

Good Registration Management Workshop for Industry 2019 (Malaysia)

We are pleased to announce that the Good Registration Management Workshop for Industry 2019 will be held on 01-02 October 2019 at the Sheraton Hotel Petaling Jaya. The workshop is organised by PhAMA in collaboration with Taylor's University and supported by NPRA. The workshop will be conducted by our certified trainers on Good Submission Practice and supported by certified trainers on Good Review Practice from NPRA. and also other workshop facilitators from NPRA and the industry. There will be practical sessions which include collaboration and interactions with officers from NPRA. The program incorporates breakout practice sessions, case studies and group discussions so that participants can be actively involved in the process of learning.

The seminar is now open for registration. Since this training program is conducted in workshop sessions, it will be limited to 50 participants on a first-come first-served basis. So please send your application soonest possible if you or your team member is interested. The registration fee is RM1,350. Registration will close by **15th September 2019**.

If you need any assistance Please contact PhAMA Event secretariat MPA SDN BHD at events@phama.org.my or janice@phama.org.my . More details are provided in the program below and the online registration form is given in the link here:

[Regulatory Training Workshop on Good Registration Management \(GRM\) 2019](#)

WHO SHOULD ATTEND:

- Regulatory staff involved in planning, preparing documents and submission of dossiers for regulatory applications.
- Anyone requiring a good understanding of Good Submission Practice (GSubP) and Good Registration Management (GRM)
- Product Registration Holders (PRH) /applicants and Regulatory Managers/Executives with 1 to 5 years' experience are encouraged to attend this training.

Kindly NOTE that this training is focused on the principles of Good Submission Practice (GSubP) and Good Registration Management (GRM), and do not intend to provide training on specific technical requirements for drug registration.

GRM Workshop for Industry 2019 (Malaysia) - Program

DAY 1 (01 October 2019)		
TIME	TOPIC	SPEAKER/MODERATOR
8:30-9:00	Registration	
9:00-9:10	Welcome Remarks	PhAMA President
9:10-9:20	Opening Speech	Pn Rosilawati Ahmad, NPRA
9:20-9:40	Special Topic: Malaysian Expectation on Good Registration Management for Medicinal Products, including Current development and practice in NPRA	Pn Rosilawati Ahmad, NPRA
9:40-10:05	Session 1: Introduction of GRM a. Basic concept of GRM b. Overview of Good Submission Practice	Ms Alice Chee
10:05-10:25	<i>Refreshment Break</i>	
10:25-11:05	c. Overview of Good Review Practice (and Sharing good practices and challenges from applicants faced by reviewer)	Ms Carol Ling Hui Ming, NPRA
11:05-11:15	<i>Ice Breaker</i>	Ms Cheah Voon Yuen
11:15 – 12:00	Session 2a: Planning for Submission	Ms Soo Li Ping
12:00-13:00	Session 2b: Practice on Planning for Submission - Case Studies NDA - Case Studies Generics	Moderator: Ms Tan Kwee Lan Ms Gan Ching Ching
14:15-15:15	Session 3a: Preparation of Application Dossier	Ms Primita Joseph
15:15-17:00	Session 3b: Practice on Preparation of Application Dossier - <i>Dossier preparation- Practice</i> 1. <i>Orientation</i> 2. <i>Practice-1</i> 3. <i>Practice-2</i> - <i>Group discussion for presentation</i> - <i>Group presentation</i>	Moderators: Ms Primita Joseph ,
17:00-17:30	<i>Refreshment</i>	

DAY 2 (02 October 2019)

TIME	TOPIC	SPEAKER/MODERATOR
8:00-8:30	REGISTRATION	
8:30-9:00	Session 4:-Comprehensive Exercises in GRM - Component Focus on Labelling a. Preparation & submission of Labelling	Ms Cheah Voon Yuen
9:00-9:30	b. Review of Labelling	Pn Nurul Farhana Mohd Sofian, NPRA
9:30-9:45	<i>Refreshment Break</i>	
9:45-10:45	c. Case Studies and Practices in Submission and Review of Labelling	Moderator: Ms Tan Kwee Lan
10:45-11:45	- Group Presentations - Summary	Moderator: Ms Tan Kwee Lan
11:45-12:15	Session 5: Effective Communications a. Overview of Communication – Industry Aspects	Ms Jayanthi Boobalan
12:15-12:45	b. Overview of Communication – Regulators’ Aspects	Pn Nurul Farhana Mohd Sofian, NPRA
12:45-14:00	<i>Lunch Break</i>	
14:00-14:20	c. Practice on Effective communication 1st Round Discussion: Communication issues and challenges you have experienced before	Moderator: Ms Jayanthi Boobalan
14:20-15:20	d. 2nd Round Group Discussion Identify Some Common Issues and Challenges from 1st Round Discussion How to resolve identified common issues and challenges	Moderator: Ms Cheah Voon Yuen
15:20-15:30	<i>Refreshment Break</i>	
15:30-16:30	- Group Presentations - Summary	Moderators: Ms Jayanthi Boobalan Ms Cheah Voon Yuen Pn Nurul Farhana Mohd Sofian Ms Carol Ling Hui Ming
16:30-17:00	Session 6: Competency & Training	Ms Peggy Hoo Yoon Fong
17:00-17:15	Closing Remarks	Prof P.T. Thomas, PhD Taylor’s University
17:15-17:45	<i>Refreshment</i>	