

Stability Studies and Documentation

Gain practical insights into designing, conducting, and documenting stability studies

Understand the requirements for designing stability studies, performing stability testing, and preparing stability documentation. In collaboration with life science experts and the Danish Medicines Agency, we cover everything from initial development to ongoing stability studies, ensuring that you meet international guidelines.

About the course

Stability studies are a critical aspect of the pharmaceutical industry and involve evaluating how the quality of a drug substance or pharmaceutical product changes over time under various conditions. The purpose of stability studies is to establish the shelf life and storage conditions for a product, ensuring its safety, efficacy, and quality throughout its intended period of use.

Stability documentation is a regulatory requirement when applying for approval of drug substances and drug products, as well as for certain post-approval changes.

Inadequate stability documentation can cause delays during the approval process. In the worst case, it can result in rejection of your application, or you may end up with a shorter shelf life than planned or storage conditions that are unsuitable for the logistics of your drug product.

After the course, you will:

- Understand the requirements for designing stability studies and performing stability testing for pharmaceutical products. This includes evaluating how the quality of a drug substance or product changes over time under various conditions.
- Be able to establish appropriate shelf life and storage conditions for pharmaceutical products, ensuring their safety, efficacy, and quality throughout their intended period of use.
- Be updated on current international guidelines, such as those from ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) and the EU, relevant to stability studies and documentation.
- Gain hands-on experience in designing stability studies and interpreting relevant guidelines from life science experts.

Sign-up

Course

Stability Studies and Documentation

Format

3 days, overnight stay included

Price next year

24.100 kr. excl. VAT

Choose date and sign up

Hillerød 14. apr – 16. apr. 2027

We have teamed up with experts from the life science industry and the Danish Medicines Agency for this intensive 3-day course. We cover stability testing and documentation from development through ongoing stability studies. When working with stability documentation, you need to understand the relevant requirements and guidelines for stability studies. This course covers current international guidelines from, for example, ICH and the EU.

The course consists of presentations from experts and regulatory authorities, combined with group work and case studies in small groups. This provides hands-on experience in designing stability studies from a high-level perspective and gives you practical experience in interpreting relevant guidelines.

The course spans three days with an overnight stay, which provides time and space for reflection, immersion, and networking across participants—and thereby significantly enhances your overall learning outcomes.

Target group

The course is intended for academics who work with stability testing of drug substances and drug products, from development through post-approval changes and ongoing stability studies, including the preparation and evaluation of stability documentation.

What you gain

Your benefits

- You understand the requirements for designing, preparing, and evaluating stability studies and performing stability testing for drug substances and drug products based on international guidelines, such as those from ICH and the EU.
- You understand the importance of bracketing and matrixing in optimizing stability testing resources, enabling you to make informed decisions about the scope and extent of studies.
- You gain statistical knowledge to effectively plan and evaluate stability studies, enhancing data-driven decision-making and ensuring accurate and reliable outcomes.

Your company's benefits

- Your employee is equipped to prepare adequate stability documentation, reducing the likelihood of unnecessary delays or complications during regulatory reviews.

- Your employee can make informed decisions about the scope and extent of stability studies, leading to cost-effective and efficient resource allocation.
- Your employee's knowledge of statistical aspects of stability testing will enhance data-driven decision-making and improve the accuracy and reliability of stability study outcomes.

Course program

The course duration is 3 days. Accommodation is included.

Day 1: 09.00 – 18.00

- Stability in the development phase
- Q1A/Q1C
- Photostability
- Stability documentation for registration of generic drug substances and drug products
- Bracketing & matrixing (ICH Q1D)
- Stability for climatic zone IV countries
- Temperature controlled distribution

Day 2: 08:30 – 18:00

- Impurities and degradation products – requirements and analysis (ICH Q3A/Q3B)
- Specifications (ICH Q6A)
- In-use stability
- Investigation and documentation for leachables from drug product packaging
- Biological products – specifications and impurities (ICH Q5C/Q5E/Q6B)
- Statistical aspects of stability testing

Day 3: 08:30 – 15:30

- Microbiological aspects of stability testing
- The CTD format
- Storage conditions
- Stability for bulk products
- Stability documentation related to variations
- Ongoing stability

The course consists of presentations from experts and the authorities, together with group work and cases in small groups. This facilitates your hands-on experience in designing stability studies from a high level

perspective and that you will get practical experience in interpretation of the relevant guidelines.