Laboratory Records and Documentation -Ultimate Checklist

Laboratory records and documentation plays an important source of information that allows a complete overview of the technical ability of the staff and overall quality control competency. The concept of "Good documentation practice" should be adopted to ensure records are archived and retrieved easily to facilitate investigation(s) whenever required. The practice must help with data collection, processing, data integrity and security. It should be ensured that the raw data are not accidentally lost or damaged or tampered.

Anything that is not recorded/documented shall be considered incomplete. This checklist will help to understand the importance of review, maintenance of data, evaluation of log books and quality of data.

Make sure to check out the other CQ checklists on Laboratory Investigation for a comprehensive approach to dealing with OOS results.

1. Reviewing Process

SR. NO.	MEASURES TAKEN	Are we following?	REMARKS
1.	Ensure to review personal analytical notebooks kept by the analysts in the laboratory and compare them with the worksheets and general lab notebooks & records.	☐ Followed ☐ Not followed ☐ Not Applicable	
2.	Examine all records and worksheets for accuracy and authenticity of the data generated.	☐ Followed ☐ Not followed ☐ Not Applicable	
3.	Ensure the raw data is retained to support the conclusions found in laboratory results.	☐ Followed ☐ Not followed ☐ Not Applicable	
4.	Review laboratory logs for the sequence of analysis versus the sequence of manufacturing dates.	☐ Followed ☐ Not followed ☐ Not Applicable	
5.	Ensure the test dates correspond to the dates when the sample should have been in the laboratory.	☐ Followed ☐ Not followed ☐ Not Applicable	

2. Maintenance of Laboratory data

S. No.	MEASURES TAKEN	OUTCOME	REMARKS
1.	Maintain a raw laboratory data in bound (not lose or scrap sheets of paper), books or on analytical sheets for which there is accountability, such as pre-numbered sheets. *(Digitalized if possible)*	☐ Followed ☐ Not followed ☐ Not Applicable	

2.	Ensure non-numbered loose sheets of paper are not employed to maintain duplicate sets of records or raw data.	☐ Followed ☐ Not followed ☐ Not Applicable	
3.	Ensure the systems are defined (with raw data identified) and validated, if the organization uses discs (digital versions) or tapes as raw data and for the storage of data.	☐ Followed ☐ Not followed ☐ Not Applicable	

3. Evaluation of Laboratory logs

S. No.	MEASURES TAKEN	Are we following?	REMARKS
1.	Examine and evaluate laboratory logs, worksheets and other records containing the raw data such as weighing, dilutions, the condition of instruments, and calculations.	☐ Followed ☐ Not followed ☐ Not Applicable	
2.	Ensure the records do not miss raw data and/or have not been rewritten, and/or the correction fluid has not been used to conceal errors.	☐ Followed ☐ Not followed ☐ Not Applicable	
3.	Ensure the results are not changed without an adequate explanation and the data that has been corrected is cross referenced to authenticate it.	☐ Followed ☐ Not followed ☐ Not Applicable	
4.	Ensure the test results are not transcribed without retention of the original records, nor the test results are recorded selectively.	☐ Followed ☐ Not followed ☐ Not Applicable	

4. Quality of data

S. No.	MEASURES TAKEN	Are we following?	REMARKS
1.	Ensure a protocol is in place for making changes to the data.	☐ Followed ☐ Not followed ☐ Not Applicable	
2.	Ensure the audit trail is in place to determine the changes made to the data.	☐ Followed ☐ Not followed ☐ Not Applicable	
3.	Ensure the products are not "tested into compliance" by arbitrarily labeling out-of-specification lab results as "laboratory errors" without an investigation.	☐ Followed ☐ Not followed ☐ Not Applicable	

4.	Examine the deletion of files in direct data entry systems, indirect data entry without verification, and changes to computerized programs to override program features.	☐ Followed ☐ Not followed ☐ Not Applicable	
5.	Maintain a written explanation when injections, particularly from a series are missing from the official work-sheets or from files.	☐ Followed ☐ Not followed ☐ Not Applicable	
6.	Maintain multiple injections record in consecutive files with consecutive injection times recorded.	☐ Followed ☐ Not followed ☐ Not Applicable	
7.	Ensure to have a written justification for all the files that are deleted.	☐ Followed ☐ Not followed ☐ Not Applicable	
8.	Determine the adequacy of the organization's procedures to ensure that the valid laboratory data are considered for determination of acceptability of components, in-process, finished product, and retained stability samples.	☐ Followed ☐ Not followed ☐ Not Applicable	
9.	Ensure the laboratory logs and document (if cross referenced) must show that data has been discarded by company officials who decided to release the product without a satisfactory explanation of the results.	☐ Followed ☐ Not followed ☐ Not Applicable	
10.	Evaluate the justification for disregarding test results that show the product failed to meet specifications.	☐ Followed ☐ Not followed ☐ Not Applicable	

COMPLIANCEQUEST
Complete Quality Transformed

ComplianceQuest Inc.
www.compliancequest.com

When results are not meeting the criteria, an investigation must take place in order to determine the root cause. With so many factors to consider, every investigation must be carefully considered, unbiased, scientifically sound, and well-documented.

With ComplianceQuest's Lab Investigation Solution, every step, test and result are effortlessly documented in a systematic approach that guarantees the compliance of your lab investigation process to all relevant regulatory and quality standards. Customizable printout formats for lab investigation plans and records help you easily share your findings with investigators while maintaining your proprietary information private.

Request A Demo

REFERENCE:
Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production - Level 2 revision- Guidance for Industry, U.S. Department of Health and Human Services Food and Drug Administration, Center for Drug Evaluation and Research (CDER), May 2022.
Pharmaceutical Quality/Manufacturing Standards Current Good Manufacturing Practice (CGMP)

Doc. CQEQMS-079 Ver1.0, eff. July 9th, 2022

About ComplianceQuest

Transform to a fully connected business with a **next-generation AI-Powered Quality and Safety management platform, built on Salesforce**. Our connected suite of solutions helps businesses of all sizes increase quality, safety and efficiency as they bring their products from concept to customer success. Our intelligent data-driven platform comes with best-in-class integrated processes to mitigate risks, protecting your employees, suppliers and brand reputation, and to increase innovation, compliance, profit and customer loyalty. ComplianceQuest is pre-validated and easy to implement, use, and maintain, allowing for streamlined communication and collaboration across the product value chain.

For more information, or to request a demo with a ComplianceQuest expert, contact ComplianceQuest today:

Visit www.compliancequest.com • **Email us at** marketing@compliancequest.com • Call us at 408-458-8343