

IT DEPARTMENT

[Appendix 6-Template of Computerized System Assessment]

Title: Computerized System A	Page	
Document No.	<document no.=""></document>	1 of 5

Computerized System Assessment for <System Name>



IT DEPARTMENT

[Appendix 6-Template of Computerized System Assessment]

APPROVAL PAGE

Prepared By:

Name	Designation	Department	Signature	Date

Reviewed By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date



IT DEPARTMENT

[Appendix 6-Template of Computerized System Assessment]

TABLE OF CONTENTS

1.0 INTRODUCTION	
2.0 PURPOSE	4
3.0 SCOPE	
4.0 RESPONSIBILITIES	
5.0 REFERENCES	4
6.0 DOCUMENTATION PROCEDURE	4
7.0 GxP ASSESSMENT CHECKLIST	Error! Bookmark not defined.
8.0 OVERALL ASSESSMENT CONCLUSION	Error! Bookmark not defined.

REVISION HISTORY

Revision No.	Effective Date	Reason for Revision
		Initial Document



IT DEPARTMENT

[Appendix 6-Template of Computerized System Assessment]

1.0 INTRODUCTION:

- 2.0 PURPOSE:
- **3.0 SCOPE:**
- 4.0 **RESPONSIBILITIES:**
- 5.0 **REFERENCES**:

6.0 DOCUMENT PROCEDURES:

7.0 COMPUTERIZED SYSTEM ASSESSMENT CHECKLIST:

This document consists of check list for below listed items:

- 1. GENERAL INFORMATION
- 2. COMPUTERIZED SYSTEM ASSESSMENT

(Tick mark " 🖍" whichever/ wherever is applicable in this document).

SECTION-A: GENERAL INFORMATION

QUESTION	RESPONSE
INSTRUMENT	
1. Does the system have an instrument? (Respond as Yes/No)	
Answer 2 and 3 if 1 is Yes, otherwise mark as NA	
2. Instrument Manufacturer Name and Model No.	Instrument/Equipment Manufacturer: Instrument/Equipment Model No.:
3. Brief description of the Instrument/Equipment	
APPLICATION/SOFTWARE	
4. Does the System have an Application/ Software? (Respond as Yes/No)	
Answer 5 and 6 if 4 is Yes, otherwise mark as NA	
5. Application/ Software Name and Application/ Software Version No.6. Brief description of the Application/ Software	Software Name: Software Version:



IT DEPARTMENT

[Appendix 6-Template of Computerized System Assessment]

SECTION-B: COMPUTERIZED SYSTEM ASSESSMENT:

Q. No.	Questions (for COMPUTERIZED SYSTEM ASSESSMENT)	($$) The Answers
Q1	Does the system have software?	Yes No
Q2	Does the system have hardware?	Yes No
Q3	Dose the system has directimpact in the business processes?	Yes No
Q4	Does the system have SOP/EOP to operate the system?	Yes No
Q5	Are there any trained personnel available in accordance with the operational SOP/EOP?	Yes No

Note: If all answer is "Yes" on all question, then system shall be Computerized System; else shall not be Computerized System.

Conclusion of Section-B: The system is: Computerized System Non-Computerized System