International Conference on the **Development and Regulatory Consideration** for Complex Products

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複雜產品開發及法規考量之國際研討會

Organizer:



Platform for Research and Inspiration in Regulatory Science, **School of Pharmacy, National Taiwan University**

臺大藥學專業學院國際藥政法規科學研究平台

2023年3月25日 (六) 09:30 am - 16:00 pm

臺灣大學藥學專業學院水森館101室 (臺北市林森南路33號) 實體 / Webex 線上同

Moderators:

- Churn-Shiouh Gau (高純琇), Ph.D. / Professor, School of Pharmacy, National Taiwan University, Taiwan
- Lin-Chau Chang (張琳巧), Ph.D. / Assistant Professor, School of Pharmacy, National Taiwan University, Taiwan

Time	Topic	Speaker
09:30~09:40	Opening	Li-Jiuan Shen (沈麗娟), Ph.D. / Dean and Professor, School of Pharmacy, National Taiwan University, Taiwan
09:40~10:30	Regulatory and Developmental Considerations for Drug-Device Combinations	Frances Richmond, Ph.D. / Director of the D. K. Kim International Center for Regulatory Science & Professor of Regulatory and Quality Sciences, Department of Regulatory and Quality Sciences, University of Southern California, USA
10:30~11:20	Addressing the Regulatory Requirements and Scientific Challenges for Generic DPI Products	Hak-Kim Chan, Ph.D. / Professor, School of Pharmacy, Faculty of Medicine and Health, The University of Sydney, Australia
11:20~11:30	Break	
11:30~12:20	A Developer's Perspective on the Evolvement and Impact of the Techniques and Regulations for Inhaled Products	William Wu (吳維修), MBA / General Manager, Intech Biopharm, Taiwan
12:20~13:10	Lunch break (<u>Lunch is provided</u>)	
13:10~14:00	Formulation & Process of Lipid Nanoparticles for Delivery of RNA Therapeutics	King Lam (林瓊), Ph.D. / Vice Director, Development Center for Biotechnology Institute Drug Evaluation Platform, Taiwan
14:00~14:50	Pharmaceutical Development and Regulatory Considerations for Liposome Products	Yun-Long Tseng (曾雲龍), Ph.D. / Vice President, Research & Development Division, TLC, Taiwan
14:50~15:00	Break	
15:00~15:50	The Regulatory Science Consideration and Experience on Complex Products	Chien-LungTu (杜建龍), MSc. / Former Reviewer, Center for Drug Evaluation, Taiwan
15:50~16:00	Closing	