MANUFACTURING AND PRODUCTION

Regulatory Affairs and Dossier Preparation for Medicines

3 day course Classroom, online or in-house

Course overview

A registration dossier is assessed by people who will never see the factory, so the file has to answer questions before they are asked and be internally consistent in every place a reviewer can cross check. This course covers building one. Delegates work through the common technical document structure and what belongs in each module. Quality documentation is covered in detail, since that is where most queries originate: drug substance, drug product, control of excipients, container closure and stability. Specification setting and justification follow. Bioequivalence requirements are addressed for generic products, including when a study is needed and when a waiver applies. Regional requirements are covered for the medicines regulators of the region, along with the harmonisation initiatives changing them. Variations, renewals and lifecycle management follow. Responding to a query is treated as a skill, including what not to volunteer. Good manufacturing practice inspection linkage is addressed. The course closes on submission planning and on the timelines a launch depends on.

What you will learn

- Structure a dossier to the common technical document format
- Compile quality documentation that answers queries in advance
- Set and justify specifications
- Determine bioequivalence requirements and waiver eligibility
- Meet regional regulator requirements and follow harmonisation changes
- Manage variations, renewals and lifecycle changes
- Respond to regulatory queries and plan submissions against launch timelines

Who should attend

- Regulatory affairs officers and managers
- Quality assurance staff supporting registrations
- Product development and technical staff
- Business development staff planning product launches
- Regulatory assessors and reviewers

Course outline

01 Assessed by people who never see the factory
02 Common technical document structure
03 Drug substance and drug product documentation
04 Excipients, container closure and stability
05 Specification setting and justification
06 Bioequivalence and waivers
07 Regional requirements and harmonisation
08 Variations, query response and submission planning

Upcoming dates

Dates	Venue	Format	Fee per delegate
4 to 6 January 2027	Online	Online	R6,500
13 to 15 January 2027	Mbabane, Eswatini	Classroom	R14,950
20 to 22 January 2027	Windhoek, Namibia	Classroom	R14,950
3 to 5 February 2027	Lagos, Nigeria	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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