Collaborative Regulatory Training Seminar 2016:

Challenges & Issues with Registration & Variation Applications

Venue: Ballroom, Eastin Hotel Date:09-10 March 2016 (Wed-Thurs)

Introduction

This training seminar is jointly organised by the Pharmaceutical Association of Malaysia (PhAMA), Malaysian Organisation of Pharmaceutical Industries (MOPI) and Malaysian Association of Pharmaceutical Suppliers (MAPS) in collaboration with the National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia.

The purpose of this seminar is for the industry to acquire a better understanding of the drug registration and variation requirements in Malaysia. Registration experts from NPCB will be covering common issues/problems encountered with the industry's submissions for drug registrations and gaps in understanding of NPCB's registration requirements, with case studies and clarification on the more challenging sections of the guidelines, as well as Do's & Don'ts and other advice for industry personnel to be more competent in generating registration applications of high quality and to obtain timely approvals from the Drug Control Authority (DCA).

Who should attend:

Key personnel involved in the drug registration submissions with NPCB and management of these registration applications for timely approvals from the DCA. Product Registration Holders/ applicants (PRH) and Regulatory Managers/ Executives are encouraged to attend.

Jointly Organised by:

PhAMA "Innovative Medicines for Malaysia" | mopi | MAPS Malaysian Association of Pharmaceutical Suppliers

In Collaboration with:

National Pharmaceutical Control Bureau (NPCB) Ministry of Health Malaysia

Day 1: Challenges & Issues with Product Registrations (Screening & Evaluation)

Time	Topic	Presenter
8:00 – 9:00	Seminar Registration by participants (Morning Tea/Coffee)	
9:00 – 9:15	Welcome & Opening	Mr Tan Ann Ling, NPCB Director
9:15 – 10:00	Registration Challenges & Issues (General)	Datin Zahura Mohamed@Ismail
10:00– 10:45	FDI & Medical Device-Drug Classification	Pn Fatimah Azman / Pn Su Siew Ching
10:45– 11:15	TEA/COFFEE BREAK	
11:15 – 12:15	Common Registration Issues with **BA/BE, Poisons and OTC** applications	BA/BE : Cik Khirul Falisa Mustafa Generik (Poison) : Pn Cynthia Albert Gunaratnam Generik (Non-Poison) : Pn Suhailah Abu Bakar
12:15 – 13:00	Common Registration Issues with **Biologics** applications	Dr Yvonne Khoo Siew Khoon
13:00 – 14:00	LUNCH BREAK	
14:00 – 14:40	Common Registration Issues with NCE applications	Pn. Azura Abdullah / Pn. Chuah Su Yin Florence
14:40 – 15:10	Common Registration Issues with Health Supplement applications	Pn. Ong Swan Wui
15:10 – 15:40	Common Registration Issues with Traditional Medicine applications	Pn. Nordalila Sabuan
15:40 – 16:10	Common Registration Issues with API applications	Pn. Roslina Ibrahim
16:10 – 16:30	End of day Q&A session	
16:30 – 17:00	Tea/Coffee	

Day 2: Challenges & Issues with Variations (Screening & Evaluation)

Time	Topic	Presenter
8:00 –8:30	Registration (Morning Tea/Coffee)	
8:30 – 9:30	Common Variation Issues with Pharmaceuticals (NCE, Poison, OTC)	NCE : Pn Siti Hidayah Kasbon (Poison & OTC Non Poison) : Ms Evelyn Loh
9:30 – 10:30	Common Variation Issues with Biologics	Pn. Jenny Thong Chen Ni
10:30 - 11:00	Tea/Coffee Break	
11:00 – 12:00	Common Variation Issues with Complementary Medicines (Health Supplements & Traditional Medicines)	HS : Ms Kam Kher Li Trad : Ms Kong Su Yi
12:00 – 12:30	Update on Orphan Drugs Designation & Registration	Pn. Anis Talib/Pn Azura Abdullah
12:30 – 13:00	Q&A session	
13:00 – 14:00	Closing /Lunch	