Pharmakon

Stability studies and documentation

There is a lot to learn

Understand the requirements for designing the stability study, performing the stability testing and finally preparing the stability documentation.

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.

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:
Abderrahman “Abdi” Bojazar, Area specialist, Novo Nordisk A/S
Mikkel Pind, GDP & Anti-Counterfeit Specialist, H. Lundbeck A/S
Carsten Worsøe, Principal Scientist, Novo Nordisk A/S
Ditte Hougaard Vestergaard, QA Manager, Ascendis Pharma A/S
Helle Mulvad, Quality Assessor, Danish Medicines Agency
Masood Hosseini, Area Specialist, Novo Nordisk A/S
Peter Thyregod, Principal CMC Statistician, Ascendis Pharma A/S
Rikke Stavnsbjerg, Manager QC Support, ALK-Abelló
Sanna Vinding Jönsson, Principal scientist, LEO Pharma A/S
Sandra Auguste-Bowler, Principal Regulatory Specialist, Novo Nordisk A/S
Cecilie Møller Kristiansen, Quality Assessor, Lægemiddelstyrelsen
Monica Pulis, Principal Professional, LEO Pharma A/S

Course facts

FORMAT
3 days

RATING
4,5 out of 5

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

Sign-up dates

Hillerød
12. mar. — **14. mar.**
2025

Do you have questions about this course?

Kontakt
Kursuskoordinator
Andreas Goldschadt
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Target group

The course is intended for Pharmacists and others 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 know the requirements for stability documentation
- you ensure an effective approval phase
- you are familiar with bracketing & matrixing.

Your company's benefits

- your employee knows the relevant guidelines for stability studies
- your employee ensures that the company's stability documentation is adequate
- your employee can use statistics during planning and evaluation of stability studies.

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

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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