Table of Contents

1.0 Purpose

This Standard Operating Procedure (SOP) defines the system for storing and archiving raw data, technical specifications, protocols, reports, batch production records, Certificates of Analysis (COAs), and other documentation generated in support of project research, development, and manufacturing activities (both GMP and non-GMP).

2.0 Scope

This SOP applies to Biopharmaceutical Development Program (BDP) personnel who are involved in the document storage and archival process. This includes BDP personnel who provide documents to Biopharmaceutical Quality Assurance Documentation (BQAD).

3.0 Overview

Work performed in support of project research, development, manufacturing, and support operations is documented to provide a reliable record of activities performed. The work is documented to provide a reliable record of the activities performed. These documents, records, and reports capture information that may be needed to meet regulatory requirements, to reconstruct events at a later time, serve as a foundation for future work, provide a mechanism for troubleshooting, and provide a means to audit the validity of subsequently reported data. The retention of documents in a manner that adequately protects the documents and facilitates retrieval is an important component of the overall documentation management system at the BDP.

In general, BQA maintains recently completed and active documents in the Document Control Room for easy reference purposes. If there is a space limitation, documents may be stored in an off-site location. Documents are considered archived when they are sent to off-site storage. Types of stored documents include, but are not limited to, Standard Operating Procedures (SOPs), Master Production Records (MPRs), Batch Production Records (BPRs), Master Equipment Files (MEFs), Quality Control Test Requests (QCTRs), and Validation documentation. An electronic Document Management System (eDMS) is also used to store documents processed within the system eDMS.

4.0 Authority and Responsibility

4.1 The Director, Regulatory Compliance (RC)/BQA has the authority to define this procedure.

4.2 It is the responsibility of BQAD to:

- Establish secure archive locations that are protected from foreseeable emergencies (fire, flood, etc.).
- Maintain the on-site Document Control Room to ensure compliance with regulatory Food and Drug Administration (FDA) and BDP requirements.
- The BQAD supervisor maintains a list of individuals with authorized access to the Documentation Room
- Manage the off-site contract archive companies to ensure compliance with regulatory (FDA) and BDP requirements.
- Maintain traceability of on and off-site documents.
- Retrieve documents from on and off-site locations as requested.
- Maintain a database of off-site archived documents.
- Maintain documents stored on-site in the Document Control Room by document type or under a project name/number.
- Pack boxes and arrange shipment of documents to the BDP off-site archives.

4.3 It is the responsibility of BDP personnel to:

- Provide BQA with completed documents for controlled storage, along with ***Form 21402-01, Archive Request***.
- Transfer to BQAD any documentation (or reference the location of any electronic data), protocols, technical specifications, reports, and COAs, and any other pertinent information for archiving at the close of the project. This includes but is not limited, Project data , reports, lab notebooks, equipment file, equipment log books and QCTRS.

5.0 Controlled Access

5.1 Access to documents stored on-site in the Document Control Room is limited to BQA / BQAD and selected BDP staff members who assist with multiple tasks that involve the documents stored in the Document Control Room.

5.2 Access is maintained through a key code and/or keycard access to the Document Control Room. The room must be locked whenever BQA/ BQAD personnel are not present.

5.3 Access to documents stored off-site is controlled by requests from BQAD to the vendor that manages the off-site storage facility (see Section 6.7 for vendor facility requirements).

5.4 Access to archive documents in the eDMS are managed through roles and rights in the system.

5.5 Documents processed through the electronic Document Management System are maintained within the system as the original documents with electronic approvals. No hard/paper copies are saved outside the System. Hard/Paper copies can be printed for reference use only.

6.0 Document Storage

6.1 Documents may be stored either in the BQA Document Control Room, the electronic Document Management System (eDMS), or in an off-site location depending upon space requirements.

6.2 Unless otherwise specified by the Frederick National Laboratory for Cancer Research (FNLCR), raw data generated by the BDP, records, protocols, technical specifications (as applicable per Current Good Manufacturing Practices (cGMP) regulations), official GMP reports and COAs generated because of a project, and any other pertinent documentation is maintained by BQAD in controlled storage (this includes storage in the eDMS). Hard copy documents completed recently may be stored on-site in the Document Control Room before being transferred to off-site storage, depending upon storage space available.

6.3 Correspondence and GMP-supporting documentation relating to the conduct of a study and the interpretation and evaluation of data, other than those documents contained in the final report, are also retained.

6.3.1 All BPRs that have been issued a lot number, must be returned to BQAD for archival. Those issued, started then aborted are placed in a green file binder in the project file.

6.4 Records related to cGMP regulated production or testing, (e.g., reagent batch preparation logs, equipment maintenance and calibration records, etc.), are maintained in material or equipment-specific files. Environmental monitoring data is maintained in files identified by Process Analytics (PA) number (QCTR).

6.5 Validation documentation for utilities, equipment, and process validation (including computer programs that are in production) are to be returned to BQAD for storage. When computer programs, equipment, utilities, or process validations are retired, the validation documentation is archived.

6.6 **On-site Storage**

6.6.1 Project-specific documents stored in the on-site BQA Document Control Room are organized in numerical order by project number. Items that are not associated with a specific project are labeled as appropriate. Non-project specific documentation (i.e., environmental data, facility validations, equipment logbooks, etc.) are organized by document type.

6.6.2 BQAD is responsible for filing of documentation and maintaining the organization of the Document Control Room.

6.6.3 Should BDP staff need to retrieve or refer to documentation from the Document Control Room they must contact BQAD Staff, verbally or via email. BQAD Staff retrieves the document and replaces it with an "out" card. The out card must indicate the date the document was removed, the title of document, and requestor's name. This ensures the original document can be located if needed. When the document is returned the "out" card is removed, and the information crossed out.

6.7 **Off-site Storage**

6.7.1 Upon request, documents may be electronically scanned to the appropriate project folder before they are archived and sent to off-site storage.

6.7.2 Off-site contract archive companies must comply with regulatory (FDA) and BDP requirements:

- Waterless fire suppression system.
- Secure, climate controlled, fireproof environment (i.e., vault).
- Documents/Boxes available for retrieval within the same day, if needed.
- Delivery.
- Monthly contract with a Pest Control Company.
- 24-hour security.
- Generator back up in case of power failure

6.7.3 See Section 7 for instructions to send documents to the off-site storage facility.

6.8 **Electronic Storage**

Documents processed through the electronic Document Management System (eDMS) are maintained within MasterControl as the original documents with electronic approvals. The system is backed up on a routine basis for data retrieval for disaster recovery by NIH IT Department.

7.0 Submitting Documents to be Archived Offsite

7.1 BQAD logs the documentation into the off-site archives using a computerized tracking system. When a document is added to the archives, the document number, document title, and date archived are entered in the Vendor's Archived Documents Database and the BQAD Archived Documents database. Additional information will be entered in the databases depending on the type of document being archived and on the additional information provided to BQAD on Form 21402-01, Archive Request. Descriptive additional information will assist with future searches for the document.

7.2 When completed documents (e.g., laboratory notebooks, equipment logbooks, etc.) need to be archived at Iron Mountain, BQAD completes Form 21402-01, Archive Request as indicated below and provide it to the Director, Regulatory Compliance for approval to end off site.

- **Document Information (Number, Title, etc.) –** document number and title, if neither is applicable, provide pertinent information regarding a description of the document. This information will be included in the description of the document in the Archived Documents Database, so it is important that it contains enough information that a reasonable search of the database would locate the document.
- **Submitted By –** name of person submitting request.
- **Date Submitted –** date request is submitted.
- **Project Name –** project name, if applicable.
- **Project Number –** project number, if applicable.
- **Attached List of Documents with Dates –** only used if multiple documents are submitted using one form.
- **Reason for Archival –** provide as much detail as possible for the reason the document is being archived (e.g., inactive document, project closed, etc.).
- **Additional Information –** provide any additional information that will assist in future searches for the document (this information will be included in the Archived Documents database).

7.3 BQAD enters the information into the Vendor's Archived Documents database according to the information provided on the Archive Request form and archives the document.

7.4 BQAD completes the bottom portion of Form 21402-01, Archive Request, and enters the information into the Vendor's Archived Documents database if the document is being archived off-site. BQAD files the form in the "Archive Requests, Form 21402-01" binder located in the Document Control Room

7.5 BQAD does not archive documentation related to a closed project off-site without approval from the Director, RC through an email request.

8.0 Retrieving and Returning Documents to Storage

8.1 The individual requiring document retrieval sends an e-mail to the NCI BDP BQAD mailbox (NCIBDPQAD@mail.nih.gov). The email should include the name, date, and number of the document requested (as applicable), and the date the document is needed.

NOTE: The standard turnaround for document retrieval from off-site storage is 24 hours if BQAD receives an e-mail request before 2:00 pm. Same day delivery is an option for critical documents. Same day delivery requires approval by QA/BQAD Manager in writing. Approval can be provided either in an email or as an internal memo.

8.2 Documents may only be removed from on-site storage in the Document Control Room by BQA/BQAD personnel. Requests for off-site archived documents is made by BQAD to the vendor that manages the off-site storage facility.

8.3 Photocopies of documents may be requested by sending an e-mail to NCI BDP BQAD. Original documents may be viewed in the Document Prep Area if necessary, or

photocopies provided as requested. Only under exceptional circumstances will the original documents be allowed out of the BQA/BQAD area.

8.4 Whenever an original document is signed out of BQAD, an "Out" card is completed and placed in the location or box where the document was stored. The "Out" card captures the date the document was checked out, to whom it was checked out to, and the document number or title. If the document was in an off-site storage box, the box remains in the BQA Document Control Room until the checked-out document is returned.

8.5 If a second individual needs the document, this individual must send an e-mail to BQA (NCIBDPQAD@mail.nih.gov) requesting the document be transferred to them. The document may not be transferred to another individual without reassigning the "Out" card to the second individual.

8.6 When the document is returned, BQAD removes the "Out" card and returns the document to the location or box where it was originally stored. Off-site boxes are stored in the BQA Document Control Room until the next time boxes are sent to the off-site location.

NOTE: Data cannot be added, nor changes made to any document that has been archived. An addendum or copy is issued for the document for the purpose of making additional entries, changes, etc. The changes are documented.

8.7 When documentation is returned to off-site storage, BQAD enters the information in the Vendor's Archived Documents Database, prints a list of the items to be returned and obtains the signature of the courier on Form 21402-02, Archived Document Pickup.

9.0 Document Retention

9.1 Archived paper documents are retained for each project for at least ten (10) years (refer to the ***SOP 21407 - Records Retention***), or in the case of fragile documents, until they no longer afford evaluation, whichever comes first. At the end of the ten (10) years, the NCI is contacted and provided with a list of documents for destruction. The Director, Regulatory Compliance and NCI, Chief Biological Resources Branch must approve any destruction of documents.

9.2 BQAD retains other records on-site such as personnel training, equipment maintenance and calibration records, batch records, etc., if they pertain to any active BDP project documents still retained by NCI.

10.0 References and Related Documents

SOP 21407	*Records Retention*
SOP 21416	*Creation and Use of Electronic Copies of GMP Documents*
SOP 21916	*Controlled Copies*
Form 21402-01	*Archive Request*
Form 21402-02	*Archived Documents Pickup*

11.0 Change Summary