



Bringing Scientific & Technical  
Resources to the African Continent

### **ADVANCED CURRENT GOOD MANUFACTURING PRACTICES(cGMP) 3 DAYS**

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.

<b>DAY 1 (19<sup>th</sup> July 2023)</b>	
<b>Principles &amp; Practices in cGMP</b> Introduction and Benefits of cGMP	<b>9.00-9.30</b>
<b>GMP –Rules &amp; guidelines;</b>  <ul style="list-style-type: none"> <li>European Union (EU) GMP and EU Guide to GMP</li> <li>GMP in the United States</li> <li>Other GMP from Around the world</li> </ul>	<b>9.30-10.30</b>
<b>Tea Break</b>	<b>10.30-11.00</b>
<b>Premise &amp; Facility Design</b>  <ul style="list-style-type: none"> <li>Suitable premises and Facility design</li> <li>Heating Ventilation and Air conditioning</li> <li>Access ,Security and Pest Control</li> </ul>	<b>11.00-1.00</b>
<b>Lunch Break</b>	<b>1.00-2.00pm</b>
<b>Equipment, Maintenance and Calibration</b> <ul style="list-style-type: none"> <li>Selection of equipment and Installation</li> <li>Planned Preventative Maintenance</li> <li>Calibration of measuring equipment's</li> </ul>	<b>2.00pm-4.30</b>
<b>Day 2 (20<sup>th</sup> July 2023)</b>	
<b>Good Manufacturing Practices(GMP) Regulations;</b>  <ul style="list-style-type: none"> <li>CRF role in cGMP Regulation</li> <li>21 CFR Part 210: Processing, Packing, or Holding</li> </ul>	<b>9.00-10.30</b>
<b>Tea Break</b>	<b>10.30-11.00</b>
<ul style="list-style-type: none"> <li>21 CFR Part 211: Finished Pharmaceuticals:</li> <li>21 CFR Part 600: Biological Products:</li> </ul>	<b>11.00-1.00</b>
<b>Lunch Break</b>	<b>1.00-2.00pm</b>

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<ul style="list-style-type: none"> <li>21 CFR Part 600: Biological Products:</li> <li>21 CFR Part 11: Electronic Records and Signatures:</li> </ul>		<b>2.00-4.30</b>
<b>DAY 3 (21<sup>st</sup> July 2023)</b>		
<b>Good Manufacturing Practices (GMP) and Quality Management System(QMS)</b>  People & Training <ul style="list-style-type: none"> <li>Organization charts, Job description and training records</li> <li>GMP and job specific training</li> <li>Training design and evaluation</li> </ul>		<b>9.00-10.30</b>
<b>Tea Break</b>		<b>10.30-11.00</b>
<b>Key Personnel in GMP</b> <ul style="list-style-type: none"> <li>The Heads of Production, QC and Qualified personnel</li> <li>The role of Quality and Quality Assurance</li> <li>The importance of Senior management</li> </ul> <b>Documentation, Records and Data integrity</b> <ul style="list-style-type: none"> <li>Control and approval of documents and records</li> <li>Data integrity and regulatory concerns</li> </ul>		<b>11.00-1.00</b>
<b>Lunch Break</b>		<b>1.00 -2.00pm</b>
<b>Quality Risk Management</b> <ul style="list-style-type: none"> <li>Decision making based on risk</li> <li>ICH Q9 and its requirements</li> <li>Reactive &amp; Proactive risk assessments</li> </ul> <b>The Quality Management Systems</b> <ul style="list-style-type: none"> <li>Batch review, and release, Product quality review, Internal, Auditing, Management review. Directors remarks and issue of certificates.</li> </ul>		<b>2.00-4.00pm</b>
<b>Date</b>	<b>Cost</b>	<b>Venue</b>
<b>19<sup>th</sup> – 21<sup>st</sup> July 2023</b>  <b>Reg ;Deadline 7<sup>th</sup> July 2023</b>	<b>Ksh 45,240.00 or USD 500.00</b>	<b>WILDLIFE RESEARCH &amp; TRAINING</b> <b>INSTITUTE - NAIVASHA</b>