



PharmAlign Solutions

QUALITY RISK MANAGEMENT

MASTERCLASS

Mastering ICH Q9 (R1) for Real-World Pharmaceutical Operations

2-Day Intensive Masterclass

2-3 June 2026

R11,500 per participant

Your partner in excellence and innovation

www.pharmalign.co.za

The Power of Quality Risk Management

Quality Risk Management is one of the most powerful systems in the pharmaceutical industry - yet one of the most misunderstood.

Every GMP system, manufacturing process, and quality decision begins with risk assessment and risk control.

When applied correctly, QRM does not create bureaucracy. It enables better decisions, prevents failures, strengthens compliance, protects patients, and ultimately saves lives.

Common Challenges in QRM Implementation

Yet many organisations still struggle with:

- Applying ICH Q9 (R1) in a practical way
- Selecting the right risk tools
- Conducting meaningful risk assessments
- Integrating risk management into daily operations
- Moving beyond documentation exercises to real risk control

About This Masterclass

PharmAlign Solutions is introducing a

2-Day Intensive Masterclass

designed to transform how pharmaceutical professionals understand and apply Quality Risk Management.

What You Will Learn

Participants will gain practical understanding of:

The principles and expectations of ICH Q9 (R1)	Combining risk tools effectively
Applying key risk tools (FMEA, HACCP, HAZOP, FTA, PHA)	Applying QRM across the pharmaceutical lifecycle
Supporting statistical tools	Moving from theory to real implementation

Key Risk Tools Covered

The masterclass provides hands-on training with industry-standard risk assessment tools:

Tool	Description
FMEA / FMECA	Failure Mode and Effects Analysis - systematic evaluation of potential failure modes
HACCP	Hazard Analysis Critical Control Points - identifying and controlling hazards
HAZOP	Hazard and Operability Study - structured examination of processes
FTA	Fault Tree Analysis - top-down approach to identify causes of failures
PHA	Preliminary Hazard Analysis - early-stage risk identification
Risk Ranking	Systematic filtering and prioritization of risks

Application Across the Pharmaceutical Lifecycle

Learn how to apply QRM principles across all aspects of pharmaceutical operations:

- Product Development
- Manufacturing Operations
- Laboratory Control
- Facilities Management
- Packaging Operations
- Supply Chain Management

Most importantly, the course shows how to move from theory to real implementation, ensuring risk management becomes a decision-making system rather than a documentation exercise.

Course Details

Duration	2-Day Intensive Masterclass
Dates	2-3 June 2026
Course Fee	R11,500 per participant
Group Discounts	Available for multiple delegates
Format	Interactive learning with limited seats

In-House Training Available

This masterclass can also be delivered in-house for your organisation, at your location and at a time convenient for your team, with content tailored to your specific operations and regulatory challenges.

Group discounts available for organisations registering multiple delegates.

Who Should Attend

This programme is highly relevant for professionals working across:

- Pharmaceutical industry
- GMP environments
- Pharmaceutical quality systems
- Regulatory compliance functions
- Organisations committed to patient safety and effective ICH Q9 risk-based approaches

PHARMALIGN SOLUTIONS

Registration & Enquiries



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