FOUNDATIONS OF GOOD MANUFACTURING PRACTICES (GMP)

(USP – Promoting the Quality of Medicines | USAID)

A comprehensive certification program covering the complete pharmaceutical manufacturing and quality compliance lifecycle.

📜 Certificate Portfolio

1. **Medicinal Products (GMP Fundamentals)**
   Principles governing safe, effective, and compliant manufacture of finished pharmaceutical products.
2. **Active Pharmaceutical Ingredients (API)**
   GMP requirements for API manufacturing, handling, testing, and quality control.
3. **Quality Risk Management (QRM)**
   ICH Q9-based risk assessment, control, review, and risk-based decision making.
4. **Deviations, Root Cause Analysis (RCA) & CAPA**
   Investigation of non-conformances, root cause identification, and corrective & preventive actions.
5. **Process & System Validation**
   Ensuring processes consistently produce products meeting predetermined quality attributes.
6. **Qualification of Facilities, Equipment & Utilities**
   DQ, IQ, OQ, PQ for pharmaceutical manufacturing infrastructure and systems.
7. **Data Integrity & Computer System Validation (CSV)**
   ALCOA+ principles, electronic records, audit trails, and 21 CFR Part 11 compliance.
8. **GMP Auditing**
   Internal and external audits, inspection readiness, and regulatory compliance verification.
9. **HVAC Systems in Pharmaceutical Facilities**
   Environmental control, contamination prevention, and cleanroom compliance.
10. **Pharmaceutical Water Systems**
    Design, validation, monitoring, and control of purified water and WFI systems.