Seven Common Steps Towards Equipment or Machine Validation

(Applicable to Medical device, In-vitro diagnostic, Pharmaceuticals, Biotech & Life Science companies)

Medical device, In-vitro diagnostic, Pharmaceuticals, Biotech & Life Science companies are highly-regulated sectors. Equipment or Machine validation is to assure the most stringent regulatory norms are met and the desired results are achieved when it comes to commercial production. As a component of quality assurance, equipment or machine validation is absolutely critical to produce consistent, high-quality products. The below checklist can help manufacturers quickly develop their validation plan and at the same time it will help the validation procedure.

STEP 1

Sl. No.	TECHNICAL SPECIFICATION & DOCUMENTS AVAILABLE	CHECK BOX	REMARKS
A.	All relevant equipment or machine drawings must be available, inspected and verified ☐ Mechanical drawings ☐ Electrical schematics ☐ Process & Instrument drawings ☐ Pressure/Vacuum Rating ASME Code Stamp ☐ Process flow chart ☐ Maintenance chart	☐	
B.	Equipment or Machine Technical Specification	☐	
C.	Equipment or Machine user manual	☐	
D.	Spare part or components master list	☐	
E.	Software documentation e-copy and hard copy	☐	
F.	Operating manual	☐	
G.	Assure DQ, IQ, OP and PQ can be made available	☐	
H.	FAT and SAT plan or protocols	☐	

STEP 2

Sl. No.	COMPLIANCE CHECK FOR CRITICAL INSTRUMENT & CALIBRATION PROVIDED	CHECK BOX	REMARKS
A.	Primary Instruments listed in the calibration program (i.e. control and process monitoring instruments, not backup indicators)	☐	
B.	Instrument Resolution and Accuracy is identified and adequate for the required process control range	☐	
C.	National or International traceable standards used	☐	
D.	Calibration Certificates for inbuilt components or part or instrument (as applicable)	☐	
E.	Test Report and Certificate of Analysis of critical components or parts installed or assembled with the Equipment or Machine	☐	

STEP 3

Sl. No.	EQUIPMENT DESIGN AND CRITICAL COMPONENT INSPECTION AVAILABLE	CHECK BOX	REMARKS
A.	All major and critical equipment or machines including components design are inspected verified via Design Qualification (example: Approved Engineering Specifications and Design Review).	☐	
B.	Certification of materials of construction used, equipment finish, etc	☐	
C.	Main components covered within preventive maintenance program	☐	
D.	Special cleaning and intervals established, if applicable	☐	
E.	Verify Calibration Certificates of inbuilt components	☐	
F.	Equipment or Machine final test reports	☐	

STEP 4

Sl. No.	LIST OF ALL UTILITIES AND SUPPLIES PROVIDED	CHECK BOX	REMARKS
A.	Electricity connections (all connections inspected, verified and recorded)	☐	
B.	Clean steam boiler (all connections are inspected, verified and recorded)	☐	
C.	Compressed air (all connections are inspected, verified and recorded)	☐	
D.	Nitrogen, if applicable (all connections are inspected, verified and recorded)	☐	
E.	Water inlets and outlets	☐	
F.	Piping's and Wirings	☐	
G.	Stands, if applicable	☐	
H.	Accessories	☐	

STEP 5

Sl. No.	OPERATIONAL AND ENIRONMENTAL REQUIREMENTS DEFINED	CHECK BOX	REMARKS
A.	Temperature range	☐	
B.	Humidity	☐	
C.	Lighting requirement	☐	
D.	Noise Level	☐	
E.	Water requirement given, if applicable	☐	
F.	Operational air pressure	☐	
G.	Electricity / Current / Voltage Specifications	☐	
H.	Electrostatic discharge isolation	☐	

STEP 6

Sl. No.	BREAKDOWN AND MAINTENANCE SCHEDULE	CHECK BOX	REMARKS
A.	Electrical wiring charts	☐	
B.	Preventive and breakdown maintenance schedule	☐	
C.	Safety instructions	☐	
D.	Cleaning schedule	☐	
E.	Software (PLC) configuration control and disaster recovery	☐	

STEP 7

Sl. No.	SAFETY REQUIREMENTS PROVIDED	CHECK BOX	REMARKS
A.	Electrical wiring/disconnects	☐	
B.	Current / Voltage specifications	☐	
C.	Safety charts and work flow	☐	
D.	Safety symbols and indications	☐	
E.	PPE and safety gear required	☐	
F.	Colour code and signals	☐	
G.	OSHA or other applicable safety standards	☐	
H.	Alarm and alarming system	☐	
G.	Emergency exit	☐	

Note: This is not a complete list but this checklist would be of immense help for Medical device, In-vitro diagnostic, Pharmaceuticals, Biotech & Life Science companies while undertaking equipment or machine validation which may affect product quality and production process. This document is intended to serve as a ready to use reference and support in developing protocols for the complex IQ, OQ, PQ, FAT or SAT documentation.

For further queries or support, please contact: marketing@compliancequest.com

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