



2018 PDA Drug Delivery of Injectables Conference

From Primary Containers to Devices

11月6~9日 | 台北晶華酒店 | 台北, 台灣

無菌製劑協會(Parenteral Drug Association, PDA)、瑞健(SHL Group)、經濟部生技醫藥產業發展推動小組(BPIPO)於11月6日至9日假台北晶華酒店舉辦「2018 PDA Drug Delivery of Injectables Conference」。以藥物傳輸裝置為主軸，邀請全球各界專家分享最新藥物傳輸裝置關鍵零組件、智慧製造、產品利基、國際品質系統法規、市場趨勢與電子醫材產品在製藥產業的應用等議題。會議期間也將開設相關培訓課程，更深入討論會議期間的主題。藉由本次會議，增進台灣製藥業者提昇國際佈局與關鍵能量，醫材廠商亦可藉此機會切入製藥領域的跨界合作，歡迎生技產業各界專家踴躍報名參加。

The Scientific Organizing Committee

- Magnus Fastmarken, SHL Group, Co-Chair
- Robin Hwang, ICP Consulting Corp., Co-Chair
- Biotechnology & Pharmaceutical Industries Promotion Office (BPIPO), Ministry of Economic Affairs, Taiwan
- Gabriele Peron, Stevanato Group
- Mathias Romacker, Pfizer, Inc.
- Wayne Wu, Intech Biopharm Corp.
- Molly O'Neill Moir, CMP, PDA
- Georg Roesling, PhD, PDA

- ◇ 會議議程、註冊與收費方式可參閱以下說明與連結，或至 PDA 官網(<https://www.pda.org/>)查詢。
- ◇ 展覽攤位參考資料下載 (<http://www.pdatc.org.tw/upload/files/PDATaiwanConferenceSponsor.pdf>)

<<優惠資訊更新>>

因來信詢問不斷，為促進學研單位與國際生醫產業對接，本次所有的 **workshop***活動提供有限名額讓政府單位、學校、研究機構、財團法人等非營利單位免費參與。符合上述規定並有興趣參與之人士，務必以英文填寫以下表格，並直接 email 至 PDA 官方窗口 moir@pda.org 進行報名。

First name	
Last name	
Professional title	
Company	
Email address	

*符合資格之人士，僅有 workshop 免費參與。Conference、training course 仍需自費參加。

MONDAY, 5-NOVEMBER-2018

2018 PDA SHL Site Visit

SHL will be hosting a site visit at their Taiwan facility for registrants of the PDA Drug Delivery of Injectables Conference. To participate in this site visit, please email moir@pda.org to reserve your spot. Only full conference attendees will be considered, and seats are limited to 25 people on a first-come first-served basis. Reserve your spot today!

Registration Fees
Complimentary for registered full conference attendees!

TUESDAY, 6-NOVEMBER-2018 – WEDNESDAY, 7-NOVEMBER-2018

2018 PDA Drug Delivery of Injectables Conference

The 2018 PDA 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.

For more information and to register, visit www.pda.org/2018Taiwan.

Registration Fees	
Members	\$895 USD
Non-members	\$1195 USD
Government/Health Authority/Academic	\$400 USD
Student	\$150 USD

THURSDAY, 8-NOVEMBER-2018

2018 PDA Connectivity Workshop: Digital and Pharma

The 2018 PDA Connectivity Workshop: Digital and Pharma will address all aspects of pharmaceutical connectivity including manufacturing, product design, patient benefit, and applications.

For more information and to register, visit www.pda.org/2018connectivityworkshop.

Registration Fees		
Members	\$495 USD	
Non-members	\$675 USD	
Government/Health Authority/Academic	\$315 USD	
Student	Members	\$200 USD
	Non-members	\$250 USD
Young Professional Member (member only)	\$270 USD	

THURSDAY, 8-NOVEMBER-2018

2018 PDA Development of a Pharmaceutical Product in an Injection Device Training Course

For more information and to register, visit www.pda.org/2018developmentproductcourse.

Registration Fees	
Members	\$495 USD
Non-members	\$675 USD

THURSDAY, 8-NOVEMBER-2018

2018 PDA Designing A Risk-Based Cleaning and Disinfection Program for Pharmaceutical, Biotech, and Medical Device Facilities Training Course

Many regulatory inspections fail because of inadequate behavior in the manufacturing environment, with the reason being often too little knowledge of cleaning and disinfection practices. The PDA Designing a Risk-Based Cleaning and Disinfection Program for Pharmaceutical, Biotech, and Medical Device Facilities Training Course will teach what the regulations ask for, how cleaning and disinfections must be performed. The Course gives the theoretical background with practical examples (with equipment) in group exercises. In a step-by step approach, participants learn how to plan, execute cleaning and disinfection, removal of residues, and how to control results. Participants learn from real case studies what needs to be done to have the cleanrooms under control.

For more information and to register, visit www.pda.org/2018RBCTaiwan.

Registration Fees	
Members	\$495 USD
Non-members	\$675 USD

THURSDAY, 8-NOVEMBER-2018 – FRIDAY, 9-NOVEMBER-2018

2018 PDA Quality Culture Assessment Tool and Training Course

PDA has developed the Quality Culture Assessment Tool and Training to guide your company to a better understanding of quality culture, how to assess it, and what actions to take to improve it.

Before you can implement this tool at your organization, you will be provided with the required comprehensive training. Over two days, you will learn how to use this tool to effectively collect verifiable data. As a result, the tool will allow you facilitate positive culture changes and continuous improvement within your

organization. The goal is to ensure that a quality mindset and behaviors are embedded into the daily work of the individuals involved in all functions to ultimately ensure the delivery of high-quality product to patients.

Take the first steps toward evaluating the quality culture at your site and identifying opportunities for improvement by enrolling in the Quality Culture Assessment Tool and Training. The quality of your product and the safety of patients depends on it!

For more information and to register, visit www.pda.org/2018TaiwanQCT.

Registration Fees	
Members	\$2800 USD
Non-members	\$3500 USD

THURSDAY, 8-NOVEMBER-2018 – FRIDAY, 9-NOVEMBER-2018

2018 PDA Extractables and Leachables Training Course

The 2018 PDA Extractables and Leachables Training Course will cover all aspects of extractables and leachables, including: understanding the polymers used in the manufacture of pharmaceutical containers and closures, understanding glass as an important material used in the manufacture of primary packaging of small volume parenterals, the mechanism of leaching, and much more!

For more information and to register, visit www.pda.org/2018TaiwanEL.

Registration Fees	
Members	\$675 USD
Non-members	\$855 USD

THURSDAY, 8-NOVEMBER-2018 – FRIDAY, 9-NOVEMBER-2018

2018 PDA Container Closure Integrity Testing Training Course

The PDA Container Closure Integrity Testing Training Course utilizes lectures, instrument demonstrations, hands-on testing exercises, case studies, and interactive group discussions to provide insight into the fast-evolving regulatory landscape in the container closure integrity field and the latest development in testing technologies. The Course introduces a practical and meaningful methodology to construct package integrity profiles using a risk-based approach and appropriate Container Closure Integrity (CCI) testing methods.

For more information and to register, visit www.pda.org/2018TaiwanCCIT.

Registration Fees	
Members	\$675 USD
Non-members	\$855 USD

VENUE

Regent Taipei

No. 3, Ln. 39, Sec. 2 Zhongshan N. Rd., Taipei 104, Taiwan

Phone: +886 2 2523 8000

Transportation

If you are driving, take the Zhongshan Expressway to the Chongqing North Road interchange, turn left at Minzu East Road, continue straight ahead and turn right on Lin Sen North Road to reach the hotel. Our hotel is conveniently located within walking distance of Zhongshan MRT station.