electronics, devices, and pharma. Taiwan is known to have very strong capabilities in semiconductor, electronics, information and communication technology (ICT), precision molding, metal processing, and mechanical engineering, which allow Taiwan to be a great partner for device manufacturing as well as for making devices “intelligent” for the pharma industry. As such, this session will also address what roles can Taiwan play and what opportunities are in Taiwan in this interdisciplinary field of electronics, devices, and pharma.</td>
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<td>Five short presentations will introduce into the topic of the panel discussion.</td>
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<td>15:00 – 15:15</td>
<td>Roles and Opportunities of Taiwan in the interdisciplinary field of Electronics, Devices, and Pharma</td>
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<td>Chi-Feng Chang, PhD, Deputy Director, Biotechnology &amp; Pharmaceutical Industries Promotion Office, Ministry of Economic Affairs, Taiwan</td>
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<td>15:15 – 15:30</td>
<td>Taiwan’s Regulations on “Intelligent” Drug Delivery Devices: A Medical Device Prospective</td>
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<td>Jai-Yen Chen, PhD, Senior Reviewer in Division of Medical Devices, Center for Drug Evaluation</td>
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<td>15:30 – 15:40</td>
<td>How Can DCB Help from Drug Discovery to Development, Biotech Incubation, and Digital Health Acceleration?</td>
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<td>Chia-Cheng Wu, PhD, Executive Director of Institute of Biologics, Development Center for Biotechnology</td>
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15:40 – 15:50
Perspective of a Representative of the Device Industry
Markus Bauss, Managing Director, SHL Connect, SHL Group

15:50 – 16:00
Perspective of a Representative of the Pharmaceutical Industry
Mathias Romacker, Senior Director, Device Strategy, Pfizer, Inc.

16:00 – 17:30
Panel Discussion to Address:
The panel discussion wants to address:
• What are the advantages for patient, doctors, pharma industry, insurance companies?
• What are the challenges and hurdles?
• What are drivers?
• What are business opportunities for Pharma, electronics and IT industry?
• What are the opportunities for Taiwan’s industry?
Panelists:
Jai-Yen Chen, PhD, Senior Reviewer in Division of Medical Devices, Center for Drug Evaluation
Kimmy Chang Chien, Sanofi Taiwan
Alex Dee, Vice President, Product Marketing, FIC
Artur Kadurin, Chief Executive Officer, Insilico Taiwan
Mathias Romacker, Senior Director, Device Strategy/Marketing, Pfizer, Inc.
Thomas Schoenknecht, PhD, Executive Director, Business Development, SHL Group

17:30
Closing Remarks
Georg Roessling, PhD, Senior Consultant, Business Development Asia, PDA