



Workshop

“Regulatory and Industry Perspectives on New Drug Development: Focusing on Non-New Chemical Entities (Non-NCE)”

February 22-23, 2022

Organized by the Faculty of Pharmaceutical Sciences, Chulalongkorn University

In partnership with the Thai Food and Drug Administration (FDA) and the Medical Research

Network of the Consortium of Thai Medical Schools (MedResNet),

And with funding support from the National Research Council of Thailand (NRCT).



February 22, 2022

Time	Topic	Speaker
08.15 - 08.45	Registration	
08.45 - 09.00	Opening remark & Training program introduction	
09.00 - 09.45	Introduction to hybrid medicinal products and applications: Eligibility and non-clinical and clinical study requirements	Dr. Kaye Robertson, Therapeutic Goods Administration (TGA), Australia
09.45 - 10.30	Overview of Thai Regulatory Processes and Requirements for New Drug Approval	Dr Suchart Chongprasert, Thai FDA
10.30 - 10.45	Break	
10.45 - 11.30	Thai FDA consultation process	Supatra Phongsri, Thai FDA
11.30 - 12.15	Thai Regulatory guideline: Common Technical Document (CTD) for New drugs developed from previously approved substances	Nalinratt Dhiraouransakun, Thai FDA
12.15 - 13.15	Lunch	
13.15 - 14.30	Product feasibility assessment: Concepts	Pravich Tanyasittisuntorn, M.D., MedResNet
14.30 - 14.45	Break	
15.00 - 15.45	Product feasibility assessment: A case example	Pravich Tanyasittisuntorn, M.D., MedResNet
15.45 - 16.30	Target Product Profile (TPP)	Asst. Prof. Dr. Boonsri Ongpipattanakul

February 23, 2022

Time	Topic	Speaker
09.00 - 9.45	Introduction to Pre-IND and Pre-NDA meeting packages	Dr. Thomayant Prueksaritanont
9.45 - 10.30	Preparation of Common Technical Document (CTD): General considerations	Pravich Tanyasittisuntorn, M.D., MedResNet
10.30 - 10.45	Break	
10.45 - 11.45	Tips for Preparation of Common Technical Document (CTD): Non-clinical and clinical focuses	Pravich Tanyasittisuntorn, M.D., MedResNet; Assoc. Prof. Dr. Suree Jianmongkol
11.45 - 12.15	Group Assignments	Asst. Prof. Dr. Boonsri Ongpipattanakul; Assoc. Prof. Dr. Suree Jianmongkol
12.15 - 13.30	Lunch	
13.00 - 14.30	Case exercise - group breakout room	Dr. Thomayant Prueksaritanont et al.
14.30 - 14.45	Break	
14.45 - 16.30	Case exercise - group presentations	Dr. Thomayant Prueksaritanont et al.
16.30 - 16.45	Q&A	Dr. Thomayant Prueksaritanont et al.
16.45 -17. 00	Closing	Dr. Thomayant Prueksaritanont

Please note program and timings are subject to change.