

# ICH-Q1 TRAINING



## ICH-Q1 Stability Training

## Learning Objectives

**When:** October 10-12, 2018

**Where:** Burlington (Boston), MA  
Northeastern University

**Who:** Regulators

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

### To Register or Submit Nominations:

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*Funding opportunities available*

