Training Seminar on ICH Stability Guidelines (ICH-Q1)

in collaboration with NEU and supported by 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:
NEU will bring international faculty from industry and academia to deliver the training, and also regulators where possible, to provide this training.

- Understand the 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 (by NPRA)

WHO SHOULD ATTEND:
- All personnel who should have a good understanding and foundation on the scientific rationale of stability studies, and who will benefit from regulatory updates on the stability requirements in ICH and the local situation in Malaysia.
- Product Registration Holders (PRH) /Applicants and Regulatory Affairs personnel
- Other personnel involved with Quality Assurance, Quality Control, Validation, Stability, R&D and Operations.

Please see more details in the attached 2.5 days training program and registration form.
Participation is on a first-come-first-served basis and registration will close by **30th June 2019**.
Participants are also invited to suggest scenarios to be considered for case studies, in the seminar registration form.

About NEU (Northeastern University, Burlington, Massachusetts, USA):
Northeastern University is committed to regulatory convergence across the globe through training and capacity building. NEU's programs expand training in the US and around the world in regulatory science, Quality management and Good Manufacturing Practices (GMP). The Northeastern Biotechnology Program and Biopharmaceutical Analysis Training Laboratory (BATL) is recognized worldwide as the leading academic center in the training for regulatory convergence, and provide expertise in biotechnology and regulatory science, and training in these areas including Drug Stability.
In addition to being formally recognized as an APEC Center of Excellence in Biotherapeutics, BATL has also been recognized as a trusted training partner for the International Council for Harmonisation, specifically the ICH-Q1 guidelines.

As more complicated drugs enter the development pipeline personnel in industry and regulatory must be technically competent and remain current with the global regulatory framework. Furthermore, as drugs are developed for global launch following ICH guidelines, education needs to be globally focused. Northeastern University is committed to delivering a leading program in Biologics and Quality that will fill the current gap in the trained workforce.

Day 1: Tuesday, August 06, 2019		
Session 1: Introduction to ICH and Stability Testing		
08:30-09:00	30’	Registration (light refreshments)
09:00-09:10	10’	Welcome
09:10-09:20	10’	Opening Remarks
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.
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
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
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)
15:10-15:45	35’	**2.3 In-use stability studies**
15:45-17:00	75’	**2.4 ICH-Q1E: Evaluation for Stability Data**
17:00-17:15	15’	Q&A Session
17:15-17:30	15’	Coffee Break *Networking*

Day 2: Wednesday, August 07, 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**
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
11:30-12:45	75’	**3.3 ICH-Q1D**: **Bracketing and Matrixing** Designs for Stability Testing of New Drug Substances and Products
12:45-13:45	60’	Lunch
13:45-15:15	90’	**3.4 Risk Based Predictive Stability**
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.)
16:45-17:15	30’	Q&A Session
Day 3: Thursday, August 08, 2019		
08:30-09:00	30’	Coffee and Breakfast
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** (totality of the data, atypical stability data, etc.)
10:15-10:30	15’	Coffee Break
10:30-11:30	50’	**3.7 ICH Q12 Life Cycle management** (in relation to Stability)
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 (R2)
12:20-12:50	30’	Final Q&A Session
12:50-13:00	10’	Closing Remarks
13:00-14:00	60’	Lunch