MANUFACTURING AND PRODUCTION

Deviation, CAPA and Quality Risk Management in Pharmaceuticals

3 day course Classroom, online or in-house

Course overview

Most corrective actions in pharmaceutical manufacturing are retraining the operator, which is what an investigation concludes when it stops at the person nearest the event. This course goes past that. Delegates work through deviation classification and the criteria that separate a minor event from one requiring full investigation. Immediate actions and product impact assessment follow, including the decision on batches already made and released. Root cause analysis is covered with techniques that resist the obvious answer, and the discipline of testing a hypothesis against the evidence. Corrective and preventive action design is addressed, including effectiveness checks and the difference between correcting an event and preventing its recurrence. Quality risk management is covered as a working method: risk identification, analysis, evaluation and control, applied to real decisions rather than to a filed assessment. Trending across deviations follows. Complaint handling and recall decisions are addressed. The course closes on inspection readiness and on the state of a quality system that keeps repeating deviations.

What you will learn

- Classify deviations against defined criteria
- Assess product impact including released batches
- Conduct root cause analysis that resists the obvious answer
- Design corrective and preventive actions with effectiveness checks
- Apply quality risk management to real decisions
- Trend deviations to find systemic causes
- Handle complaints, make recall decisions and stay inspection ready

Who should attend

- Quality assurance staff handling deviations
- Production supervisors involved in investigations
- Quality managers and qualified persons
- Compliance and regulatory affairs staff
- Auditors of pharmaceutical quality systems

Course outline

01 Retraining the nearest operator
02 Deviation classification criteria
03 Immediate actions and product impact
04 Released batches and the recall question
05 Root cause analysis technique
06 Corrective and preventive action design
07 Effectiveness checks and trending
08 Quality risk management, complaints and inspection readiness

Upcoming dates

Dates	Venue	Format	Fee per delegate
9 to 11 November 2026	Online	Online	R6,500
25 to 27 November 2026	Dar es Salaam, Tanzania	Classroom	USD 995
9 to 11 December 2026	Pretoria, South Africa	Classroom	R14,950

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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