Chrom Africa

Bringing Scientific & Technical Resources to the Africa Continent

ADVANCED CURRENT GOOD MANUFACTURING PRACTICES(cGMP)

26th - 28th MARCH 2025

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	26-03-25	EVENTS
		Registration and Climate Setting
9:00 – 09:30 am		**Principles & Practices in cGMP** • Introduction and Benefits of cGMP
09:30 – 10:30 am		***TEA- BREAK***
11:00 – 13:00 p.m		**GMP –Rules & guidelines;** • European Union (EU) GMP and EU Guide to GMP • GMP in the United States Other GMP from Around the world
13:00 – 14:00 p.m		***LUNCH - BREAK***
14:00 – 16:30 p.m		**Equipment, Maintenance and Calibration** • Selection of equipment and Installation • Planned Preventative Maintenance Calibration of measuring equipment's

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Day 2	27-03-25	EVENTS
9:00 – 10:30 am		**Good Manufacturing Practices(GMP) Regulations;** • CRF role in cGMP Regulation • 21 CFR Part 210: Processing, Packing, or Holding
10:30 – 11:00 am		**TEA- BREAK**
11:00 – 13:00 p.m		• 21 CFR Part 211: Finished Pharmaceuticals • 21 CFR Part 600: Biological Products
13:00 – 14:00 p.m		**LUNCH - BREAK**
14:00 – 16:30 p.m		• 21 CFR Part 600: Biological Products: • 21 CFR Part 11: Electronic Records and Signatures

Day 3	28-03-25	EVENTS
9:00 – 10:30 am		**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 am		**TEA- BREAK**
11:00 – 13:00 p.m		**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 p.m		**LUNCH - BREAK**
14:00 – 15:30 p.m		**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 p.m		**Directors remarks and issue of certificates**

Deadline: 16th March 2025

26th – 28th MARCH 2025

Cost Kes. 63,800.00
or USD 638.00

NAIROBI

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