



# Data Integrity Checklist for Life Sciences

## Data Integrity Checklist

### Purpose

In the life sciences industry, maintaining data integrity is critical to ensuring data accuracy, consistency, and security. This document is designed to provide you with the knowledge and tools needed to uphold data integrity practices, support quality assurance, and ensure regulatory compliance.

Whether you are a novice or an experienced professional, this checklist will help you navigate the complexities of data integrity requirements and implement effective solutions.

### Scope

This checklist has been designed following the requirements essential for maintaining GxP (good practice) quality guidelines and standards.

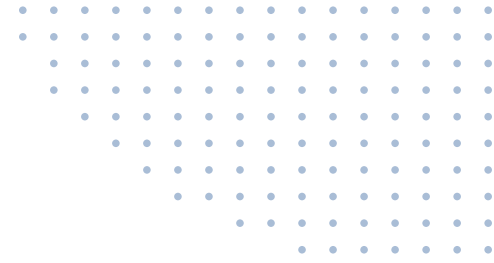
Formulated in accordance with the FDA 21 CFR Part 11 and the EU GMP Annex 11 regulations, this guide aligns with the structured guidance provided by the PIC/S.

Our Compliance Solutions checklist emphasizes Data Capture, Transfer, and Protection as part of the dedicated section on Computerized Systems. This focus ensures a robust data integrity framework for monitoring systems, thereby facilitating regulatory compliance, and maintaining the highest standards of quality.

### Instructions

For each aspect, we present a checkpoint question. Simply provide a verification by marking the appropriate response with a checkmark or indicating "Yes," "No," or "N/A" as applicable.



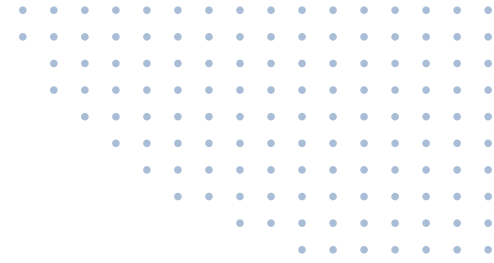


SECTION

# Data Capture

Data capture is the foundational step in maintaining data integrity. Accurate and reliable data capture ensures that the information collected is precise, consistent, and ready for further processing. In this section, we will explore best practices for sensor installation, calibration verification, and data review to ensure that your data capture processes meet industry standards.

Aspects	Checkpoints	Completed?
<b>Sensor Installation and Validation</b>	Is the correct model and serial number of the sensor installed, verified against inventory records?	
<b>Sensor Installation and Validation</b>	Is the sensor located at the designated monitoring point?	
<b>Sensor Installation and Validation</b>	Is the sensor securely fixed in place to prevent data variability?	
<b>Calibration Verification</b>	Does the calibration management SOP apply to the sensors used and is it approved?	
<b>Calibration Verification</b>	Are calibration certificates reviewed for validity and proper storage, and cross-checked with supplier records?	
<b>Calibration Verification</b>	Is there a current and valid calibration sticker on the sensor?	
<b>Data Review and Validation</b>	Is there an approved SOP for data review?	
<b>Data Review and Validation</b>	Does the SOP specify responsibilities for data review and define acceptable data standards?	
<b>Data Review and Validation</b>	Are procedures in place for handling data that does not meet the established criteria?	
<b>Data Review and Validation</b>	Is the timestamp for each data entry synchronized with an approved time standard (e.g., NTP server)?	
<b>Data Review and Validation</b>	Are measures in place to ensure that the timestamp cannot be altered by unauthorized users?	



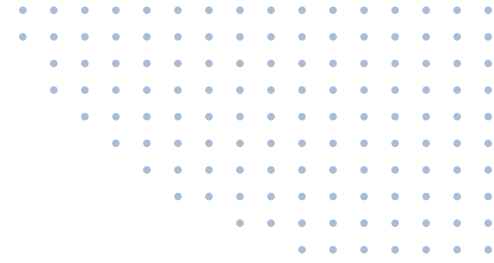
SECTION

# Data Transfer

Effective data transfer processes are crucial for maintaining data integrity as data moves across systems and interfaces. Ensuring secure and accurate data transmission prevents data tampering and loss. This section provides insights into securing system interfaces, implementing encryption, and managing legacy data to maintain the integrity of your data during transfer.

Aspects	Checkpoints	Completed?
<b>System Interfaces and Data Transmission Security</b>	Are data transfer interfaces secure and do they prevent data tampering?	
<b>System Interfaces and Data Transmission Security</b>	Are data encryption and checksums in place to ensure data integrity during transfer?	
<b>System Interfaces and Data Transmission Security</b>	Is there a protocol for maintaining system updates to ensure ongoing data accessibility?	
<b>System Interfaces and Data Transmission Security</b>	Is the retrieval and integrity of the backed-up data periodically reviewed, and has the backup and restore functionality been validated?	
<b>Legacy Data Management</b>	Is there a comprehensive migration strategy in place for legacy data that includes assessment, conversion, and validation protocols to ensure data accuracy and usability in the new system despite initial compatibility challenges?	
<b>Legacy Data Management</b>	Are old data formats compatible with new systems or is there a conversion process in place?	



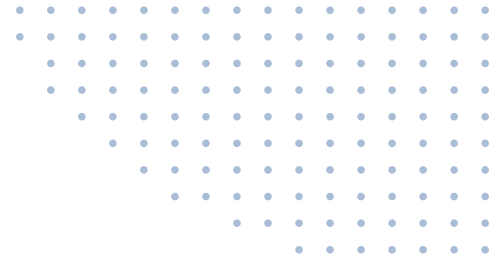


SECTION

# Data Protection

Protecting data from unauthorized access and ensuring its integrity over time is vital for compliance and operational reliability. This section covers access control measures, security protocols, and audit trail requirements to safeguard your data. Implementing these practices will help you prevent data breaches and ensure that your data remains accurate and secure.

Aspects	Checkpoints	Completed?
<b>Access Control and Security Measures</b>	Does the system require unique identification for each user?	
<b>Access Control and Security Measures</b>	Are there protocols for user access levels and administrative task segregation?	
<b>Access Control and Security Measures</b>	Are all data changes logged in a secure and comprehensive audit trail?	
<b>Access Control and Security Measures</b>	Does the system lock-out the user after a defined number of unsuccessful login attempts?	
<b>Access Control and Security Measures</b>	Does the system time-out after a defined period of user inactivity?	
<b>Data Security and Integrity Protocols</b>	Are electronic records produced in a non-editable format (.pdf) to ensure integrity?	
<b>Data Security and Integrity Protocols</b>	Are physical and IT security procedures routinely reviewed and updated?	
<b>Data Security and Integrity Protocols</b>	Is data backup performed regularly, with secure off-site storage solutions?	
<b>Data Security and Integrity Protocols</b>	Are security measures in place to protect the system's clock settings from unauthorized changes?	
<b>Data Security and Integrity Protocols</b>	Is there a regular audit to verify the synchronization and protection of timestamps?	
<b>Data Security and Integrity Protocols</b>	Does the system's audit trail include detailed information for each entry, such as the name of the user, the date and time of the event, the previous and current value of the data, and a reason for the change?	
<b>Compliance and SOP Verification</b>	Are all related SOPs, including those for change management and disaster recovery, current and inclusive of the monitoring system?	
<b>Compliance and SOP Verification</b>	Is there a regular review process for SOP compliance and system readiness?	



By completing our Data Integrity Checklist and assessing and addressing these key points, you are proactively taking the necessary steps to preserve your organization's data and to ensure its accuracy.

Guaranteeing data integrity isn't just about compliance; it's about making informed decisions, upholding reliability, and mitigating risks. With Ellab's continuous monitoring solution your assets will be protected: always be inspection ready while ensuring a timely and quick response to any anomalies with our TrackView Pro solution for continuous monitoring.

Read more about [our continuous monitoring solutions](#) and find out how Ellab can help you with asset preservation.



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### **Ellab Benelux**

Tel. +31 74 205 12 34

**E:** [benelux@ellab.com](mailto:benelux@ellab.com)

### **Ellab Denmark**

Tel. +45 4452 0500

**E:** [contact@ellab.com](mailto:contact@ellab.com)

### **Ellab Dubai**

Tel. +971 502049520

**E:** [dubai@ellab.com](mailto:dubai@ellab.com)

### **Ellab France**

Tel. +33 344 2302 57

**E:** [france@ellab.com](mailto:france@ellab.com)

### **Ellab DACH**

Tel. +49 4286 92662 0

**E:** [germany@ellab.com](mailto:germany@ellab.com)

### **Ellab UK**

Tel. +44 151 355 1314

**E:** [uk@ellab.com](mailto:uk@ellab.com)

### **Ellab Ireland**

Tel. +353 801 3770

**E:** [ireland@ellab.com](mailto:ireland@ellab.com)

### **Ellab Italy**

Tel. +39 02349 1751

**E:** [italy@ellab.com](mailto:italy@ellab.com)

### **Ellab Philippines**

Tel. +632 621 9174

**E:** [ph@ellab.com](mailto:ph@ellab.com)

### **Ellab US**

Tel. +1 303 425 3370

**E:** [usa@ellab.com](mailto:usa@ellab.com)



### **Ellab A/S**

Trollesmindealle 25

3400 Hillerød

Denmark

[www.ellab.com](http://www.ellab.com)