2026

PharmAlign Solutions

GMP Excellence

MASTERCLASS

From Principles to Inspection Readiness

3-Day Intensive Masterclass

14-16 June 2026

R7,500 per participant

Your partner in excellence and innovation

www.pharmalign.co.za

Elevate Your GMP Expertise. Lead With Confidence.

Pharmaceutical quality is not built on compliance alone — it is built on systems, discipline, and deep understanding.

The GMP Excellence Masterclass™ by PharmAlign Solutions is a high-impact, advanced-level programme designed to equip professionals with the knowledge, tools, and mindset required to operate, manage, and continuously improve GMP systems in real-world pharmaceutical environments.

This is not theory.
This is practical GMP mastery.

Course Overview

This intensive 3-day masterclass provides a comprehensive, end-to-end understanding of Good Manufacturing Practice (GMP) — from its global origins to its application in modern pharmaceutical manufacturing.

Participants will gain deep insight into quality systems, deviations, investigations, CAPA, change control, validation, and inspection readiness, aligned with global regulatory expectations including:

- World Health Organization (WHO)
- Pharmaceutical Inspection Co-operation Scheme (PIC/S)
- South African Health Products Regulatory Authority (SAHPRA)
- U.S. Food and Drug Administration (FDA)
- European Medicines Agency (EMA)

Who Should Attend

This masterclass is designed for:

- Quality Assurance (QA) professionals
- Quality Control (QC) personnel
- Manufacturing and Production staff
- Engineering and Technical teams
- Regulatory Affairs professionals
- Consultants and auditors
- Anyone involved in GMP-regulated environments

What You Will Learn

1. GMP Foundations & Global Context

- Origin and evolution of GMP
- Key regulatory frameworks and expectations
- The role of GMP in patient safety

2. Pharmaceutical Quality Systems

Aligned with ICH Q10 Pharmaceutical Quality System:

- Quality system lifecycle management
- Management responsibilities
- Continual improvement
- Knowledge management

3. The Core Pillars of GMP

- Personnel and training systems
- Premises, facilities, and utilities
- Documentation systems and Good Documentation Practices (GDP)
- Data integrity and ALCOA++

4. Production & Process Control

- Batch manufacturing controls
- Process validation
- Cleaning validation
- Equipment qualification (IQ, OQ, PQ)
- Contamination control strategy

5. Deviations & Investigations

- Root cause analysis methodologies
- Investigation writing techniques
- Human error vs system failures
- Practical investigation workshops

6. CAPA Systems

- Corrective vs Preventive Actions
- CAPA lifecycle management
- Effectiveness checks
- Trending and continuous improvement

7. Change Control Systems

- Managing change in GMP environments
- Risk-based change classification
- Regulatory impact assessments
- Integration with quality systems

8. Validation & Qualification

- Validation lifecycle approach
- Equipment and process qualification
- Cleaning validation principles
- Maintaining validated state

9. Internal Audits & Inspection Readiness

- Self-inspection programmes
- Preparing for regulatory inspections
- Mock audit simulations
- Common inspection findings and responses

10. Data Integrity & ALCOA++

- Data governance principles
- Electronic systems and audit trails
- Regulatory expectations
- Avoiding critical data integrity failures

How You Will Learn

This programme is designed for maximum practical impact:

- Real-world case studies
- Interactive workshops
- Group discussions and problem-solving
- Practical tools and templates
- Inspection scenario simulations

Course Details

Duration: 3 Days
Dates: 14 – 16 July 2026
Venue: TBA (To Be Announced)

Certification

Participants will receive a:

Certificate of Completion
Issued by PharmAlign Solutions

Key Benefits

By the end of this masterclass, you will be able to:

- Confidently apply GMP principles in real-world environments
- Strengthen and improve pharmaceutical quality systems
- Conduct effective investigations and CAPA
- Manage change in a controlled, compliant manner
- Prepare for and successfully navigate GMP inspections
- Drive a culture of quality and continuous improvement

Why PharmAlign Solutions

PharmAlign Solutions is a **specialized regulatory and quality consulting firm** focused on:

- GMP compliance and inspection readiness
- Quality Management Systems (QMS)
- Regulatory strategy and submissions
- Training and capability development

We combine deep regulatory expertise with practical industry experience to deliver training that is relevant, impactful, and immediately applicable.

Secure Your Seat

Limited seats available to ensure high engagement and quality interaction.

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PHARMALIGN SOLUTIONS

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