Information written in colored text include instructions (red) and examples (blue) for populating the template. Delete this information when you complete populating each section.

1.0 PURPOSE

Outline the purpose of the document. Identify what the system does — its intended use.

Example:

The purpose of this document is to outline the system requirements for the XXXX system operated by XXX software. This document will outline all the system requirements to ensure the equipment is suitable for its intended use.

2.0 SCOPE

The scope defines to what equipment/system the document does or does not apply.

State the range of activities the document applies to, as well as any limitations or exceptions.

Example:

This document applies to the XXXXX operated by XXXX software used in support of cGMP activities in XXXX Quality Control Laboratory.

This document does not apply to the XXX system in the R&D laboratory.

3.0 REFERENCES

List supporting documentation necessary to demonstrate control and qualification of the system (e.g., operational SOP, qualification protocols, etc.), as well as any regulations or harmonized standards, if applicable.

List the number and title of the document/procedure being followed and that apply to the qualification and operation of the system.

Example:

Document #	Title
QA-SOP-xxxx	Training Program
FA-QP-xxxx	System Data Archiving Verification
FA-QP-xxxx	System Security Verification

4.0 DEFINITIONS

Define terms used in the document that require explanation, clarify terms that are not universally recognized by the audience.

List term or NA

Term	Definition

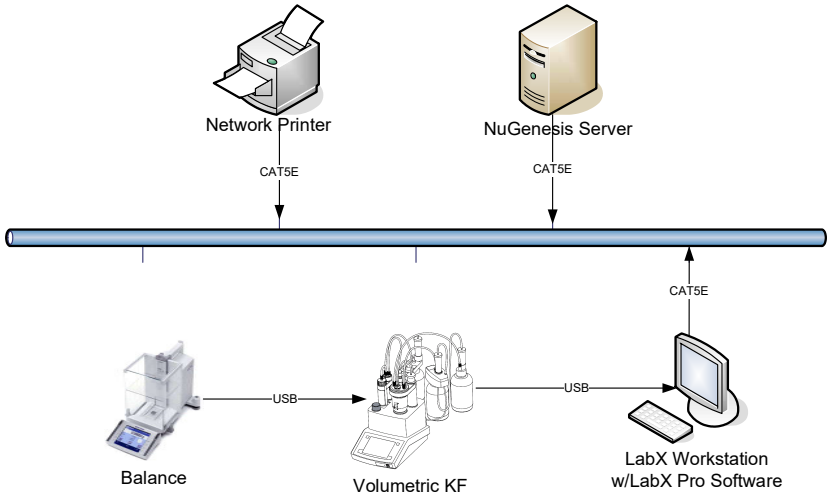
5.0 SYSTEM DESCRIPTION

Provide conceptual diagram of the system if the analytical instrument, for example, consists of multiple components. For simple systems, a text description is deemed sufficient.

Example:

The system undergoing qualification is a XXXX that includes sensors, pump, peripherals (e.g., balance, printer), homogenizer with stand, and a titrator, controlled by XXX software installed on a standalone workstation. The XXXX software automates the data acquisition, control and reporting. The system includes a secure Structured Query Language (SQL) database that, along with the profiles and privileges will be configured in compliance with 21 CFR Part 11 requirements. The conceptual diagram of the system is shown in Figure 1:

Figure 1: Conceptual Diagram



6.0 SYSTEM REQUIREMENTS

6.1 Intended Use

Describe the system and its intended use.

Example:

The XXX system will be used for moisture determination of XXXX drug substance and drug product samples.

6.2 Regulatory Requirements

6.2.1 Identify a set of requirements based on all applicable regulatory needs. List these requirements in Table 1.

Example:

The following requirements apply to the XXX system and are identified in the tables that follow. System subject to 21 CFR Part 11.

Table 1: 21 CFR Part 11 Requirements

Req #	Section	Subject	Requirements	Reference
Req 1	11.10 (a)	Validation	The system will be validated (qualified).	FA-SOP-xxx
Req 2	11.10 (b)	Generate Accurate, Complete Records for Inspection and Review	The system shall be able to produce accurate and complete copies of records in electronic form for inspections, review, and copying.	Reference OQ protocols
Req 3	11.10 (c)	Electronic Record, Retention Period, Archiving	The records shall be readily retrievable throughout their retention period.	
Req 4	11.10 (d)	Login, Access Protection, Authorization User, Administrator	The system access shall be limited to authorized individuals.	
Req 5	11.10 (g)	Login, Access, Protection, Authorization, User, Administration	The system shall ensure that only authorized individuals can: • use the system, • electronically sign records, • access the operation or computer system input or output device, • process a record or perform other operations	

Req #	Section	Subject	Requirements	Reference
Req 6	11.10 (i)	Training, Support, User Administrator	There shall be documented training, including on-the-job training for system users, developers, and IT support staff.	
Req 7	11.10 (j)	Policy, Responsibility, Electronic Signature	There shall be a written policy that makes individuals fully accountable and responsible for actions initiated under their electronic signatures.	
Req 8	11.10 (k)	Systems Documentation Controls	The distribution of, access to, and use of systems operation and maintenance documentation shall be controlled.	
Req 9	11.10 (k)	Revision/Change Controls	There shall be a formal change control procedure for system modifications.	
Req 10	11.300 (a)	Uniqueness, Password, Access Protection	Controls shall be in place to maintain the uniqueness of each combined identification code and password. No two individuals can have the same combination of ID code and password.	
Req 11	11.300 (b)	Validity, Access Protection, Password Expiry	A procedure shall be in place to ensure that the validity of identification codes is periodically checked. Passwords shall expire periodically.	
Req 12	11.300 (b)	Login, Access Protection	A procedure shall be in place for recalling identification and passwords if a person leaves or is transferred.	
Req 13	11.300 (c)	Disable User Access, ID, Login, Access Protection, Lost of ID Card	A procedure shall be in place for electronically disabling an identification code or password if it is potentially compromised or lost.	
Req 14	11.300 (d)	Unauthorized Use, Login, Access Protection	A procedure shall be in place for detecting attempts at unauthorized use and for informing security. Repeated or serious attempts at unauthorized use shall be reported to management.	

The following requirements are based on 21 CFR Part 211 regulations and are applicable. These requirements apply to current Good Manufacturing Practices (cGMP) for finished pharmaceuticals.

Table 2: 21 CFR Part 211 Requirements

Req#	Section	Subject	Requirement	Reference
Req 1	25	Personnel Qualifications (Training)	Personnel using the system must have the appropriate education, training, and/or experience to complete their assigned functions.	QA-SOP-xxxx
Req 2	67(b) (c)	Equipment Cleaning and Maintenance	Only authorized personnel are allowed to maintain the system. The system shall be maintained on a routine schedule. Maintenance procedures will be written.	Operational SOP for specific system
Req 3	68(a) (b)	Automatic, Mechanical and Electronic Equipment	Automated, mechanical or electronic equipment shall be routinely calibrated, inspected or checked according to a written program. Written records shall be maintained. Appropriate controls are instituted to assure that changes are instituted only by authorized personnel.	FA-SOP-xxx QA-SOP-xxx QA-SOP-xxx

6.3 User Requirements

6.3.1 Identify a set of generic, non-specific user requirements and list them in Table 2. Perform a functional risk assessment according to FA-SOP-xxx and prioritize each requirement as either mandatory (M) or desired (D) and critical (C) or non-critical (N).

Table 2: User Requirements

Req#	User Requirement	Priority M/D	Need C/N
Usr 1	Interface with data archiving system		
Usr 2	System security is enabled		
Usr 3	Interface with balance		
Usr 4			

6.4 Risk Remediation Requirements

6.4.1 Perform a risk assessment according to QA-SOP-xxx. The outcome of this assessment identifies key system requirements that are added to Table 3. These requirements are considered both mandatory and critical.

Table 3

Req#	Risk Remediation Requirement
Rsk 1	
Rsk 2	

Req#	Risk Remediation Requirement
Rsk 3	

6.5 Functional Requirements

6.5.1 Determine if any regulatory, user, or risk remediation requirements are too generic for proper validation testing and develop a detailed subset of functional requirements for each generic requirement that is specific and testable. List them in Table 4.

Table 4: Functional Requirements

Req#	Functional Requirement
Func 1	
Func 2	
Func 3	

7.0 Appendix (Optional)

Appendices contain data, vendor documentation, or supporting documentation, as needed. If appendices are included, they must be referenced within the report.

Examples of numbering assigned for appendices are:
Appendix A, Appendix B, Appendix C or Appendix I, Appendix II, Appendix III