

PERFORMING AUDIT TRAIL REVIEW

Note: The below tables do not contain the complete set of items to be evaluated as part of Audit Trail Review and only serves as a guidance for the aspects to be covered during an audit trail review. Based on the applicable local regulations, processes at your organization, data criticality and the technical controls implemented in the control software, tailor the template as needed.

Business/Experimental Data Audit Trail Review: This review should be performed by a Supervisor/Quality Unit before the data is used for any quality, efficacy, or safety decisions.

S.No	Question	Response (Yes, No, N/A)	Corrective Action
1.	<p>Is there any orphan data generated as part of this GMP analysis?</p> <p>If “Yes”, is there documented justification for generating orphan data and why it is acceptable not to report/archive the data?</p> <p><i>From the audit trail, identify whether all data generated during the analysis time range has been signed off/accounted for/reported.</i></p>		
2.	<p>Are there any discrepancies in the operation information?</p> <p><i>Discrepancies may include incorrect operation information such as username, user role, instrument used, date and time of operation, calibration or user standardizations performed before sample analysis.</i></p>		
3.	<p>Are there any unauthorized and/or unjustified modifications to the data?</p> <p><i>Modifications may include deletion of data/ renaming the data file/saving data to an unauthorized location.</i></p>		
4.	<p>Are there any unauthorized and/or unjustified modifications to sample identification?</p>		

S.No	Question	Response (Yes, No, N/A)	Corrective Action
5.	Are there any unauthorized and/or unjustified modifications to sample run sequences? <i>Modifications may include modifying sequence information, pausing or stopping a run, re-runs.</i>		
6.	Are there any unauthorized and/or unjustified modifications to critical process parameters?		
7.	Are there any unjustified data processing actions?		
8.	Are there any unauthorized and/or unjustified export of data from the system?		
Completed By: (Sign and Date)			

Functional/System Audit Trail Review: This review should be performed by a second person from the System Administrator group/independent reviewer on a frequency defined based on the system criticality and control mechanisms. The table below only covers the elements of periodic review that can be reviewed from the audit trail of the system.

S.No	Question	Response (Yes, No, N/A)	Corrective Action
1.	Have changes been made in privileges to user types without appropriate change control?		
2.	Are there any discrepancies in user access to the software? <i>User Access may include invalid login attempts, user lock outs, user addition/deletion/disabling.</i>		
3.	Have modifications been made to the system configuration without appropriate change control? <i>System Configuration may include data save location, report configuration, archive and back up settings, password policies, software upgrade, e-signature, audit trail settings etc.</i>		
4.	Has the administrator generated data or performed any unjustified modifications to data and metadata? <i>Modifications may include data deletion, modifying sample/run information.</i>		
5.	Have audit trails been deleted/disabled?		
Completed By: (Sign and Date)			
Reviewed By: (Sign and Date)			

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