



MANUFACTURING AND PRODUCTION

Stability Studies and Shelf Life Determination for Medicines

3 day course

Classroom, online or in-house

Course overview

A shelf life is a commitment that a medicine will still meet specification years after it left the factory, made on the strength of data collected before it was ever sold. This course covers generating data that supports the claim. Delegates work through the purpose of stability testing and the difference between long term, intermediate and accelerated conditions. Climatic zones are addressed directly, since much of this region falls into the hottest and most humid zone and data generated for temperate markets does not transfer. Study design follows: batch selection, container closure, orientation, bracketing and matrixing. Testing schedules and the attributes that must be followed are covered. Stability indicating methods are addressed, including forced degradation and specificity. Data evaluation and shelf life extrapolation are covered with their statistical basis and their limits. Ongoing stability programmes and post approval commitments follow. Out of specification and out of trend results are addressed. The course closes on storage statements and on transport excursions.

What you will learn

- Distinguish long term, intermediate and accelerated conditions
- Apply the correct climatic zone for the intended market
- Design studies using bracketing and matrixing where justified
- Develop stability indicating methods with forced degradation
- Evaluate data and extrapolate shelf life within statistical limits
- Run ongoing stability and post approval commitments
- Handle out of specification results and justify storage statements

Who should attend

- Stability study coordinators and analysts
- Quality control laboratory staff
- Regulatory affairs staff compiling stability data
- Formulation and development scientists
- Quality assurance managers approving shelf lives

Course outline

- 01 A promise made before the first sale
- 02 Long term, intermediate and accelerated conditions
- 03 Climatic zones and market relevance
- 04 Batch selection and container closure
- 05 Bracketing, matrixing and testing schedules
- 06 Stability indicating methods and forced degradation
- 07 Data evaluation and extrapolation
- 08 Ongoing stability, excursions and storage statements

Upcoming dates



Dates	Venue	Format	Fee per delegate
30 September to 2 October 2026	Kampala, Uganda	Classroom	USD 995
26 to 28 October 2026	Online	Online	R6,500
2 to 4 December 2026	Harare, Zimbabwe	Classroom	USD 995
13 to 15 January 2027	Dar es Salaam, Tanzania	Classroom	USD 995

Fees and how to register

This 3 day course is **R6,500** per delegate online, **R14,950** in the classroom in South Africa, Botswana, Namibia, Lesotho and Eswatini, and **USD 995** in the classroom elsewhere in Africa. In-house training is quotation on request. Book 2 or more delegates on this course and save 10%.

To register or request an in-house proposal, visit www.afrisciencegroup.com, email info@afriScience.co.za, or WhatsApp us on **+27 63 479 1136**.

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