



# Archiving in GxP Processes: Requirements and Pitfalls



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# Introduction

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- GxP (Good Laboratory, Clinical, Manufacturing, or Distribution Practices) regulations govern data management and archival in the pharmaceutical and life sciences industries.
- With the transition from paper documents to digital systems like LIMS (Laboratory Information Management System), new challenges and opportunities arise in data archiving.

# Agenda

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- Definition of data types and their electronic management
- Regulatory requirements
- Archiving Timing
- Roles and Privileges Management
- Data Storage potential Risks
- Data Integrity for Archived Studies
- LIMS and Instruments Data Management
- Project Experience

# Differences between data types

- **Proprietary Raw Data**

- Proprietary raw data are machine-generated and may not be easily understood by humans
- These data are in a format that is not readily interpretable by humans
- essential for scientific accuracy and reproducibility, must be stored
- These data are typically in a format that is specific to the instrument or software that generated them



# Differences between data types

- **Human-readable Data**

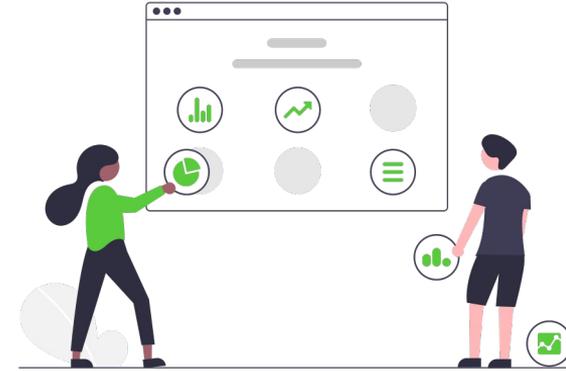
- processed, analyzed, and presented in a format that can be easily understood by humans
- This data is often presented in tables, charts, reports, or documents that scientists, researchers, and regulators can readily comprehend
- These data are typically the end product of data analysis and are used for scientific reporting, decision-making, and communication



# Differences between data types

- **Metadata**

- Metadata is data that provides context and information about other data, which can include both raw data and human-readable data
- Examples of metadata might include information about sample sources, instrument settings, timestamps, and data processing steps
- In essence, metadata is needed to structure the data to either present it human readable output but also to categorize and document for further machine calculations and processing



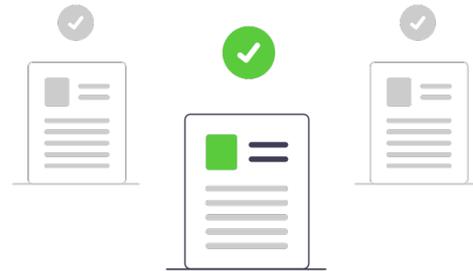
# Regulatory Requirements for Raw Data Archiving

- **Data Retention Period:** The duration for which data must be retained varies depending on the type of data and the specific GxP regulations applicable
- **Data Integrity:** All data must be secure, accurate, and accessible throughout the data lifecycle
- **Security and Access Control:** Access to archived data must be controlled and limited to authorized personnel
- **Data Backup and Recovery:** Robust data backup and disaster recovery procedures must be in place to protect against data loss



# Regulatory Requirements for Raw Data Archiving

- **Audit Trails:** An audit trail should be maintained for all changes to raw data, showing who made the change, when, and why
- **Data Format and Documentation:** Data, especially raw data, should be stored in a format that ensures its original content and meaning are preserved
- **Data Migration and Legacy Systems:** When transitioning to new systems or technologies, the integrity and accessibility of archived raw data must be maintained



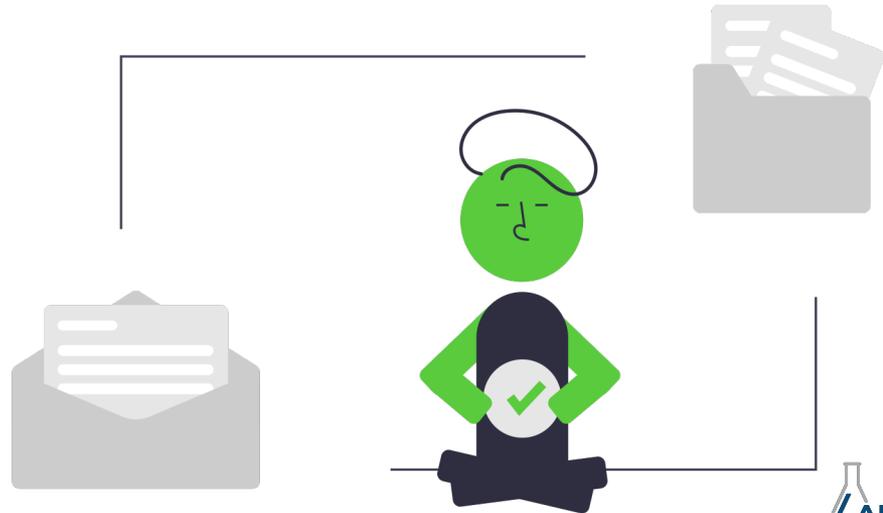
# Required Timing for the Archiving Process from a GxP Perspective

- Data should be archived **as soon as possible**. This ensures that data is not lost, altered, or tampered
- Standard Operating Procedures (**SOPs**) help ensure consistency and compliance with archiving practices
- **Real-Time data access** should always be available for authorized personnel
- Regulatory Guidelines and **Retention Periods** are strict and depend on the area
  - Entire life-cycle of the drug for Pharma companies managing the study and data themselves
  - Usually 3-5 years for CROs, after this an agreement with the sponsor will define how to handle the data the rest of the time



# Roles and Privileges Management for the Archivist Role

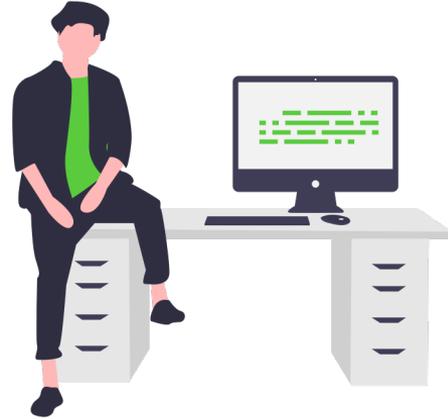
- Archivists are essential for ensuring data integrity, accuracy, and regulatory compliance
- Archivists should have appropriate access to data archiving systems, but this access should be carefully controlled



# Responsibilities of the Archivist

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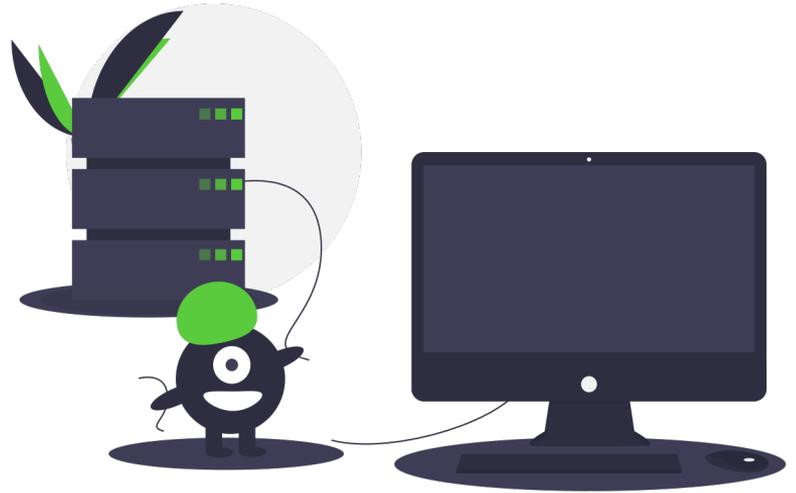
- Initiating the archiving process.
- Verifying the accuracy and completeness of data.
- Ensuring data is archived in accordance with established procedures and regulatory requirements.
- Maintaining records of archiving activities.
- Collaborating with other personnel, such as data generators and quality assurance teams.
- Providing access to archived data as needed for audits and inspections.



# Data Storage Management Potential Risks and Pitfalls

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- Risks include
  - data loss
  - data corruption
  - data fragmentation
  - unauthorized access
  - obsolete storage systems
  - scalability issues
  - Data migration challenges
  - Many more...



# Data Storage Management Potential Risks and Pitfalls

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- Mitigation of risk
  - Long term stability of the archive media
  - Logical and Physical access protection of the facilities
  - Computer system validation of the system used
  - Written procedural instructions of the use of the system



# ALCOA + Principles

**A**

Attributable

- Clearly indicates who recorded the data or performed the activity
- Signed / dated
- Who wrote it / when

**L**

Legible

- It must be possible to read or interpret the data after it is recorded
- Permanent
- No unexplained hieroglyphics
- Properly corrected if necessary

**C**

Contemporaneous

- Data must be recorded at the time it was generated
- Close Proximity to occurrence

**O**

Original

- Data must be preserved in its unaltered state
- If not, why not
- Certified copies

**A**

Accurate

- Data must correctly reflect the action / observation made
- Data checked where necessary
- Modifications explained if not self-evident

**C**

Complete

- All information needed for replication and understanding is required

**C**

Consistent

- Chronological order of data
- Comments and modifications must also have a timestamp

**E**

Enduring

- Data must be available and readable during the whole lifetime

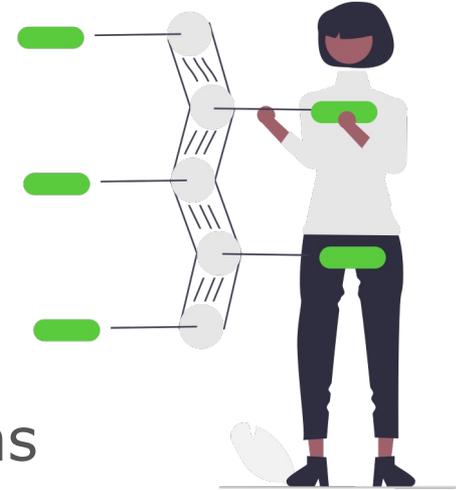
**A**

Available

- Data must be accessible during the whole lifetime

# LIMS and Instruments Data Management

- Role of LIMS
  - Integration with instrument data ensures automated, accurate, and compliant data capture
  - enforces data standardization by applying consistent naming conventions and units of measurement
  - allows to implement strict access controls
  - maintains detailed audit trails that record all changes made to data
  - can track the calibration and maintenance history of instruments



# LIMS and Instruments Data Management

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- LIMS must undergo validation to demonstrate that it operates reliably and consistently
- LIMS can export data in various formats, including PDF and CSV, facilitating data sharing and reporting for regulatory submissions
- LIMS can perform data integrity checks and enforce data integrity principles
- Properly train personnel involved in data management and archiving to ensure best practices



# Project Experience

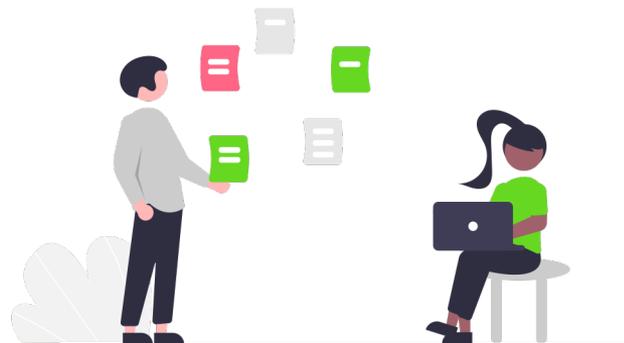
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- Project A
  - Full archive of the whole LIMS
  - Challenge: prerequisites such as application server OS, database and maintenance must be available, software and hardware upgrades over time, IT workload
- Project B
  - No archive of the LIMS, only the final study report
  - Challenge: Business team needs to decide which data is truly important, continuous check of data required, business workload



# Project Experience

- Project C
  - Archive per study and keep data logical separated
  - Challenge: which data can truly be separated in LIMS, which data is used by other studies too
- Project D
  - Archive and export data to send back to sponsor
  - Challenge: which data to select and which data format is accepted by sponsor, sending and deletion of data must be secure



# Conclusion

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- Archiving GxP data is a complex process with many facets.
- Compliance with regulations, sound data management practices, and proper training for personnel are critical to successful archiving in the modern, digital laboratory setting
- LIMS play a pivotal role in capturing and standardizing data and ensuring integration of various instruments while maintaining data integrity



# Questions?

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