MANUFACTURING AND PRODUCTION

Pharmacovigilance and Post Market Safety

3 day course Classroom, online or in-house

Course overview

A medicine is approved on data from a few thousand patients and then used by populations large enough to reveal effects the trials could never have detected, which makes post market surveillance the only place some risks will ever be found. This course covers running that surveillance. Delegates work through the pharmacovigilance system and the responsibilities a marketing authorisation holder carries. Adverse event definitions are covered, including seriousness, expectedness and causality assessment. Case processing follows: intake from all sources, triage, data entry, medical review and the timelines for expedited reporting. Signal detection is addressed, including disproportionality analysis and the judgement that turns a statistical signal into an action. Risk management plans and minimisation measures follow. Periodic safety reports are covered. Product complaints and their interface with quality are addressed, since a complaint can be both. Inspection and audit of a pharmacovigilance system follow. The course closes on recalls and safety communication to prescribers and patients.

What you will learn

- Explain the responsibilities of a marketing authorisation holder
- Assess seriousness, expectedness and causality of adverse events
- Process cases from intake through medical review within reporting timelines
- Detect signals and judge when a signal requires action
- Build risk management plans and minimisation measures
- Compile periodic safety reports
- Manage the quality interface, withstand audit and communicate safety issues

Who should attend

- Pharmacovigilance officers and drug safety staff
- Regulatory affairs professionals
- Medical affairs and medical information staff
- Quality assurance staff handling complaints
- Regulators supervising post market safety

Course outline

01 Effects trials could not detect
02 The pharmacovigilance system and responsibilities
03 Seriousness, expectedness and causality
04 Case intake, triage and medical review
05 Expedited reporting timelines
06 Signal detection and disproportionality
07 Risk management plans and periodic reports
08 Quality interface, audit, recalls and safety communication

Upcoming dates

Dates	Venue	Format	Fee per delegate
7 to 9 October 2026	Online	Online	R6,500
9 to 11 November 2026	Pretoria, South Africa	Classroom	R14,950
17 to 19 March 2027	Maputo, Mozambique	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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