



VER: 25-12-19

## **International Regulatory Science Forum 2026**

**Global Landscape of Advanced Therapy Medicinal Products (ATMP) in Health Care**

**March 20, 2026**

**Venue: Rajaratana Building (Room 206), Faculty of Pharmacy, Mahidol University**

**Continuing Pharmacy Education Code: 1002-2-000-008-03-2569 (4.75 credit)**

**Continuing Medical Education: Code: 1-1100-207000-207100/260320-01 (7.75 credit)**

### **Rationale and Background**

The Global Landscape of Advanced Therapy Medicinal Products (ATMPs) in Healthcare conference, hosted by Mahidol University and co-hosted by the University of Southern California, USA, National Yang Ming Chiao Tung University, and Taipei Medical University Hospital, Taiwan, aims to strengthen international collaboration in addressing the scientific, regulatory, and policy challenges associated with the development and integration of ATMPs. These advanced therapies including gene therapy, cell-based therapy, and tissue-engineered products, hold the potential to revolutionize treatment paradigms for a wide range of serious and rare diseases. However, their advancement is accompanied by significant complexities, including regulatory uncertainties, safety and efficacy evaluation, high production costs, and challenges in ensuring equitable patient access.

In this rapidly evolving global healthcare environment, collaborative efforts between academia, regulatory bodies, industry, and healthcare professionals are essential to accelerate innovation while maintaining rigorous standards for patient safety and public health. Within this framework, the Faculty of Pharmacy, Mahidol University plays a critical leadership role in advancing regulatory science and fostering regional and international cooperation. As a leading academic institution in Thailand, Mahidol University is uniquely positioned to bridge scientific research, regulatory policy, and clinical application.

The conference brings together a distinguished group of stakeholders, including international universities, regulatory experts, professional associations, and representatives from the Thai Food and Drug Administration (Thai FDA). This diverse and multidisciplinary participation underscores the growing need for harmonized regulatory approaches, transparent data-sharing practices, and capacity-building initiatives that support the safe and efficient development of ATMPs. Ultimately, this conference enhances Mahidol University's role as a regional hub for health innovation and regulatory excellence, while providing a global platform to advance shared goals in regulatory harmonization, cross-border collaboration, and equitable access to life-changing medical technologies.

## **Objectives**

1. To enhance collaborations among Mahidol University and co-hosted by the University of Southern California, USA, National Yang Ming Chiao Tung University, and Taipei Medical University Hospital, Taiwan, and other partners to strengthen academic and regulatory science exchange.
2. To cultivate interactions among regulatory agencies, and regulatory affairs professionals within Thailand and internationally.
3. To promote global cooperation in the development, regulation, and equitable access of ATMPs through the convergence of regulatory standards.

## **Host Organizations**

### **Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Mahidol University**

- Prof. Dr. Leena Suntornsuk, Email: leena.sun@mahidol.ac.th
- Assoc. Prof. Dr. Chutima Phechkrajang, Email: chutima.mat@mahidol.ac.th
- Assoc. Prof. Dr. Nantana Nuchtavorn, Email: nantana.nuc@mahidol.ac.th
- Tel. 0-2644-8695 during business hours

### **Academic Service Supporting Unit, Faculty of Pharmacy, Mahidol University**

- Email: mupy.conference.regis@gmail.com, Mobile: 088-982-9049

## **Participants**

International and local pharmacists, regulators and scientists in the field of ATMPs from both public and private sectors, faculty members, students and those who are interested.

## **Conference's Date, Time, and Venue:**

March 20, 2026 at Rajaratana Building (Room 206), Faculty of Pharmacy, Mahidol University

## **Expected Outcomes**

In alignment with the first objective, this conference will foster a strong and sustainable partnership between the Faculty of Pharmacy, Mahidol University, and the University of Southern California's Department of Regulatory and Quality Sciences, which is globally recognized for its comprehensive academic offerings. This collaboration combines global expertise in regulatory science, enhancing research capabilities and promoting innovative approaches in the regulation and development of ATMPs. This synergy will position Mahidol University as a regional leader in advanced therapy regulation.

Regarding the second objective, the conference will enhance active engagement and dialogue among key stakeholders, including regulatory agencies such as the Thai FDA and international counterparts. This interaction will foster mutual understanding between government authorities, industry representatives, and academia, contributing to the creation of a cohesive ecosystem that supports the efficient development, approval, and commercialization of ATMPs within Thailand and beyond. Increased communication will promote shared best practices, regulatory alignment, and capacity building across sectors.

For the third objective, the conference's unique assembly of participants from Thailand, the United States, and other countries will provide invaluable insights into diverse regulatory landscapes and industry capabilities. Learning from the mature regulatory frameworks and

advanced industry practices in the U.S., alongside Thailand's growing manufacturing capacity and regional expertise, will inspire innovation and accelerate the adoption of cutting-edge ATMP technologies locally. This exchange is anticipated to drive harmonized regulatory standards, promote cross-border collaborations, and improve equitable patient access to next-generation therapies, ultimately contributing to improved healthcare outcomes and sustainable development of advanced medical products.

### **Key Performance Indicators**

1. Participants not less than 80
2. Satisfaction not less than 4/5

**Conference Fee:** 1,500 Thai Baht \*including lunch and refreshment\*

### **Registration:**

Online registration for the conference can be made at the website: TBD

### **Invited Speakers**

#### **Thai Speakers \*confirmed\***

**1) Prof. Dr. Leena Suntornsuk**

Professor in Pharmaceutical Chemistry from the Pharmaceutical Chemistry Department, Faculty of Pharmacy, Mahidol University, Thailand

Topic: Overview of Global Regulatory Framework for Advanced Therapy Medicinal Products (ATMPs)

**2) Asst. Prof. Rochapon Wacharotayankun**

Pharmacy Council Advisor, Thailand

Topic: Landscape of ATMPs Products in Thailand

**3) Dr. Piyanant Boonprasert**

Thai FDA senior officer, Medicines Regulation Division, Thai FDA

Topic: Regulation of ATMPs in Thailand: Current, Future Trends and Challenges

**4) Assoc. Prof. Supannikar Tawinwung**

Associate professor from Faculty of Pharmacy, Chulalongkorn University, Thailand

Topic: Manufacturing and Quality Control of ATMPs: From Bench to Bedside

#### **International Speakers \*confirmed\***

**1) Assoc. Prof. Eunjoo Huisung Pacifici**

Chair, Department of Regulatory and Quality Sciences, University of Southern California, USA

Topic: The Regulatory Landscape of ATMPs in United States

**2) Distinguished Prof. Chi-Ying Huang**

Dean, College of Pharmaceutical Sciences, National Yang Ming Chiao Tung University, Taiwan

Topic: AI-Powered Dual-Action BesKne-Exo® Extracellular Vesicle Therapy: from bench to regulatory consideration

**3) Dr. Ocean Wan-Hsuan Chou**

GCRA (Genetic Cancer Risk Assessment) specialist, Taipei Medical University Hospital, Taiwan  
Topic: AI-driven neoantigen identification and cancer vaccine

**4) Prof. Shawn Hsiang-Yin Chen**

Vice Dean, College of Pharmacy, Taipei Medical University, Taiwan  
Topic: Artificial Intelligence and Machine Learning–based Software as a Medical Device:  
Addressing the Regulatory Gap Between Research Innovation and Clinical Implementation

**5) Assist. Prof. Shao-chin Chiang**

Assistant professor from National Yang Ming Chiao Tung University, Taiwan  
Topic: Comparing the Guidances on the Healthcare Professionals' Handling of Gene Therapy  
Medicinal Products from Different Countries

**6) Dr. Martin Koning-Bastiaan**

Executive Director of Human Research Protections and Research Technology, University of  
Southern California, USA  
Topic: Traceability as a Regulatory Control in Cell-Based ATMPs

**Confirmed International Participants from USC**

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| 1) Assist. Prof. Chiaoyun Benson Kuo | USC Professor |
| 2) Ms. Mika Baumgardner              | USC Student   |
| 3) Mr. Lennor Johnston               | USC Student   |
| 4) Ms. Manasa Kancharla              | USC Student   |
| 5) Ms. Angie Lainez                  | USC Student   |
| 6) Ms. Jin Seo                       | USC Student   |
| 7) Mr. Brian Vuong                   | USC Student   |