Part I (System Information)

Section A (Participant Information)

Field Name	Description
Participant Name	Please PRINT the full name
Role	Some example roles include Project Manager, System Owner, Validation Lead, Technical Lead, Support Lead and Quality Assurance. One person may have multiple roles.

Section B (General Information for All Systems)

Field Name	Description
Business Unit	Identify the name of the Business Unit(s) using the system.
System Description	Describe the definition of the "system" in terms of its logical and physical boundaries and interfaces with other systems. Be sure to identify which systems are interfaced to this system. Identify the data going in and the data (reports) going out. Describe the automated aspects of the system and the paper aspects of the system.
Local or Global System (if global, list the site names)	Specify LOCAL or GLOBAL. If Global, list all the site names.
Does a System Diagram Exist?	Include an architectural diagram if available.
System Location	Use as appropriate, however, it is recommended that the building and room location be specified.
Number of Users	Specify the total number of authorized users not the number of users which may be on-line at any one time.
Date of Implementation (if known)	Use the format DD-MMM-YYYY
Plans to replace and when	If there are plans to replace the system, please describe. Use the format DD-MMM-YYYY for when the system might be replaced.
Other Information	Attach additional pages as appropriate.

Section C (Record and Report Information for All Systems)

Field Name	Description
Purpose of Data	Describe how the data/results are used If asked to produce information for an inspector, will any information be obtained from the computerized system?
Source(s) of Data	Reference the data input to a system, as by data entry or from an instrument, a barcode scanner, or another system
Predicate FDA (21 CFR) Rule and/or Business Practice that Applies	Reference the predicate rule that applies (GLP, GMP, GCP). Please identify the section number of the predicate rule that applies. In some cases, business practices exist that are used to demonstrate compliance to a predicate rule, such as data trending, signatures on training records etc.

Section I (Part 11 Applicability Questions)

Field Name	Description
Q1	This includes systems that have data that will go directly into a regulatory document and also systems that may provide supporting data in case of a query or inspection. Indicate the predicate rule (and section) which applies.
Q2	Some regulations specify paper records or documents (GLP and GMPs do not). For these cases, electronic records are prohibited. One example is that physical copies of master labels and package inserts must be retained.
Q3	A closed system is when data and system access is solely controlled by the site (including the Agents) who are responsible for the content of the electronic records on the system. An open system is when data and system access is not solely controlled by the site (including Agents) who are responsible for the content of the electronic records on the system. A system may initially be considered to be open but then controls are applied to make it a closed system.
Q4	Be sure to differentiate between "signature" and "identification". If the intent is to use the applied identification to authenticate the electronic record, the n identification is an electronic signature. If the intent is to merely identify who did something, then the identification is not an electronic signature. A question to help determine if it's a "signature" or "identification" is "IF I sign 'Jack Handy', does that mean I have attested that I did or saw something, or that I'm authorizing some action?" If you have to sign the paper copy, you have to sign the electronic copy. Whether or not to use electronic signatures is not the system owner's choice. The choice is whether to use electronic records or not. That choice (plus the predicate rules) dictates whether electronic signatures are required or not. A question to help determine if signatures are required is "If these were printed out, would you need to sign them?" • Does the predicate rule require signatures on the record? • Does a company policy require signatures on the record? • Identify every display screen and report generated by the computerized system where an electronic signature is represented. Each occurrence should be separately assessed for compliance.

Section	Preamble Reference	Additional Questions to Consider
	75, 76, 77, 78, 93	questions : • Does the system generate automatic, electronic audit trail information (who, what, when)? ▪ Does the audit trail include the reason for change (if required by the predicate rule)? ▪ Is the audit trail function always ON, or is it turned OFF and ON manually? If manual, who and what triggers audit trail recording? Does it get turned on early enough in the process? Is it reliable (i.e., can they forget to turn it on)? ▪ Does the audit trail capture every user action that creates, modified, or deletes records, without exceptions? ▪ When information is changed, does the audit trail record/save the previous value? ▪ Are audit trail entries made at the time the action/operation was conducted electronically? ▪ Is the audit trail ever monitored or reviewed to detect possible misuse or unauthorized activity? ▪ Is it possible to reconstruct events (delete, modify, etc) to any point in time by only using the audit trail information and the original record? ▪ Are electronic audit trails (all or any part) readily available for FDA review and copying? In paper format? ▪ Does the audit trail contain date and time stamps? Can time local to the activity be derived? ▪ Are meaningful units of time chosen in terms of documenting human actions? (For example, seconds might be used in a data collection system while minutes might be appropriate for a document management system.) --- ▪ Is the audit trail completely transparent to, and outside the control and access of, the user? ▪ How is audit trail data protected from accidental or intentional modification or deletion? ▪ System Administrators and DBA's typically make changes. Do those changes have audit trails? If not, do procedural controls exist over use of such administrator tools? ▪ Does the records retention program cover audit trails? ▪ Are electronic audit trails kept for at least as long as their respective electronic records? ▪ What ensures that the system time and date are correct? How frequently are the time and date synchronized with a reliable source? ▪ Can users readily change the system time/date? ▪ Are time/date stamps applied by the local workstation or by a server (or equivalent)? ▪ Is there test evidence for the audit trail functionality?
11.10(f)	59, 79, 80, 81	▪ Are there sequences of operations, or sequential events, or sequential data entry, that is important to this system? ▪ If so, what are they? ▪ If so, how does the system ensure that steps are followed in the

