

# **Good Registration Management (GRM)**

## **in Action :**

### **Thailand's Experience**

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**Director, Bureau of Drug Control  
Food and Drug Administration**

# Why GRM ?

**Goal of GRM: To benefit the patients with timely access of medical products of safe, efficacious and good quality**

➤ **Good Review Practice (GRevP)**

To strengthen the performance, predictability, and transparency of regulatory agencies through the implementation or enhancement of GRevP and quality measures stepwise in each interested APEC economy

➤ **Good Submission Practice (GSP)**

To enhance the quality and efficiency of the medical product registration process by improving the quality of submission as well as its management

# Success Story Local GRM Conference (1)

1<sup>st</sup> Good Registration Management Conference :

26<sup>th</sup> – 28<sup>th</sup> June 2018



## SPEAKER

International : Taiwan FDA

Domestic : Thai FDA, Academic

## PARTICIPANT

### Day 1: Plenary session

❖ 338 participants

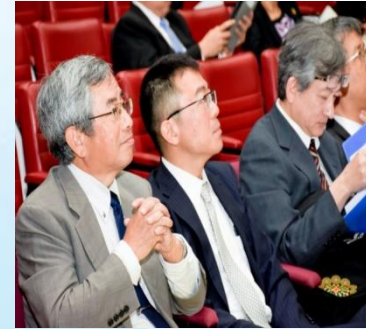
### Day 2-3: Parallel sessions

❖ GRevP: 60 participants  
(Thai FDA and Experts)

❖ GSubP: 59 participants  
(Industries: PReMA, TPMA,  
TSMIA, RAPAT and TIPA)

# Local GRM Training Program Experience (2)

## Plenary Session



## Good Review Practice Workshop



## Good Submission Practice Workshop







14 March 2019

*Dr Suchart Chongprasert*  
*Director*  
*Bureau of Drug Control, Food and Drug Administration*  
*88/24 Food and Drug Administration, Ministry of Public Health,*  
*Tiwanon Road, Nonthaburi 11000, Thailand*

Dear *Dr Suchart Chongprasert*,

Thank you for your application to host an APEC LSIF RHSC Training Center of Excellence (CoE) for Regulatory Science pilot for *Good Registration Management*. On behalf of the APEC LSIF Regulatory Harmonization Steering Committee (RHSC), we are pleased to notify you of the RHSC's endorsement of this pilot.

As outlined in the *APEC LSIF RHSC Training Centers of Excellence for Regulatory Science Operating Model*, a PWA CoE Program Committee, including representatives from the Champion Economy(ies), other interested economies and interested industry coalitions, will support and collaborate with your organization in this effort. Other pertinent information on the conduct of APEC CoE pilot programs can be found in the *Operating Guidelines and Steps to Formalize a CoE*.

Should you have any questions, please feel free to contact the Champion Economy(ies) or the RHSC Co-Chairs for assistance.

Thank you for your participation in this exciting initiative.

Sincerely,

Dr Michelle Limoli  
Co-Chair APEC RHSC

Dr Nobumasa Nakashima  
Co-Chair APEC RHSC

Thank You