MANUFACTURING AND PRODUCTION

Process Validation and Qualification in Pharmaceutical Manufacturing

5 day course Classroom, online or in-house

Course overview

Validation is frequently run as a documentation exercise completed once and filed, which produces a folder that satisfies nobody and a process that nobody actually understands. This course treats it as the lifecycle it is. Delegates work through the three stages, process design, process qualification and continued verification, and what each is meant to establish. Critical quality attributes and critical process parameters are covered, including how they are identified rather than asserted. Design space and the relationship between parameters follow. Equipment qualification is addressed across design, installation, operational and performance stages, with the documentation each requires. Process performance qualification batches are covered, including how many and why. Sampling plans and statistical justification follow, since a plan without statistics cannot support a conclusion. Continued process verification is addressed with control charts and trend review. Change control and revalidation triggers are covered. The course closes on validation master planning and on defending a validation package to an inspector.

What you will learn

- Apply the three stage validation lifecycle
- Identify critical quality attributes and process parameters with evidence
- Define a design space and parameter relationships
- Qualify equipment through design, installation, operational and performance stages
- Justify the number and sampling of performance qualification batches
- Run continued process verification with control charts
- Manage change control, revalidation triggers and the validation master plan

Who should attend

- Validation engineers and specialists
- Quality assurance managers in pharmaceutical plants
- Production and technical services staff
- Engineering staff commissioning pharmaceutical equipment
- Regulatory affairs staff compiling validation sections

Course outline

01 A folder nobody uses
02 The three stage lifecycle
03 Critical quality attributes and parameters
04 Design space and parameter relationships
05 Design, installation and operational qualification
06 Performance qualification batches
07 Sampling plans and statistical justification
08 Continued verification, change control and inspection defence

Upcoming dates

Dates	Venue	Format	Fee per delegate
28 September to 2 October 2026	Durban, South Africa	Classroom	R19,950
21 to 25 December 2026	Accra, Ghana	Classroom	USD 1,325
22 to 26 February 2027	Nairobi, Kenya	Classroom	USD 1,325
22 to 26 March 2027	Online	Online	R8,500

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**.