Bringing Scientific & Technical Resources to the African Continent

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ADVANCED CURRENT GOOD MANUFACTURING PRACTICES(cGMP) 3 DAYS 8th – 10th MAY 2024

This course is presented over 3 days and provides a real depth of information on the main aspects of pharmaceutical GMP. During the course the **main GMP requirements Quality Control and batch release** are covered. In addition, the course also covers the main elements of the **Quality Management System** needed to provide medicines of the highest quality, including the requirements for **documentation, training and system monitoring and review**. The course is full of **interactive exercises** and workshops throughout the programme.

DAY 1 (8th May 2024)	
9.00-9.30	**Principles & Practices in cGMP** Introduction and Benefits of cGMP
9.30-10.30	**GMP –Rules & guidelines;** • European Union (EU) GMP and EU Guide to GMP • GMP in the United States Other GMP from Around the world
10.30 – 11.00	***Tea Break***
11.00-13.00	**Premise & Facility Design** • Suitable premises and Facility design • Heating Ventilation and Air conditioning Access ,Security and Pest Control
13.00- 14.00	***Lunch Break***
14.00 – 16.30	**Equipment, Maintenance and Calibration** • Selection of equipment and Installation • Planned Preventative Maintenance Calibration of measuring equipment's
Day 2 (9th May 2024)	
9.00 – 10.30	**Good Manufacturing Practices(GMP) Regulations;** • CRF role in cGMP Regulation • 21 CFR Part 210: Processing, Packing, or Holding
10.30 – 11.00	**Tea Break**
11.00 – 13.00	• 21 CFR Part 211: Finished Pharmaceuticals • 21 CFR Part 600: Biological Products
13.00 – 14.00	***Lunch Break***
14.00 -16.30	• 21 CFR Part 600: Biological Products: 21 CFR Part 11: Electronic Records and Signatures
DAY 3 (10th May 2024)	
09.00 – 10.30	**Good Manufacturing Practices (GMP) and Quality Management System(QMS)** People & Training • Organization charts, Job description and training records • GMP and job specific training Training design and evaluation
10.30 – 11.00	***Tea Break***

11.00 – 13.00	**Key Personnel in GMP** • The Heads of Production, QC and Qualified personnel • The role of Quality and Quality Assurance • The importance of Senior management **Documentation, Records and Data integrity** • Control and approval of documents and records Data integrity and regulatory concerns
13.00 – 14.00	***Lunch Break***
14.00 – 15.30	**Quality Risk Management** • Decision making based on risk • ICH Q9 and its requirements • Reactive & Proactive risk assessments **The Quality Management Systems** Batch review, and release, Product quality review, Internal, Auditing, Management review.
15.30 – 16.00	Directors remarks and issue of certificates

Date	Cost	Venue
8th – 10th May 2024 **Reg: Deadline 25th April 2024**	**Ksh 63,800.00 or USD 638.00**	**NAIROBI**