

NATIONAL REGULATORY CONFERENCE 2013

DAY 1: 7 May 2013 (TUESDAY)

7.30am – 9.00am	Registration		
9.00am – 9.15am	Welcoming Remarks <i>Y. Bhg. Dato' Eisah A. Rahman</i> Senior Director of Pharmaceutical Services, Ministry of Health Malaysia		
9.15am – 9.30am	Opening Ceremony <i>Y.B. Dato' Sri Liow Tiong Lai</i> Minister of Health Malaysia		
9.30am – 10.00am	Key Note Address <i>Y. Bhg Datuk Dr. Noor Hisham Abdullah</i> Director General of Health, Ministry of Health Malaysia		
10.00am – 10.30am	COFFEE BREAK		
MORNING PLENARY SESSION			
Chairperson: <i>Dr. Tajuddin Akasah, National Pharmaceutical Control Bureau (NPCB), Ministry of Health (MOH)Malaysia</i>			
10.30am – 11.30am	Plenary 1:- Updates on Current and Future Regulatory Developments in Malaysia <i>Mr. Tan Ann Ling</i> Director, National Pharmaceutical Control Bureau (NPCB), Ministry of Health (MOH)Malaysia		
11.30am – 12.30pm	Plenary 2:- Malaysia Adherence to Organisation for Economic Cooperation and Development (OECD) Good Laboratory Practice (GLP) Mutual Acceptance of Data (MAD) System <i>Dr. Hasenah Ali</i> Head of GLP Section, NPCB, MOH		
12.30pm – 2.00pm	LUNCH		
AFTERNOON TRACK SESSIONS			
	Track 1: Traditional Medicines and Health Supplements (TMHS) Chairperson: <i>Ms. Mazli Muhammad NPCB</i>	Track 2: Pharmaceutical Products Chairperson: <i>Mr. Radzmi Rahmat</i> Malaysian Association of Pharmaceutical Suppliers (MAPS)	Track 3: Biologic Products Chairperson: <i>Ms. June Oi</i> Pharmaceutical Association of Malaysia (PhAMA)
2.00pm – 2.30pm	Herbal Product Development in Malaysia <i>Hj Ibrahim bin Saleh</i> Delivery Management Office, Ministry of Agriculture (MOA)	The Way Forward for Local Pharmaceutical Industries <i>Mr. Jamaludin Elis</i> Pharmaniaga Manufacturing Berhad	Clinical Considerations for Biosimilars and Existing Regulatory Guidance <i>Dr Martina Sersch</i> Genentech/ F. Hoffmann-La Roche
2.30pm – 3.00pm	Helping SME industries to Go Global <i>Mr. Azman Md. Yusof</i> Malaysia External Trade Development Cooperation (MATRADE)	Quality Risk Management <i>Mr. Steve Slater</i> Traque Asia, Singapore	
3.00pm – 3.30pm	Integration of Traditional Medicine into Allopathic Healthcare System <i>Dr. Zalilah Abdullah</i> Traditional & Complimentary Medicine Division, MOH	Implementation of Bioequivalence Study for Generic Medicines in Malaysia <i>Ms. Mazuwin Zainal Abidin</i> NPCB	Cell and Tissue Therapies: Current Trend and Challenges <i>Prof Dr. Ruszymah Hj Idrus</i> Tissue Engineering Centre, UKM Medical Centre
3.30pm – 4.00pm	Guidelines on Higher Claims for Complementary Medicine in Malaysia <i>Datin Shantini Thevendran</i> NPCB	Design Updates and Requirements in Bioequivalence Study <i>Dr. Lee Toong Chow</i> Info Kinetics Sdn. Bhd.	Malaysian Vaccine Programme: Pathway for Malaysia's Nascent Vaccine Industry <i>Mr. Jay Padasian,</i> Malaysian Biotechnology Corporation (BiotechCorp)
4.00pm – 4.30pm	Q & A	Q & A	Q & A
4.30pm – 5.00pm	ADJOURN & COFFEE		
7:30pm	OFFICIAL DINNER		

DAY 2: 8 May 2013 (WEDNESDAY)

MORNING PLENARY SESSION

Chairperson: Dr. Kamaruzaman Saleh, National Pharmaceutical Control Bureau (NPCB), Ministry of Health (MOH) Malaysia

8.30am – 9.15am	<p>Plenary 3:- Regulation of Cellular and Gene Therapy Products (CGTPs) in Malaysia <i>Ms. Arpah Abas</i> <i>Head of Biologics Section, NPCB, MOH</i></p>
9.15am – 10.00am	<p>Plenary 4:- Global Regulatory Trends: Challenges and Implications – Is Asia Breaking Out of the Age of Innocence? <i>Mr. Chew Kwee Tat</i> <i>Director, Regulatory Strategist, Strategic Drug Development Asia, Quintiles East Asia Pte Ltd. , Singapore</i></p>
10.00am – 10.30am	COFFEE BREAK
10.30am – 11.15am	<p>Plenary 5:- Biotherapeutics: What's Right for Patients Moving Forward? <i>Karen M. Hauda</i> <i>Senior Director, Biotherapeutic Strategic Initiatives, AbbVie Inc., United States of America</i></p>
11.15am – 12.00am	<p>Plenary 6:- Supply Chain Management <i>Mr. Steve Slater</i> <i>Director, Traque Asia, Singapore</i></p>
12.00am – 12.45pm	<p>Plenary 7:- Current Global Landscape of Pharmacovigilance <i>Dr. Pia Caduff-Janosa</i> <i>Chief Medical Officer , Uppsala Monitoring Centre(UMC), Sweden</i></p>
12.45pm – 2.00pm	LUNCH

AFTERNOON TRACK SESSIONS

	<p>Track 1: Traditional Medicines and Health Supplements (TMHS) <i>Chairperson: Dato' Dr Rajen M Malaysian Dietary Supplement Association (MADSA)</i></p>	<p>Track 2: Pharmaceutical Products <i>Chairperson: Mr. Jimmy Piong Malaysian Organisation of Pharmaceutical Industries (MOPI)</i></p>	<p>Track 4: Cosmetic Products <i>Chairperson: Mr. Seng San Bing Federation of Malaysian Manufacturers-Malaysian Cosmetics and Toiletries Industry Group (FMM-MCTIG)</i></p>
2.00pm – 2.30pm	<p>Standardization of Herbal Extract <i>Prof. Zhari Ismail</i> <i>Universiti Sains Malaysia (USM)</i></p>	<p>Nano Medicines in Pharmaceuticals <i>Assoc. Prof. Shaharum Shamsuddin</i> <i>Universiti Sains Malaysia (USM)</i></p>	<p>New Breakthrough in Cosmetic: Skin Measurement Methodology Development <i>Dr Kukizo Miyamoto, P & G Japan</i></p>
2.30pm – 3.00pm	<p>Non-Clinical Studies for Herbal Products <i>Dr. Zakiah Ismail, Institute Medical Research (IMR), MOH</i></p>	<p>Risk Benefit Assessment and Risk Management <i>Dr. Pia Caduff-Janosa</i> <i>UMC, Sweden</i></p>	<p>Safety Assessment of Cosmetics <i>Mr. Mohd Helme Mohd Helan, SIRIM Berhad</i></p>
3.00pm – 3.30pm	<p>Global Trends in Health Supplement Regulations <i>Ms. Michelle Stout</i> <i>Amway Corporation, CA, USA</i></p>	<p>Understanding the Similarities and Differences Between the Innovator and Biosimilar Comparability Exercise <i>Karen M. Hauda</i> <i>AbbVie Inc., USA</i></p>	<p>Cosmetic Advertising & Product Claim <i>Ms. Zuraida Abdullah</i> <i>NPCB</i></p>
3.30pm – 4.00pm	<p>Trending of Adulteration – Adverse Drug Reactions (ADR) in TMHS Products <i>Ms. Basmiah Md. Isa, NPCB</i></p>	<p>Updates on Malaysian Variation Guidelines for Pharmaceutical <i>Mr. Chai Che Leong</i> <i>NPCB</i></p>	<p>Product Information File (PIF): What to Expect from The Audit? <i>Ms. Nik Shamsiah Nik Salleh</i> <i>NPCB</i></p>
4.00pm – 4.30pm	Q & A	Q & A	Q & A
4.30pm – 5.00pm	ADJOURN & COFFEE		

DAY 3: 9 May 2013 (THURSDAY)

PLENARY SESSION

Chairperson: Mr. Sulaiman Hj Ahmad, National Pharmaceutical Control Bureau (NPCB), Ministry of Health (MOH) Malaysia

8.30am – 9.15am	Plenary 8:- Updates on National Medicines Policy (DUNAS) <i>Dr. Salmah Bahri</i> <i>Director of Pharmacy Practice and Development, Pharmaceutical Services Division, MOH</i>
9.15am – 10.00am	Plenary 9: Halal Pharmaceuticals: A Regulator's Perspective – MS 2424 <i>Dr. Tajuddin Akasah</i> <i>Deputy Director, NPCB, MOH</i>
10.00am – 10.45am	Plenary 10:- Pharmacy Legislative Transformation <i>Mr Mohd Zulkifli Bin Abdul Latif</i> <i>Deputy Director, Legislation, Pharmacy Enforcement, Pharmaceutical Services Division, MOH</i>
10.45am – 11.15am	COFFEE BREAK
11.15am – 12.00pm	Plenary 11:- Advertisement: Self-Regulation and Enforcement <i>Mr. Muhammad Lukmani Ibrahim</i> <i>Secretary of Medicine Advertisement Board, MOH</i>
12.00pm – 12.45pm	Plenary 12:- Regulation of Medical Devices in Malaysia <i>Mr. Zamane Abd Rahman</i> <i>Chief Executive Officer, Medical Device Authority, MOH</i>
12.45pm – 1.15pm	Plenary 13:- QUEST 3+: Issues and Challenges <i>Ms. Siti Aida Abdullah</i> <i>Deputy Director, NPCB, MOH</i>
1.15pm – 1.30pm	Closing remarks <i>Mr. Tan Ann Ling</i> <i>Director, National Pharmaceutical Control Bureau (NPCB), MOH</i>
1.30pm	LUNCH