Electronic Records and Signatures Compliance Assessment

(Ref. SOP _____)

1. INTRODUCTION

1.1. Purpose

The purpose of this report is to summarize the Electronic Records and Electronic Signatures (ERES), assessment made on the <Name of System> against the FDA 21 CFR Part 11 requirements.

1.2. Scope

The scope is to describe the assessment of the <Name of System> for FDA 21 CFR Part 11 compliance, using the standardized approach.

1.3. Glossary

For a list of definitions, terms, acronyms and abbreviations used in this document, refer to the Glossary of Terms [x].

1.4. References

Reference	Document Title	Document Number
[1]		
[2]		
[3]		

2. ERES ASSESMENT

The Electronic Records and Electronic Signatures Compliance Assessment Worksheet (Appendix 1) is detailed in two parts ï Part 1 is System Information and Part II is System Assessment and ERES Compliance assessment.

3. CONCLUSION

To conclude the outcome of the ERES assessment and state any deficiencies encountered (see Section K).

4. REVISION HISTORY

Version	Date	Revised By	Revision Details

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	make and model number.
Additional Software (1) (Optional)	
Additional Software Name and Version (1)	Indicate other software components that make up the system and its version.
Additional Software Vendor Name (1)	Specify the name of the vendor who provides the additional software. Include their address, phone or other related information if it is available.
Operating System Name and Version (1)	Indicate the operating system (NT, Unix, etc) and its version.
Hardware Information for Additional Software (1)	Indicate what hardware was implemented to run the additional software. Please include the make and model number.
Additional Software (2) (Optional)	
Additional Software Name and Version (2)	Indicate other software components that make up the system and its version.
Additional Software Vendor Name (2)	Specify the name of the vendor who provides the additional software. Include their address, phone or other related information if it is available.
Operating System Name and Version (2)	Indicate the operating system (NT, Unix, etc) and its version.
Hardware Information for Additional Software (2)	Indicate what hardware was implemented to run the additional software. Please include the make and model number.
Database Information	
Database Software Name / Version	Indicate database software name and its version.
Database Software Vendor Name	Specify the name of the vendor who provides the database software. Include their address, phone or other related information if it is available.
Operating System Name and Version	Indicate the operating system (NT, Unix, etc) and its version.
Hardware Information for Database Software	Indicate what hardware was implemented to run the database software. Please include the make and model number.

Section E: Equipment/Instrument Information

Equipment/Instrument Name	Indicate the equipment/instrument name.
Equipment/Instrument Vendor	Specify the name of the vendor who provides the equipment/instrument. Include their address, phone or other related information if it is available.
Model Number	Specify the model number.

Section F: Built-in PLC or Firmware

Controller Make and Model	Specify the controller make and model.
Software or Ladder Logic Version or Date	Specify the software name and version

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Section J: ERES Compliance Assessment

Part 11 Reqm't No	Requirements	Assessment Result (Yes, No, N/A)	Remarks
Electronic Records Questions			
11.10(a)	▪ Has the system been validated in order to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records?		Insert remarks here. If Assessment Result is NA, include a justification.
11.10(b)	▪ Is the system capable of generating accurate and complete copies of all required records in both human readable and electronic form suitable for inspection, review and copying by the FDA?		Insert remarks here. If Assessment Result is NA, include a justification.
11.10(c)	▪ Are the records protected to enable the accurate and ready retrieval throughout the record retention period?		Insert remarks here. If Assessment Result is NA, include a justification.
11.10(d)	▪ Is system access limited to authorized individuals?		Insert remarks here. If Assessment Result is NA, include a justification.
11.10(e)	▪ Is there a secure, computer-generated, time-stamped audit trail that independently records the date and time of operator entries and actions that create, modify, or delete electronic records?		Insert remarks here. If Assessment Result is NA, include a justification.
	▪ Upon making a change to an electronic record, is previously recorded information still available?		Insert remarks here. If Assessment Result is NA, include a justification.
	▪ Are electronic audit trails kept for a period at least as long as their subject electronic records and available for agency review and copying?		Insert remarks here. If Assessment Result is NA, include a justification.
11.10(f)	▪ Are operational system checks used to enforce permitted sequencing of steps and events?		Insert remarks here. If Assessment Result is NA, include a justification.

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Part 11 Reqm't No	Requirements	Assessment Result (Yes, No, N/A)	Remarks
	devices that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner?		justification.
	▪ Are there controls in place to periodically test devices that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner?		Insert remarks here. If Assessment Result is NA, include a justification.
Biometric Signature Questions			
11.200 (b)	▪ Is the electronic signature designed to ensure that they cannot be used by anyone other than their genuine owner?		Insert remarks here. If Assessment Result is NA, include a justification.

Section K: Assessment Action Items

System Name:	Insert System Name here.

Action Item No.	Section No.	Part 11 Req No.	Description of Action Item	Assignee	Open / Closed	Remarks

Legends

System Name	Indicate the system name.
Action Item No.	1, 2, 3, etc.
Section No	Reference the section number of the checklist (A, B, C, etc.) where the action item was identified.
Part 11 Requirement No	Reference the section number of 21 CFR Part 11 where the action item was identified.
Description of Action Item	Describe the proposed action item.