Bringing Scientific and Technical Resources to the African Continent

(NITA/TRN/875)

PHARMACEUTICAL QUALITY MANAGEMENT SYSTEMS.

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 (Wed 23/11/2022)	
Registration & Introduction	**8.00am -8.30am**
➢ The what, how and why of a Pharmaceutical Quality System ➢ Benefits of a Quality Management Systems (QMS) ➢ Elements and Requirements of a Quality Management System (QMS)	**8.30am -10.30am**
Tea Break	**10.30am -11.00am**
➢ Establishing and Implementing Quality Management System (QMS) ➢ Steps to Implementing a Quality Management System	**11.00am -1.00pm**
Lunch Break	**1.00pm -2.00pm**
➢ Basic Requirements of cGMP ➢ Basic Requirements of Quality Control ➢ Product Quality Review ➢ Quality Risk Management	**2.00pm-4.30pm**
DAY 2 (Thursday 24/11/2022)	
➢ 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	**9.00am -10.30am**

Tea Break	**10.30am -11.00am**
➢ Establish and Maintain a State of Control Facilitate Continuous Improvement. ➢ Enablers: Knowledge Management and Quality Risk Management	**11.00am-1.00pm**
Lunch Break	**1.00pm-2.00pm**
➢ QMS Design and Content Considerations, Quality Manual ➢ Management Responsibilities ➢ Continual Improvement of Process Performance and Product Quality	**2.00pm-4.30pm**
DAY 3 (Friday 23/11/2022)	
➢ Continual Improvement of Process Performance and Product Quality ➢ Lifecycle Stage Goals ➢ Pharmaceutical Development ➢ Technology Transfer ➢ Pharmaceutical Quality System Elements	**9.00am -10.30am**
Tea Break	**10.30am -11.00am**
➢ 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.	**11.00am -1.00 pm**
Lunch Break	**1.00pm -2.00pm**
➢ Outcomes of Management Review and Monitoring. ➢ Basic Terms & Definitions related to Pharmaceutical Quality System. ➢ Directors speech and issue of Certificates.	**2.00pm-4.00pm.**
Dates: 23rd – 25th November 2022 **Registration deadline** **4th November 2022**	**Cost:** **Ksh: 55,680.00 (VAT** **Inclusive)** **Venue: Melili Hotel -** **Nairobi**

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