GMP Analytical Instrument Qualification Performa

Comprehensive DQ, IQ, OQ and PQ Template for Pharmaceutical QC Laboratories

Document No.	
Instrument Name	
Instrument ID / Asset No.	
Manufacturer	
Model No.	
Location	
Department	Quality Control
Effective Date	
Prepared By	
Reviewed By	
Approved By (QA)	

Design Qualification (DQ)

Requirement	Yes/No	Comments
User Requirement Specification (URS) approved		
Intended use defined		
21 CFR Part 11/Data Integrity requirements assessed		
Vendor assessment completed		
Risk assessment completed		
Calibration and maintenance requirements defined		
Software requirements reviewed		
DQ approval obtained		

Installation Qualification (IQ)

Requirement	Yes/No	Comments
Equipment received without damage		
Serial number verified		
Utilities verified		
Installation location approved		
Operating manuals available		
Calibration certificates available		
Software installed and verified		
IQ deviations documented and closed		

Operational Qualification (OQ)

Requirement	Yes/No	Comments
Critical functions challenged		
Alarm verification completed		
System suitability checks performed		
Operating ranges verified		
Access controls tested		
Audit trail functionality verified		
Backup and recovery verified		
OQ acceptance criteria met		

Performance Qualification (PQ)

Requirement	Yes/No	Comments
Routine testing performed		

Multiple analysts evaluated		
System suitability passed		
Method performance acceptable		
Trend review completed		
PQ acceptance criteria met		
Qualified for intended use		

Qualification Summary & Approval

Qualification Phase	Status
DQ	
IQ	
OQ	
PQ	

Final Conclusion:

The instrument is / is not qualified for its intended GMP use based on successful completion of DQ, IQ, OQ and PQ activities.

Prepared By		Date
Reviewed By		Date
Approved By (QA)		Date