Title: Periodic Review Reportfor < Equipment / System>		
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Periodic Review Report
for
<System Name>

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APPROVAL PAGE

Prepared By:

Name	Designation	Department	Signature	Date

Reviewed By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date

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REVISION HISTORY

Revision No.	Effective Date	Reason for Revision

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1.0 PURPOSE:

2.0 OBJECTIVE:

3.0 SCOPE:

4.0 REFERENCES:

Document Number/ Name	Description

5.0 RESPONSIBILITY:

Role	Responsibility

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6.0 SUMMARY OF REVIEW:

6.1 BASIC EVALUATION FOR LAB EQUIPMENT [If Applicable or else marked N/A]

Equipment Name:		**Location:**	
Equipment ID.:		**Evaluation duration:**	

S. No.	Questions	Yes/No	Change Control/ Deviation No. (If any)	Comments
1.	Are there any Changes in **Hardware**? (Make/Model/Serial No.)			
2.	Are there any changes in **Operating System**?			
3.	Are there any changes in **Application Software Functionality**?			
4.	Are there any changes in Data **Backup and Restore** Path or Procedure?			
5.	Any changes regarding **Adding/Removing** this system to/from Network/Server?			
6.	Are there any changes in contents of the **Audit Trail**?			
7.	**Others (If any)**			

- If any of the above questions answer "Yes" then carry out further Revalidation Activity based on requirement

Remarks:	
Is Revalidation Activity needs to be carry out?	**(YES/NO)**

6.2 BASIC EVALUATION FOR PLC/HMI/SCADA Based System [If Applicable or else marked N/A]:

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Equipment Name:		**Location:**	
Equipment ID.:		**Evaluation duration:**	

Sr. No.	Questions	Yes/No	Change Control/ Deviation No. (If any)	Comments
1.	Are there any changes in Process?			
2.	Are there any changes in PLC Make/Model/Sr. no.?			
3.	Are there any changes for HMI Make /Model/Sr. no?			
4.	Are there any changes in PLC/HMI Program or Logic?			
5.	Are there any changes in Wiring Diagram or PLC I/O list?			
6.	Is Electronic Records and Signature applicable for the system?			
7.	If Questions 6 Answers Yes then, Is there any change for Electronic Records and Signature?			
8.	**Others (If any)**			

- If any of the above questions answer "Yes" then carry out further Revalidation Activity based on requirement

Remarks:	
Is Revalidation Activity needs to be carry out?	**(YES/NO)**

6.3 Previous Open Items

List open items reviewed: Open Items at Validation Report or last Periodic Validation Review; Inspection Findings, Audit Findings, Unplanned Deviations and CAPAs raised since Validation Report or last Periodic Validation Review.

Ref Validation Report	<Validation Report>	
Ref Periodic Validation Review	<Periodic Validation Review Report or N/A>	
Action Item	**Status (Open/Closed)**	**Remark**

CAPAs arising from Unplanned Deviation, Audit Finding or Regulatory Observation		
Deviation / CAPA Ref	**Status (Open/Closed)**	**Remark**

6.4 GxP Assessment

Doc Reference	Version	Approved Date	Has system usage changed leading to need for reclassification?
<Doc Number>	*<Version>*	*<Approval Date>*	*<Yes/No>*

6.5 Summary of Change Control:

Sample change requests raised since validation report or last periodic validation review. Where possible sample system generated change log and trace back to change request.

Total Number of Change Requests Raised					
Number of Change Requests Sampled					
Change Request Sampled: **write pass/fail to indicate whether adherence or deviation from applicable Change Control SOP**					
Change Request Reference	**Pre-approval**	**Documents**	**Testing**	**Release approval**	**Other**
	<Pass/Fail>	<Pass/Fail>	<Pass/Fail>	<Pass/Fail>	<Pass/Fail>
System Generated Report of Changes				**<refer to or attach>**	
Total Number of Changes Recorded					
Number of System Changes Sampled					
System Changes Sampled: **write the change request to which each system change pertains – remark on any reconciliation issues**					
System Change Reference	**Associated Change Request**	**Remark (if not reconciled to a CR)**			
Any comments on the review process (for example explanation if reverse sampling is not possible)					

6.6 Summary of User Access Control:

Sample user access management requests raised since validation report or last periodic validation review. Sample staff leavers lists versus active users in the system.

Number of User Access Management Requests raised	
System generated user privileges list	<refer to or attach>
Number of Sampled User Access Management Requests	

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User Access Management Requests Sampled: **write pass/fail to indicate whether adherence or deviation from applicable User Access SOP**			
UAM Ref (Creation)	**Approval**	**Privileges**	**Remark**
	<Pass/Fail>	<Pass/Fail>	
UAM Ref (Modification)	**Approval**	**Privileges**	**Remark**
	<Pass/Fail>	<Pass/Fail>	
UAM Ref (Deactivation)	**Approval**	**Privileges**	**Remark**
	<Pass/Fail>	<Pass/Fail>	
UAM Ref (Reactivation)	**Approval**	**Privileges**	**Remark**
	<Pass/Fail>	<Pass/Fail>	
Number of active user accounts in the system			
Number of sampled accounts in system generated user privileges report			
User accounts sampled: **write pass/fail to indicate whether adherence or deviation from applicable User Access SOP**			
User account ID	**UAM Ref**	**Privileges match approved UAM?**	
		<Pass/Fail>	
Report of leavers			<refer to or attach>
Number of sampled individuals from report of leavers			
Users accounts sampled: **write pass/fail to indicate whether adherence or deviation from applicable User Access SOP**			

Leaver name	User account ID	Is account inactive or deleted?
		<Pass/Fail>

6.7 Accountability of User Action:

Review system generated audit trails and activities logs, verify that there have been no cGxP actions performed by users using a generic user account.

Generic User Account	Has cGxP actions been performed?	Remark
<Generic User Account Name>	<Pass/Fail>	

6.8 Generic and Administrative Accounts:

Review all active user accounts with administrative privileges:

System generated report of generic and administrative accounts	<refer to or attach>
Number active user accounts with system administration privileges	
Number of generic active system administration user accounts	
Number of system administration user accounts that are used to perform business operations	

Review of all administrative and generic user accounts:		
Admin Account ID	**Not used for Business Operations**	**Remark**
	<Pass/Fail>	
Generic User Account ID	**Has it been used?**	**Is its use justified in writing?**
	<Yes/No>	<Pass/Fail>

6.9 Review of Audit Trail:

ReviewAudit Trail since validation report or last periodic validation review as per below table

Electronic Record	Pass/Fail	Anomalous	Remarks
Check Audit trail for User Creation/Deletion/Activate/Deactivate	<Pass/Fail>	<Yes/No>	
Check Audit trail for Recipe Creation/Method Creation	<Pass/Fail>	<Yes/No>	
Check audit trail of Changes in critical set parameter	<Pass/Fail>	<Yes/No>	

6.10 Backup and Restore:

Review Backup and Restore Plan and its latest Backup Test Results.

Backup and Restore Plan	<refer to or attach>
Date of Approval of Backup and Restore Plan	
Date of Execution of last Backup Restore Test	
Last Backup Restore Test Result	<Pass/Fail>
Is Backup and Restore Plan up to date and approved, and has the restore test has successfully executed within last 12 months	<Pass/Fail>

Observations:

Area	Observation

7.0 Recommendation and Responsible Person:

Recommendation	Responsible Person	Change Control Number

8.0 Conclusion:

The system is fit for use	<Yes/No>
The system may not be used until remediation measures are implemented	<Yes/No>
Define required remediation measures	

9.0 Abbreviations: