MANUFACTURING AND PRODUCTION

Sterile Manufacturing and Aseptic Processing

5 day course Classroom, online or in-house

Course overview

Sterility cannot be tested into a product, because the test examines a tiny fraction of a batch and would miss contamination in almost every unit, so assurance has to come from the process itself. This course builds that assurance. Delegates work through the difference between terminal sterilisation and aseptic processing, and the decision tree that determines which a product must use. Sterilisation methods are covered across moist heat, dry heat, filtration, irradiation and gas, with the validation each requires. Sterile filtration is addressed including integrity testing before and after use. Aseptic technique is treated in operational detail: gowning, behaviour, intervention discipline and the fact that people are the principal contamination source. Media fill simulations and their acceptance criteria follow. Isolators and restricted access barriers are covered. Environmental monitoring is addressed, including trend interpretation and excursion response. The course closes on contamination investigation, on sterility assurance level and on regulatory expectations for sterile facilities.

What you will learn

- Explain why sterility cannot be tested into a product
- Choose between terminal sterilisation and aseptic processing
- Validate moist heat, dry heat, filtration, irradiation and gas methods
- Perform sterile filtration with integrity testing
- Apply aseptic technique, gowning and intervention discipline
- Run media fill simulations against acceptance criteria
- Monitor the environment, respond to excursions and investigate contamination

Who should attend

- Sterile production operators and supervisors
- Microbiologists supporting sterile manufacturing
- Quality assurance staff in injectable production
- Validation engineers on sterile facilities
- Regulatory staff inspecting sterile operations

Course outline

01 Sterility cannot be tested in
02 Terminal sterilisation against aseptic processing
03 Moist heat, dry heat and irradiation
04 Sterile filtration and integrity testing
05 Gowning, behaviour and interventions
06 Media fill simulations
07 Isolators and barrier systems
08 Environmental monitoring, excursions and investigations

Upcoming dates

Dates	Venue	Format	Fee per delegate
12 to 16 October 2026	Lusaka, Zambia	Classroom	USD 1,325
2 to 6 November 2026	Dar es Salaam, Tanzania	Classroom	USD 1,325
23 to 27 November 2026	Online	Online	R8,500
25 to 29 January 2027	Windhoek, Namibia	Classroom	R19,950

Fees and how to register

This 5 day course is **R8,500** per delegate online, **R19,950** in the classroom in South Africa, Botswana, Namibia, Lesotho and Eswatini, and **USD 1,325** 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**.