Training Seminar on ICH Stability Guidelines (ICH-Q1)

in collaboration with NEU and supported by National Pharmaceutical Regulatory Agency (NPRA)

PhAMA 'Innovative Medicines for Malaysia'

Northeastern Biopharmaceutical Analysis Training Laboratory

NPRA

Date: August 6th – 8th, 2019

Venue: Dorsett Grand Subang, Jalan SS 12/1, 47500 Subang Jaya, Selangor, Malaysia

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Learning Objectives:

- Understand the and expectations on stability studies and appreciate use of risk management
- Describe the stability testing of drug substances and products as outlined in the ICH-Q1A(R2) and ICH Q5C guidelines.
- Explain the importance of photostability testing of new drug substances and products in ICH-Q1B.
- Define stability testing for new dosage forms as outlined in ICH-Q1C.
- Demonstrate the bracketing and matrixing ICH-Q1D
- Evaluation used for stability testing as explained in ICH-Q1E.
- Describe the WHO guidelines on stability testing of active pharmaceuticals in climatic zones III and IV, which replaced ICH-Q1F.
- Describe Life Cycle Management for stability changes (ICH Q12)
- Current practice in Malaysia

PhAMA: Pharmaceutical Association of Malaysia

NEU: Northeastern University, Burlington, Massachusetts, USA

NPRA: National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia

Day 1: Tuesday, August 6, 2019			
Session 1: Introduction to ICH and Stability Testing			
08:30-09:00	30′	Registration (light refreshments)	
09:00-09:10	10′	Welcome	*PhAMA*
09:10-09:20	10′	Opening Remarks	*NPRA*
09:20-09:30	10′	Group Photo	
09:30-10.15	45′	**1.1 ICH introduction and overview** of ICH stability guidelines and its Importance.	*Jared Auclair (NEU)*
10:15 – 10:30	15′	Coffee Break	*Networking*
10:30-12:00	90′	**1.2 ICH-Q1A(R2) and ICH-Q1C:** - **Stability Testing** of Drug Substances and Products Q1A(R2); - Stability Testing for New Dosage Forms (Q1C) with CASE STUDY	*Dinesh Khokal (Amgen)* *Chi-wan Chen (Pfizer)*
Session 2: Setting the scene			
12:00-13:00	60′	**2.1** A science and risk-based approach to utilize stability data **to set specifications** Proposed Topics to be covered in this part: • Importance of Degradation studies – selecting the right degradation products to monitor • Building a body of knowledge - Importance of primarily studies: clinical material, predictive stability, formulation compatibility studies • Batch selection – What criteria to use for Drug Substance and Drug Product • Setting Specifications based upon release data and stability data • Impact on Product shelf life and In-Use period	*Kayla Woodlief (Biogen)*
13:00-14:00	60′	Lunch	
14:00-15:10	70′	**2.2 WHO - Stability testing** of active pharmaceutical ingredients and finished pharmaceutical products (replaces ICH-Q1F)	*Kayla Woodlief (Biogen)*
15:10-15:45	35′	**2.3 In-use stability studies**	*Open*

15:45-17:00	75′	**2.4 ICH-Q1E: Evaluation for Stability Data**	*Chi-wan Chen (Pfizer)*
17:00-17:15	15′	Q&A Session	All Speakers & NPRA Representatives
17:15-17:30	15′	Coffee Break	*Networking*
Day 2: Wednesday, August 7, 2019			
Session 3: Specific expectations			
08:30-09:00	30′	Coffee and Breakfast	*Networking*
09:00-10:15	75′	**3.1 ICH-Q5C: Stability of Biotechnology products**	*German Lastra (Amgen)* –
10:15-10:30	15′	Coffee Break	*Networking*
10:30-11:30	60′	**3.2 ICH-Q1B**: Stability Testing: **Photostability Testing** of New Drug Substances and Products with CASE STUDY	*Open*
11:30-12:45	75′	**3.3 ICH-Q1D**: **Bracketing and Matrixing** Designs for Stability Testing of New Drug Substances and Products	*Open*
12:45-13:45	60′	Lunch	
13:45-15:15	90′	**3.4 Risk Based Predictive Stability**	*Open*
15:00-15:15	15′	Coffee Break	*Networking*
15:15-16:45	90′	**3.5** Science based harmonized **regulations for stability data and its relevance** to patients: Industry and Regulator Perspective **Case Studies**: **Risk Based Evaluation of stability** (totality of the data, atypical stability data, etc.)	*Quan Yang (Merck)*
16:45-17:15	30′	Q&A Session	All Speakers & NPRA Representatives
Day 3: Thursday, August 8, 2019			
08:30-09:00	30′	Coffee and Breakfast	*Networking*
09:00-10:15	75′	**3.6** Science based harmonized **regulations for stability data and its relevance** to patients: Industry and Regulator Perspective **Case Studies**: **Risk Based Evaluation of stability**	*Cedric Strassel (ROCHE*

		(totality of the data, atypical stability data, etc.)	
10:15-10:30	15′	Coffee Break	*Networking*
10:30-11:30	50′	**3.7 ICH Q12 Life Cycle management** (in relation to Stability)	*German Lastra (Amgen)*
11:30-12:20	60′	**3.8 Presentation on local perspectives**: • Current practice in Malaysia • Expectations for submission – Shortcomings, Do's & Don'ts etc. • Comparison with ASEAN-MY requirements • updates in ASEAN Guideline on Stability Study of Drug Product (R1)	• *Dr Seetha, NPRA*
12:20-12:50	30′	Final Q&A Session	All Speakers & NPRA Representatives
12:50-13:00	10′	Closing Remarks	*Jared Auclair (NEU)*
13:00-14:00	60′	Lunch	

Registration details

Please register via the online registration form at https://docs.google.com/forms/d/1YOOzV6AGpHtvnVsxfDVvhAsxKxP3N9doCdVpJyu3rMY/viewform?edit_requested=true

Participation is on a first-come-first-served basis and registration will close **by 17th July 2019**. Please contact PhAMA Event secretariat **MPA SDN BHD** at events@phama.org.my or janice@phama.org.my if you need any assistance. Registration Fee for industry is RM 1800.