**Document approval**

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# Purpose

The purpose of this Standard Operating Procedure (SOP) is to establish the minimum requirements for archiving procedures, file storage and file management in all data systems to ensure that all files created in accordance with GxP, business, legal, regulatory, or other requirements are maintained and available in a timely manner.

# Scope

This SOP is valid at Grau Pharma GmbH for the whole Organization. The respective training shall be given in accordance with **SOP-10 Training Management**.

# Responsibilities

Responsible for the content of this SOP is Managing Director Tradelaw.

|  |  |
| --- | --- |
| **Role** | **Definition/Task** |
| Managing Director Tradelaw | * ensures adequate storage and archiving of GxP, business, legal, and regulatory related documents * retrieves documentation upon loan request * provides monitoring of archiving functions to ensure the proper storage and maintenance of archival files, their timely tracking and retrieval, and the destruction and management of obsolete files * reviews documentation to determine whether a document should be re-archived or destroyed * serve as interim coordinator for other files until an archival or equivalent function is available for other business sections as well |
| Managing Director Tradelaw | * ensures periodic review of archival documentation |
| Department Head / Line Manager | * is the document owner * authorizes the release of documents from the file * authorizes archival documents destruction |
| Requestor | * completes archiving and loan requests for particular documents * compiles documents for archiving * sets desired document’s revision date * makes sure that all data specified in the archiving request form are filled in correctly * transfers all registered documents to the file and forwards to Managing Director Tradelaw |

# Definitions, terms, and abbreviations

| **Term/abbreviation** | **Definition at Grau Pharma GmbH** |
| --- | --- |
| Archive | This is a safe place or a reliable way to keep documents that are not actively used but that must be kept for a predetermined period of time. |

# Workflow

# 5.1 Archive Controls

An Archive for hard-copy, paper documents are kept in a secure, waterproof, environmentally friendly building. The following environment must be provided for the Archive:

* Adequate pest and temperature/humidity control measures are taken.
* Fire alarms are connected to the site system.

# 5.2 Archiving initiation

The Requestor (document owner or designee):

* transfers all registered documents to the file folders and boxes,
* provides information about the file location of the documents to be archived, document type, document number,
* sets the proposed revision date according to the document's retention period,
* makes sure that all data specified in the **Archiving Request Form** are filled in correctly,
* completes **Archiving Request Form**.

The Document Owner must check the document(s) to be archived against the information provided in the **Archiving Request Form**, e.g., for completeness and accuracy. If an error is detected, the entire package is returned to the Requestor for correction.

# 5.3 Documentation types and archiving

Once a document is forwarded to Managing Director Tradelaw for archiving, a document type must be performed.

Managing Director Tradelaw verifies a document type for each document that comes from a type and numeric identifier (unique code /number).

The types are as follows but are not limited to:

|  |
| --- |
| **Examples of Document types** |
| QMS related Documentation (SOPs, records)  Suppliers/Customers profiles related documentation  Operational related documentation (distribution protocols, CoAs, Certificates, temperature monitoring reports, etc.) |

Managing Director Tradelaw verifies proposed revision dates for each particular document type according to the document's retention period.

After confirming acceptance of the documents to be archived in **Archiving Request Form**, the Managing Director Tradelaw updates **Archiving Register** labels files appropriately, places files in archiving storage, and ensures appropriate storage location traceability. updates **Archiving Register** reflects all previously archived documents, their status, actual location, and other data required for quick searching and extraction upon request.

# 5.4 Document Loans

Documents can be requested from the Archive for a loan. Managing Director Tradelaw oversees this process. The Requestor completes the list of requested documents in **Document Loan Request**. The request shall be allowed by the Managing Director Tradelaw and authorized by the Line Manager (original document owner).

Managing Director Tradelaw updates **Archiving Register** and reflects who loaned the archived document(s) and when it was loaned (retrieved) to indicate that the document has been removed from the Archive. Thereafter Managing Director Tradelaw:

* Checks the contents of the file against the filing form and delivers it to the Requester. If a copy of the document is required, the requirements of **SOP-02 Good Documentation Practice** must also be followed. Loaned documents and controlled copies must be returned to Archive.
* Sets a reminder to contact the Requestor if the file has not been returned in one (1) week. If the file cannot be returned within this period, sets an additional reminder. The extension must be justified, and a note must be reflected in **Document Loan Request**.
* Checks the file returned by the requestor for proper content to make sure it is complete and completes the section on Document Loan Flow in **Document Loan Request**.
* Returns the documents to the Archive file and updates **Archiving Register**.

# 5.5 Retention Period

GDP relevant Documents, Records, Data should be retained for the period stated in national legislation but at least five years. Personal data should be deleted or anonymized as soon as their storage is no longer than necessary for the purpose of distribution activities.

# 5.6 Review Procedure

Managing Director Tradelaw checks **Archiving Register** annually for all expiring documents by revision date. This ensures that documents are not stored longer than necessary for long-term retention. The status of all documents (archived, loaned, and destroyed) shall be reflected in **Archiving Register**.

A decision must be made to re-archive the data (archiving prolongation) or destroy it confidentially.

The review process for all archival documents is monitored by the Managing Director Tradelaw and ensured by the Managing Director Tradelaw.

* All records placed in the Archives must be reviewed at the expiration of the retention periods specified in the Retention Period.
* The date of review of documents is the total period of 10 years unless it is superseded by the retention periods mentioned above. This is due to the fact that the withdrawal date of the product will not be known at the time of archiving.
* The review period is the archiving request date plus the allotted document retention period.

Managing Director Tradelaw checks annually at the beginning of the year the **Archiving Register** to determine which documents are expiring in that calendar year, and

* retrieves documents from the Archive, ensuring completion.
* ensures that verification is completed within the specified time frame.
* if necessary, re-archives all documents, including adding a new revision date, and updating
* **Archiving Register**.
* ensures that any documents are destroyed confidentially as required.
* ensures that **Archiving Register** is updated accordingly.
* completes **Document Destruction Request** for documents that no longer need to be stored and used.

# Applicable documents

SOP-01 Documentation Management

SOP-02 Good Documentation Practice

SOP-10 Training Management

# Appendices

The following appendices are an integral part of this SOP:

Appendix Archiving Request Form

Appendix Archiving Register Form

Appendix Document Loan Request Form

Appendix Document Destruction Request Form

# Document revision history

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Valid from** | **Description of the revision** | **Reason for the revision** |
| 1 | See header | Document created | QMS implementation |