

ICH-Q1 TRAINING



ICH-Q1 Stability Training

When: August 7-8, 2018

Where: ANVISA Brasilia, Brazil

Who: LATAM Regulators
(invitation only)

Learning Objectives

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-Q1F.

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

