pharmakon

Stability Studies and Documentation

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

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

Stability studies are a critical aspect of the pharmaceutical industry and involve the evaluation of how the quality of a drug 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 duration of use.

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

Inadequate stability documentation can cause delays in the approval phase. Worst case is rejection of your application, or you can end up with a shorter shelf life than planned, inappropriate for suitable logistic for your drug product.

After the course you
• Understand the requirements for designing stability studies and performing stability testing for pharmaceutical products. This includes evaluating how the quality of a drug or product changes over time under various conditions.

• Can establish appropriate shelf life and storage conditions for pharmaceutical products, ensuring their safety, efficacy, and quality throughout their intended duration of use.

• Are updated with the current international guidelines, such as those from ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) and EU, that are relevant to stability studies and documentation.

• Learn hands-on experience in designing stability studies and interpreting relevant guidelines from life science experts.

We have teamed up with experts from life science and The Danish Medicines Agency in this intensive 3-day course. We go through stability testing and documentation from development to ongoing stability. When working with stability documentation you need to know the relevant requirements and guidelines for stability studies. This course covers current international guidelines from e.g. ICH and EU.

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.

The course language is English

At the course you will meet:

Helle Mulvad, Quality Assessor, Danish Medicines Agency

Sanna Vinding Jönsson, Principal Scientist, LEO Pharma A/S
Abderrahman “Abdi” Bojazar, Area specialist, Novo Nordisk A/S
Carsten Worsøe, Principal Scientist, Novo Nordisk A/S
Ditte Vestergaard, Director Non-Clinical Quality, Novo Nordisk A/S
Masood Hosseini, Area Specialist, Novo Nordisk A/S

Course facts

FORMAT
3 days

RATING
4,5 out of 5

PRICE THIS YEAR
24.100 DKK excl. VAT, overnight stay included

Peter Thyregod, Principal CMC Statistician, Ascendis Pharma A/S
Rikke Stavnsbjerg, Manager QC Support, ALK-Abelló
Sandra Auguste-Bowler, Principal Regulatory Specialist, Novo Nordisk A/S
Marianne Gundel, Principal Analytical Scientist, LEO Pharma A/S
Monica Pulis, Principal Professional, LEO Pharma A/S

Sign-up dates

Hillerød

14. apr. — **16. apr.**
2027

Do you have questions about this course?

Kontakt
Kursuskoordinator
Andreas Goldschadt
+45 48 20 62 63
ag@pharmakon.dk

Target group

The course is intended for academics who work with stability testing of drug substances and drug products, from development to post approval changes as well as on-going stability including the preparation and evaluation of stability documentation.

Your benefits

• you understand the requirements to design, prepare, and evaluate stability studies and performing stability testing for drug substances and drug products based on international guidelines, such as those from ICH and 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's 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 employees knowledge of statistical aspects of stability testing will enhance data-driven decision-making and improve the accuracy and reliability of stability study outcomes.

Course agenda

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 facilitate 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.

The course language is English
The tutors are Danish i.e. questions can be asked both in Danish and in English.

Sign up online at
www.pharmakon.dk