Chrom Africa

Bringing Scientific & T echnica l Resources to the Africa Continent

QUALITY MANAGEMENT SYSTE M S (QMS) FOR PHARMACEUTICAL MANUFACTURING

28th - 30th AUGUST 2024

WHO SHOULD ATTEND:

This benefit various industries such as the Pharmaceutical, Biotechnology, Drug, Biologics, Medical Device and In-vitro Diagnostics Product Manufacturing Industries, especially those within various departments such as Quality Assurance Personnel and Management, Quality Control Personnel and Management, Laboratory Managers, Testing Analysts and Technicians, Manufacturing Personnel and Management, Supplier Quality Assurance Personnel and Management, Regulatory Affairs Personnel and Management, Shipping and Receiving Personnel and Management, Facility and Maintenance Personnel and Management, Microbiologist Personnel and Management, Engineering Personnel and Management, Materials Management Personnel and Management.

LEARNING OBJECTIVES:

Upon completion of this training, you will be able to:

- Define the who, why and how of a Pharmaceutical Quality System (PQS)
- Describe the Benefits, elements, composition and how to implement an effective Quality Management Systems (QMS)
- Explain the requirements of Product Quality Review and Quality Risk Management
- Describe the five (5) segments and Contents of ICH Q10: Pharmaceutical Quality System
- Define Management responsibilities, Continual Improvement of Process Performance, Product Quality and Pharmaceutical Quality System.

Day 1	28-08-24	Activity
9.00 – 9.30 am		**Registration and Climate Setting**
9.30 – 10.00 am		• The what, how and why of a Pharmaceutical Quality System
10.00 – 10.30 am		**TEA- BREAK**
11.00 – 12.30 p.m		• Benefits of a Quality Management Systems (QMS) • Elements and Requirements of a Quality Management System (QMS)
12-30 – 14.00 p.m		**LUNCH - BREAK**
14.00 – 16.30 p.m		• Establishing and Implementing Quality Management System (QMS) • Steps to Implementing a Quality Management System

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Day 2	29-08-24	Activity
9.30 – 10.30 am		• Basic Requirements of cGMP • Basic Requirements of Quality Control • Product Quality Review • Quality Risk Management
10.30 – 11.00 am		**TEA- BREAK**
11.00 – 12.30 p.m		• Contents of Pharmaceutical Quality Management System • Relationship of ICH Q10 to Regional GMP Requirements, ISO Standards and ICH Q7, Relationship of ICH Q10 to Regulatory Approaches • ICH Q10 Objectives: • Achieve Product Realization
12-30 – 14.00 p.m		**LUNCH - BREAK**
14.00 – 16.30 p.m		• Establish and Maintain a State of Control Facilitate Continuous Improvement. • Enablers: Knowledge Management and Quality Risk Management

Day 3	30-08-24	Activity
9.00 – 10.30 am		• QMS Design and Content Considerations, Quality Manual • Management Responsibilities • Continual Improvement of Process Performance and Product Quality • Continual Improvement of Process Performance and Product Quality • Lifecycle Stage Goals • Pharmaceutical Development • Technology Transfer • Pharmaceutical Quality System Elements
10.30 – 11.00 am		**TEA- BREAK**
11.00 – 12.30 p.m		• Continual Improvement of the Pharmaceutical Quality System • Management Review of the Pharmaceutical Quality System • Monitoring of Internal and External Factors Impacting the Pharmaceutical Quality System • Outcomes of Management Review and Monitoring. • Basic Terms & Definitions related to Pharmaceutical Quality System
12-30 – 14.00 p.m		**LUNCH - BREAK**
14.00 – 15.00 p.m		• Directors speech and issue of certificates

Deadline: 19th August 2024

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Cost Kes. 63,800.00 or USD 638.00

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