**Document approval**

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| --- | --- | --- | --- |
|  | **Name** | **Date** | **Signature** |
| **Author’s designation**  **e.g., Quality Specialist** |  |  |  |
| **Reviewer’s designation**  **e.g., Quality Management Director Deputy** |  |  |  |
| **Approver’s designation**  **e.g., Quality Management Director** |  |  |  |

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| --- | --- |
| **Effective Date** |  |

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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 NBE-Therapeutics for all Organization. The respective training shall be given in accordance with **SOP-10 Training Management**.

# Responsibilities

Responsible for the content of this SOP is e.g., Quality Management Director.

|  |  |
| --- | --- |
| **Role** | **Definition/Task** |
| e.g., Archiving Specialist | * ensures adequate storage and archiving of GxP, business, legal, 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 |
| e.g., Quality Management Director | * ensures periodic review of archival documentation |
| Department Head / Line Manager | * is 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 e.g., Archiving Specialist |

# Definitions, terms and abbreviations

| **Term/abbreviation** | **Definition at NBE-Therapeutics** |
| --- | --- |
| 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 is 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 e.g., Archiving Specialist for archiving, a document type must be performed.

e.g., Archiving Specialist verifies a document type to each document that comes from a type and numeric identifier (unique code /number).

The types are as follows but are not limited to:

|  |  |  |
| --- | --- | --- |
| **Examples for Document types** | | |
| Analytical Results | Method Validation | Quality Documentation |
| Analytical Protocols | Miscellaneous | Recalls, Field Alerts, Complaints |
| Analytical Reports | Monographs | Clinical Study Files |
| Batch Analysis (IPs, CoA)  Change Controls | Analytical Transfer (Protocols, Reports) | Validation Reports |
| Deviations | Process Transfer (Protocols,  Reports) |  |

e.g., Archiving Specialist 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 e.g., Archiving Specialist 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 loan. e.g., Archiving Specialist oversees this process. The Requestor completes the list of requested documents in **Document Loan Request**. The request shall be allowed by the e.g., Archiving Specialist and authorized by the Line Manager (original document owner).

e.g., Archiving Specialist 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 e.g., Archiving Specialist:

* 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 document 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 time 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, completes section on Document Loan Flow in **Document Loan Request**.
* Returns the documents to the Archive file and updates **Archiving Register**.

# 5.5 Retention Period

Depending on the type of document, the following retention periods are determined:

|  |  |
| --- | --- |
| **Field and Document type** | **Retention Period** |
| Batch Records | Batch Expiry +2 years |
| Reference Samples | Release date + 2 years |
| Product Specification Documentation (e.g., validation package and manufacturing formulas for a regulatory filing) | Until final withdrawal of the product from the market +10 years |
| Complaints | Closure date +1 year |
| Facility Documentation | Until last productive use or superseded + 10 years |
| Organizational and Personnel Records | 10 years after superdense or end of employment |
| Pharmaceutical Product files | 10 years |
| Other (e.g., litigation cases) | Depending on the legislation |

# 5.6 Review Procedure

e.g., Archiving Specialist 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 in a confidential manner.

The review process for all archival documents is monitored by the e.g., Archiving Specialist and ensured by the e.g., Quality Management Director.

* 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.

e.g., Archiving Specialist 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 in a confidential manner 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 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 |