1st GRM Training

in Thailand

Presented at 7th APAC
10 April 2018

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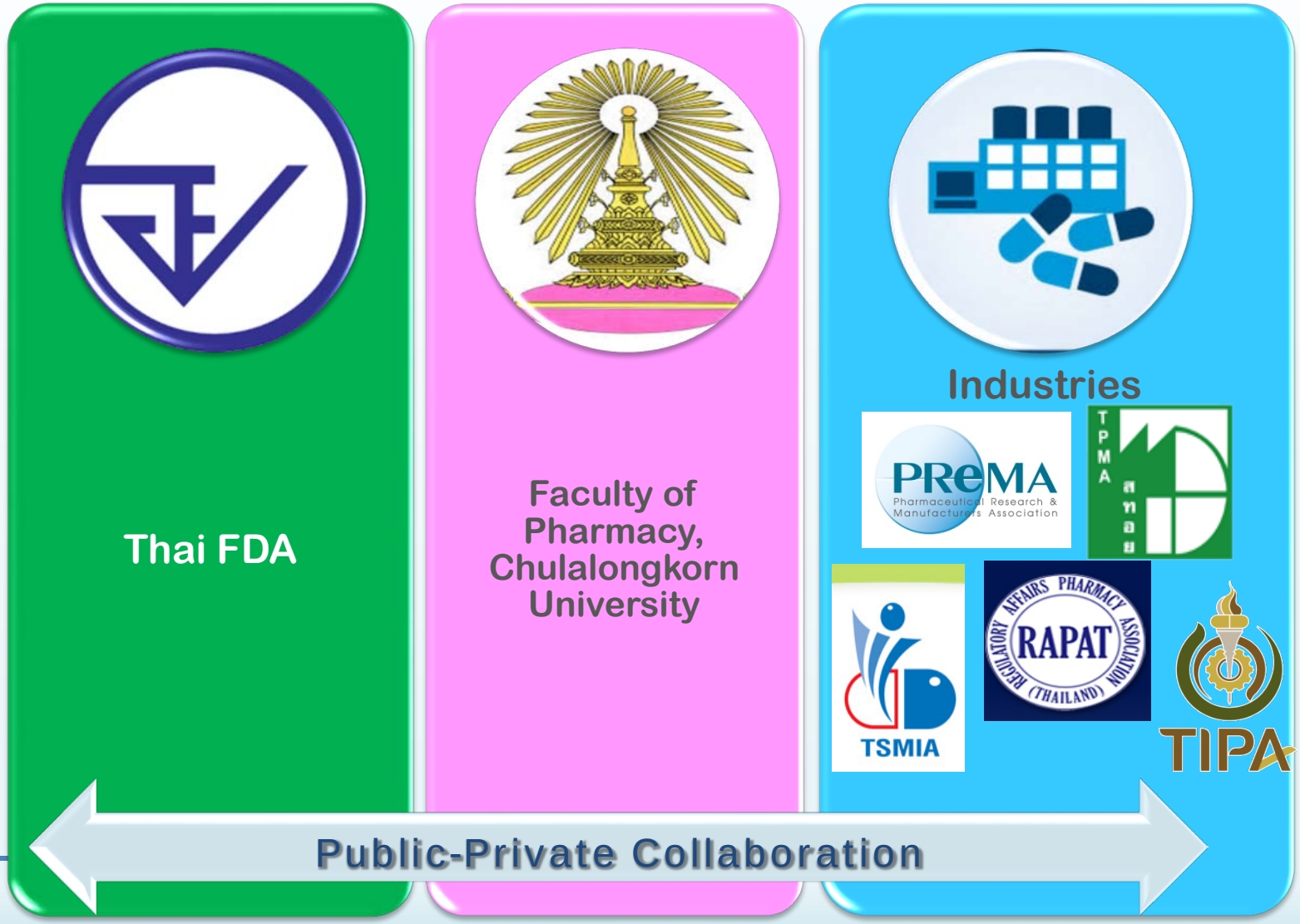
PReMA

1st GRM Training in Thailand
Public-Private Collaboration Initiative



GRM in Thailand

Training on GRM in Thailand

Date: 26-28 June 2018

Format of training:

26 June: Plenary

27-28 June: Parallel Workshops:

- Good Review Practice (GRevP)
- Good Submission Practice (GSubP)

Audiences: Thai FDA officers, reviewers, industries

- Day 1: 26 June – 200-250 pax
  - open to all interested
- Day 2-3: 27-28 June – 50 pax each (GRevP & GSubP)
  - audiences must have at least 2-5 years’ experiences

Venue: Chulalongkorn University

Day 1-26 June 2018

TIME	TOPICS / SPEAKERS
8:30-9:00	REGISTRATION
9:00-9:40	**OPENING REMARKS** ***THAI FDA - Secretary-General*** Introduction of GRM: Thailand policy and Future ahead ***Dr. Suchart, Dr. Rungpetch,*** Industry Group photo
	Common Sessions
9:40-10:00	REFRESHMENT BREAK
10:00-11:00	**Session 1**: Basic Concept of GRM ***Speaker: TAIWAN FDA or WHO***
11:00-12:00	**Session 2**: An Overview of Good Review Practice – WHO GRevP guidelines ***Speaker: TAIWAN FDA (confirmed)***
12:00-13:00	LUNCHEON
13:00-14:00	**Session 3**: An Overview of Good Submission Practice – APEC GSubP guidelines ***Speaker: JPMA (confirmed)***
14:00–14:30	**Session 4:** Experiences Sharing from other APEC economies – Reviewer ***Speaker: TAIWAN FDA***
14:30-15:00	REFRESHMENT BREAK
15:00:-15:30	**Session 5:** Experiences Sharing from other APEC economies (cont.) - Applicant ***Speaker: JPMA (confirmed)***
15.30-16.30	**Session 6:** Regulatory Competency Framework How to build competency – Applicant ***Speaker: Dr. Noppadol*** How to build competency – Reviewer ***Speaker: Dr.Suchart***
16:30-17:00	**Session 7:** Wrap-up for Common Sessions ***Speaker: Dr.Suchart***

Parallel Sessions:27-28 June 2018

GRevP	GSubP
Day 2: Good Review Practice – Managing and Conducting the review - Taiwan FDA & Health Canada	Day 2: Session A1: Planning of Application - PReMA & TIPA team
Good Review Practice– Review personnel - Thai FDA & Chula team	Session A2: Preparation of applicant dossier/ Practice: How to prepare application dossier - PReMA team
Day 3: Good Review Practice – Communication - Taiwan FDA or Health Canada	Day 3: Session A3: Effective communications - Focusing follow-up actions during review period /Practice: Case study of how to handle inquiries - PReMA team
Common Session – Wrap Up	
Part 1: How to define the core competency of applicants Part 2: Reviewer expertise, competencies, and training	

Thailand Ecosystem for Innovative Medicine in 2020

- **Become one of global supply chain for innovative medicine to accelerate patient access**
- **Collaborative action of Government + Academia + Industry (dosmestic + MNC): PICs, GLP, GRM, GCP etc.**
- **GRM and other Thai FDA strategic action achieving Thailand Regional Registration Hub**