



International Regulatory Science Forum 2024
Navigating Digital Health Product Development in Southeast Asia
Amid Evolving FDA Regulations

Under the Support from the Reinventing University: Drug Discovery & Development
March 12-15, 2024

Venue: Rajaratana Building (Room 206), Faculty of Pharmacy, Mahidol University
Continuing Pharmacy Education Code: 1002-2-000-002-03-2567 (14.25 credit)
Continuing Medical Education: Code: 1-1100-207-2071/240312 (24.75 credit)

Date/time	Topic	Speaker
12 March 2024		
08.35-08.40	Chairperson's remark	Prof. Leena Suntornsuk Faculty of Pharmacy, Mahidol University
08.40-09.00	Opening ceremony Welcome remark	Prof. Banchong Mahaisavariya, M.D. President of Mahidol University Prof. Hong-Chen Chen, Executive Vice President NCKU, Taiwan Ms. Hsiu- Mei Hsueh, Deputy representative of Taipei Economic and Cultural Office, Thailand Assoc. Prof. Eunjoo Huisung Pacifici, Chair, Department of Regulatory and Quality Sciences, USC, USA
09.00-09.30	Keynote lecture I : FDA regulates digital health devices	Assist. Prof. Chiaoyun Benson Kuo, USC, USA
09.30-10.00	Keynote lecture II : Implementation of digital health and current digital health products in Thailand	Mr. Pongpat Techavijit, Medical Device Control Division, FDA, Thailand
10.00-10.30	Keynote lecture III : Medical device safety and performance	Prof. Kuo-Sheng Cheng, NCKU, Taiwan
10.30-10.45	Break	
10.45-11.15	Plenary lecture I : Strategic navigation of FDA registration for digital health innovation: An industry perspective	Mr. Wirun Wetsiri, Pharm Connection (Thailand) Co., Ltd.
11.15-11.45	Plenary lecture II : Medical Device Regulations in Taiwan and its Actions Promoting AI/ML-based Medical Device	Dr. Chia-Hung Chien, Deputy Director Taiwan FDA, Taiwan Mr. Shang-Ching Lin, Associate Technical Specialist Taiwan FDA, Taiwan
11.45-12.15	Plenary lecture III : FDA clinical validation requirements for AI/ML-enabled medical devices	Mr. Yu Zhao, Bridging Consulting, USA
12.15-13.30	Lunch break	
13.30-14.00	Plenary lecture IV : Labeling requirements for digital health devices	Assoc. Prof. Eunjoo Huisung Pacifici, USC, USA
14.00-14.30	Invited lecture I : Software as medical device &AI How to implement and regulate in Thailand	Mr. Nakorn Tangwancharoenchai, Medical Device Control Division, FDA, Thailand

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14.30-15.00	Invited lecture II : The key elements of QMS and/or ISO 13485 for digital health devices	Dr. Lequina Myles, USC, USA
15.00-15.15	Break	
15.15-15.45	Invited lecture III : Digital technology transforms the designs and implementations of clinical trials	Prof. Frances Richmond, USC, USA
15.45-16.15	Invited lecture IV : Regulation of 3D printing medical device	Dr. Chen-Hsun Weng, NCKU, Taiwan
16.15-16.45	Invited lecture V : Exploring the FDA regulatory framework for AI/ML-enabled medical devices	Dr. Mary Wilhelm, USC, USA
13 March 2024		
08.30-09.00	Invited lecture VI : Anticancer drug-loaded Polymeric Implants for Brain Cancer Treatment and Nano-coating of Medical Devices	Prof. Dr. Norased Nasongkla, Faculty of Engineering, Mahidol university, Thailand
09.00-9.30	Invited lecture VII : Design considerations for digital health devices	Prof. Gerald Loeb, Biomedical Engineering, USC, USA
9.30-10.00	Invited lecture VIII : Bringing a medical device to the market: Regulatory and commercializing challenges	Dr. I-Ching Fang, CEO of Codent Technial Industry Co. Ltd, Taiwan
10.00-10.30	Invited lecture IX : Development of rehabilitation system and software	Assoc. Prof. Panrasee Ritthipravat, Faculty of Engineering, Mahidol university, Thailand
10.30-10.45	Break	
10.45-11.15	Invited lecture X : Cybersecurity	Dr. Samuel Wang, Consultant of MDIC and GEM Consultants International CORP, Taiwan
11.15-11.45	Invited lecture XI : AI applications in pharmacy	Assoc. Prof. Natapol Pornputtapon, Faculty of Pharmaceutical Sciences, Chulalongkorn University, Thailand
11.45-12.15	Invited lecture: XII: Pharmacy informatics and digital health system	Assoc. Prof. Anuchai Theeraroungchaisri, Faculty of Pharmaceutical Sciences, Chulalongkorn University, Thailand
12.15-13.30	Lunch break	
13.30-14.00	Invited lecture XIII : Drug identification information technology for healthcare providers	Asst. Prof. Brompoj Prutthiwanasan, Faculty of Pharmacy, Mahidol University, Thailand
14.00-14.30	Invited lecture XIV : Digital disruption in dentistry	Assoc. Prof. Pong Pongprueksa, Faculty of Dentistry, Mahidol University, Thailand
14.30-14.45	Break	
14.45-16.00	Workshop I : Digital health : Introduction	Dr. Lequina Myles, USC, USA
16.00-17.15	Workshop II : The Q-Submission program	Mr. Yu Zhao, Bridging Consulting, USA
14 March 2024		
09.00-10.30	Workshop III : 510k vs. De Dovo process	Mr. Yu Zhao, Bridging Consulting, USA
10.30-10.45	Break	
10.45-12.15	Workshop IV : Software as a medical device	Mr. Yu Zhao, Bridging Consulting, USA
12.15-13.30	Lunch break	
13.30-14.00	Exhibition	
14.00-15.30	Workshop V : AI/ML-enabled medical devices	Dr. Mary Wilhelm, USC, USA Mr. Yu Zhao, Bridging Consulting, USA
15.30-15.45	Break	
15.45-17.15	Workshop VI : Cybersecurity	Assist. Prof. Chiaoyun Benson Kuo, USC, USA