BIO SCIENCE PROJECT MANAGEMENT CICLE

ON TIME DELIVERY

USER REQUIREMENTS SPECIFICATION (URS) → **FUNCTIONAL SPECIFICATION (FS)** → **DESIGN QUALIFICATION (DQ)** → **FACTORY ACCEPTANCE TESTING (FAT) & SITE ACCEPTANCE TESTING (SAT)** → **PROCESS VALIDATION (PV)**

VALIDATION MASTER PLAN (VMP)

- QUALIFICATION AND VALIDATION POLICY;
- THE ORGANISATIONAL STRUCTURE INCLUDING ROLES AND RESPONSIBILITIES FOR QUALIFICATION AND VALIDATION ACTIVITIES;
- SUMMARY OF THE FACILITIES, EQUIPMENT, SYSTEMS, PROCESSES ON SITE AND THE QUALIFICATION AND VALIDATION STATUS;
- CHANGE CONTROL AND DEVIATION MANAGEMENT FOR QUALIFICATION AND VALIDATION;
- GUIDANCE ON DEVELOPING ACCEPTANCE CRITERIA;
- REFERENCES TO EXISTING DOCUMENTS;

GOOD MANUFACTURING PRACTICES (GMP)

- VERIFICATION OF USER REQUIREMENTS SPECIFICATIONS.
- COMPLIANCE OF THE DESIGN WITH GMP SHOULD BE DEMONSTRATED AND DOCUMENTED.

INSTALLATION QUALIFICATION (IQ)

- VERIFICATION OF THE CORRECT INSTALLATION OF COMPONENTS, INSTRUMENTATION, EQUIPMENT, PIPE WORK AND SERVICES AGAINST THE ENGINEERING DRAWINGS AND SPECIFICATIONS.

OPERATIONAL QUALIFICATION (OQ)

- DOCUMENTED VERIFICATION TO ENSURE THE SYSTEM IS OPERATING AS DESIGNED.
- TESTS WILL COVER OPERATING CONDITIONS AND WORST CASE OPERATING LIMITS.

PERFORMANCE QUALIFICATION (PQ)

- TESTS TO ENSURE THE PRODUCT HAS EQUIVALENT BEHAVIOUR UNDER NORMAL OPERATING CONDITIONS AND WORST CASE OPERATING LIMITS.

GOOD MANUFACTURING PRACTICES (GMP

- INSTALLATION, OPERATING AND MAINTENANCE MANUAL
- CALCULATION SHEET
- DATASHEETS
- DRAWING & BOM (BILL OF MATERIAL)
- SPARE 2 YEARS OPERATION
- SPARE LIST FOR COMMISIONING & START UP
- TEST RESULTS
- MATERIAL CERTIFICATION
- FINAL QUALITY DOSSIER
- INSTRUMENTS CALIBRATION CERTIFICATES.