

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)

GOOD MANUFACTURING PRACTICES (GMP)

SPECIFICATIONS.

DOCUMENTED.

VERIFICATION OF USER REQUIREMENTS

SHOULD BE DEMONSTRATED AND

COMPLIANCE OF THE DESIGN WITH GMP

QUALIFICATION (IQ)

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

SPECIFICATIONS.

INSTALLATION

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.

- 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;