



สำนักงานคณะกรรมการอาหารและยา
Food and Drug Administration



Applicant Specific Sessions

DAY 2 | 27 June, 2018 Auditorium, 10th Floor, Innovation Building

TIME	TOPICS / SPEAKERS
27 June, 2018 8:30-9:00	REGISTRATION
9:00-12:00	Session A1: Planning of Application <i>Session Leader and/or Speaker 1: Krisana Winitthumkul, PReMA</i> <i>Speaker 2: Kanokwon Prasitporn, TIPA</i>
12:00-13:00	LUNCH
13:00-17:00	Session A2: Preparation of Applicant Dossier Practice: How to Prepare Application Dossier <i>Session Leader and/or Speaker 1: Usanee Harnpramukkul, PReMA</i> <i>Speaker 2: Wipada Rodtanaporn, PReMA</i>

DAY 3 | 28 June, 2018 Auditorium, 10th Floor, Innovation Building

TIME	TOPICS / SPEAKERS
8:30-9:00	REGISTRATION
9:00-10:30	Good Review Practice – Communications - Fundamentals of Communication for Regulatory Authorities and Experience Sharing on Interagency communication <i>Dr. Hsien-Yi Lin, Taiwan Food and Drug Administration</i> <i>Dr. Chi-Hsun Chen, Center of Drug Evaluation, Taiwan</i>
10:30-12:15	Session A3: Effective Communications - Focusing Follow-up Actions During Review Period /Practice: Case Study of How to Handle Inquires <i>Session Leader and/or Speaker 1: Pattaree Sinananpat, PReMA</i> <i>Speaker 2: Wannapa Withaporn, PReMA</i>
12:15-13:00	LUNCH
13:00-14:45	Session A4: Rolling out the GRM Training Program in Your Organization <i>Session Leader and/or Speaker 1: Dr. Wanchai Chongcharoen, Faculty of Pharmaceutical Sciences, CU</i> <i>Speaker 1: Speaker 2 : Krisana Winitthumkul</i>
14:45-15:00	REFRESHMENT BREAK
All participants (Group photo)	
15:00-16:45	Session A5: Panel Discussion - Wrap-up for Common Sessions Part 1: How to Define the Core Competency of Applicants Part 2: Reviewer Expertise, Competencies, and Training <i>Moderator: Dr. Rungpetch Sakulbumrungsil, CU</i> <i>Panelist: Dr. Suchart Chongprasert, Thai FDA</i> <i>Ms. Busakorn Lerswatanasivalee, PReMA</i>
16:45-17:00	CLOSING REMARKS <i>Dr. Suchart Chongprasert, Thai FDA</i> <i>Ms. Busakorn Lerswatanasivalee, PReMA</i> <i>Dr. Rungpetch Sakulbumrungsil, Faculty of Pharmaceutical Sciences, CU</i>