Accredited Africa Training Institute for Capacity Development
Unit FO409, Hatfield Plaza · 1122 Burnett St, Hatfield 0028 · Pretoria, Gauteng · South Africa
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COURSE BROCHURE

Quality Assurance in Pharmaceutical Manufacturing

Health Sciences and Social Services / Curative Health

Unit Standard 256555 · NQF Level 4 · 10 Credits · 7 Days

COURSE OVERVIEW

This course equips learners with the knowledge and skills to implement quality assurance (QA) principles in a pharmaceutical manufacturing environment. It covers regulatory requirements, good manufacturing practices (GMP), and QA systems to ensure product safety and efficacy. By the end, participants will be able to monitor and improve QA processes in line with South African and international standards.

Category	Health Sciences and Social Services
Subfield	Curative Health
Unit Standard	256555
Accreditation	SAQA Accredited · NQF Level 4 · 10 Credits
Duration	7 days
Training Method	Online, On-Campus, In-House
Certificate	Issued via AATICD LMS — verifiable online

LEARNING OUTCOMES

- Apply the principles of quality assurance to pharmaceutical manufacturing processes.
- Implement Good Manufacturing Practice (GMP) requirements in accordance with SAHPRA and WHO guidelines.
- Monitor and evaluate QA systems to ensure compliance with regulatory standards.
- Analyze deviations and non-conformances to identify root causes and implement corrective actions.
- Demonstrate documentation practices essential for QA, including batch records and standard operating procedures.
- Evaluate the effectiveness of QA systems through internal audits and inspections.

WHO SHOULD ATTEND

- This course is designed for quality assurance officers, production supervisors, and technical staff working in pharmaceutical manufacturing.
- It is also suitable for new entrants seeking to understand QA fundamentals in the pharmaceutical sector.

COURSE OUTLINE

Day 1: Introduction to Pharmaceutical Quality Assurance

- Overview of pharmaceutical manufacturing processes
- Definition and scope of quality assurance vs. quality control
- Introduction to Good Manufacturing Practices (GMP
- Regulatory bodies: SAHPRA, WHO, PIC/S, FDA
- Key quality concepts: quality by design, risk management
- Documentation and record-keeping basics
- Case study: Consequences of poor quality

Day 2: GMP Principles and Facility Design

- GMP guidelines: premises, equipment, personnel
- Cleanroom classifications and environmental monitoring
- HVAC systems and air handling
- Water purification systems (PW, WFI
- Sanitation and pest control programs
- Personnel hygiene and gowning procedures
- Equipment qualification: IQ, OQ, PQ
- Documentation of facility maintenance

Day 3: Documentation, Standard Operating Procedures, and Batch Records

- Types of documents: SOPs, batch records, specifications, logs
- Structure and content of SOPs
- Batch record review process
- Document numbering, version control, and archiving
- Good documentation practices: legibility, corrections, signatures
- Data integrity principles (ALCOA+
- Practical: Writing and reviewing an SOP

Day 4: Quality Control, Sampling, and Testing

- QC laboratory organization and safety
- Sampling methods and statistical sampling plans
- Pharmacopoeial testing: USP, BP, EP
- Chemical, physical, and microbiological tests
- Stability studies and shelf-life determination
- OOS investigation procedures
- Role of reference standards and reagents
- Practical: Sampling and basic QC test simulation

Day 5: Validation, Qualification, and Risk Management

- Validation master plan and qualification stages
- Process validation: traditional, continuous, and hybrid
- Cleaning validation: limits and sampling
- Analytical method validation parameters
- Change control and deviation management
- Risk assessment tools: FMEA, HACCP
- Practical: Developing a validation protocol

Day 6: **Audits, Inspections, and Regulatory Compliance**

- Types of audits: internal, supplier, regulatory
- Audit planning, checklists, and conduct
- Common audit findings and how to avoid them
- Regulatory inspection readiness
- CAPA system: identification, root cause analysis, effectiveness
- Quality metrics and trending
- Practical: Mock audit exercise

Day 7: **Integration, Continuous Improvement, and Final Assessment**

- Quality management system (QMS) overview
- Continuous improvement methodologies
- Handling complaints and recalls
- Quality culture and human factors
- Review of key learnings
- Final written assessment and feedback

ASSESSMENT & CERTIFICATION

Delegates are assessed through exercises and a final test. A mark of **50% or above** earns an **AATICD Certificate of Completion**, issued digitally with a unique verification code. This course carries **10 NQF credits** at **NQF Level 4**.

PRICING (PER DELEGATE, EX-VAT)

Delegates	Training Method	Price per Delegate	Total
1	Online	R 28,200.00	**R 28,200.00**
1	In-House	R 36,700.00	**R 36,700.00**
1	On-Campus (Pretoria)	R 42,300.00	**R 42,300.00**

UPCOMING SESSIONS

Start	End	Method	Venue
11 Aug 2026	19 Aug 2026	On-Campus	Cape Town, South Africa
12 Aug 2026	20 Aug 2026	On-Campus	Dubai, UAE
13 Aug 2026	21 Aug 2026	On-Campus	Pretoria, South Africa
14 Aug 2026	24 Aug 2026	On-Campus	Abu Dhabi, UAE
17 Aug 2026	25 Aug 2026	On-Campus	Shenzhen, China
18 Aug 2026	26 Aug 2026	On-Campus	Harare, Zimbabwe
18 Aug 2026	26 Aug 2026	On-Campus	Dubai, UAE
19 Aug 2026	27 Aug 2026	On-Campus	Pretoria, South Africa

Contact us if no suitable date is listed — on-demand sessions can be arranged for groups.

HOW TO GET A QUOTE OR APPLY

1. **Get an instant quotation online:** visit **www.aaticd.co.za**, open the page for this course (Unit Standard 256555) and click **Get A Quote / Apply**. Select your training method and number of delegates — your quotation is generated immediately and emailed to you with the course brochure attached.
2. **Apply by email:** send the course title, your preferred training method (Online, In-House or On-Campus Pretoria), the number of delegates and your preferred dates to **apply@aaticd.co.za** — our team will reply with a formal quotation.
3. **Apply by phone or WhatsApp:** call **+27 12 004 8389** or WhatsApp **+27 65 077 6310** and we will prepare your quotation and reserve your seats.
4. **Confirm your booking:** accept the quotation and settle the invoice. As soon as payment is confirmed your delegates are enrolled and receive their AATICD LMS login details by email, along with joining instructions for their chosen training method.

Group discounts apply automatically — the more delegates you enrol, the lower the price per delegate. No payment is required to request a quotation.

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