Frederick National Laboratory for Cancer Research, Frederick, MD

BDP

Biopharmaceutical Development Program

Standard Operating Procedure

Title: Records Retention

SOP Number: 21407

Revision Number: 05

Supersedes: Revision 04

Effective Date: SEP 15 2016

Originator/Date: [redacted]

Approval/Date:

Approval/Date:

Table of Contents

1.0 Purpose

This Standard Operating Procedure (SOP) defines the Records Retention System for the Biopharmaceutical Development Program (BDP) and ensures that essential records are retained, made available as required, and that vital records are protected in compliance with cGMP requirements.

2.0 Scope

This SOP applies to documents that the Biopharmaceutical Quality Assurance (BQA) group maintains, protects, retains, and disposes of in accordance with cGMP regulations. This SOP **does not apply** to financial records or other similar business records kept by BDP Operations Management. See ***SOP 21402, Document Storage and Archival Process***.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

3.0 Overview

The BDP Records Retention SOP defines the period of time during which records are maintained and specifies the disposition of records.

4.0 Authority and Responsibility

4.1 The Director, Biopharmaceutical Quality Assurance (BQA) has the authority to define this procedure.

4.2 The Managers/Supervisors of the BDP are responsible for ensuring that their functional area(s) follow this procedure when submitting documents for retention to BQA.

4.3 BQA is responsible for maintaining, filing, archiving, and disposing of records.

4.4 BQA management is responsible for:

- Monitoring records transfer and destruction.
- Selecting off-site archival services when necessary.
- Maintaining the database of archived documents.

4.5 BQA is responsible for quality oversight of this operation.

5.0 Objectives

5.1 Identify BDP documents, for example SOPs, MPRs, validation documents (IOQs), et cetera.

5.2 Maintain BDP records in a manner that reduces operating costs.

5.3 Ensure prompt and accurate retrieval of records.

5.4 Ensure compliance with regulatory requirements and minimization of litigation risks (See Section 8.0).

5.5 Protect vital information in the event of a disaster.

5.6 Document the types, quantities, and dates of the records destroyed.

5.7 Implement audit and enforcement procedures.

5.8 Meet or exceed the guidelines provided in the Code of Federal Regulations (See Section 9).

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6.0 Records

6.1 The BDP mainly organizes its records according to projects assigned by the National Cancer Institute (NCI). When new project documentation is received by BQA, a project file is established and maintained by BQA in the Document Control Room. This project file usually contains, as a minimum, the following.

- Batch Production Records
- Certificates of Analysis
- Chemistry, Manufacturing, and Control Documents
- Correspondence
- Deviations
- In-Process Audits
- Labeling information
- Master Specifications
- Release letters
- Test information
- General Project File information
- Out-of-Specifications
- Material Safety Datasheets
- MMIC Inventory Forms

6.2 Below are other records maintained by BQA. This list is not inclusive and may be added to as necessary.

- Environmental Monitoring Data
- Cleaning Logs
- Engineering Events
- Equipment Logbooks
- Failure Notifications
- Historical Project Information
- Laboratory Notebooks
- Logsheets
- Master Equipment Files
- Validation Protocols and Packages
- Quality Control Test Requests
- Raw Material Specifications
- Regulatory Documents
- Standard Operating Procedures
- Vendor Audit Reports
- Test Protocols
- Training Records
- Reagent Preparations
- Chart Records

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7.0 Procedure

7.1 Retention periods apply to the original document, known as the "record copy," and refer to the minimum number of years the record must be maintained following the conclusion of the project, or in some cases contract fiscal year in which the document is created, unless otherwise indicated. For example, a document that was generated during FY 2009 has a retention period of ten years and could be marked for destruction at the beginning of FY 2019.

Note: At ten years, a review can be conducted on a case-by-case basis to determine whether the documents can be destroyed after ten years. GMP documents cannot be destroyed for at least ten years. No document can be destroyed without documented approval of the Chief of the BRB/NCI (See Form 21407-01, Attachment 1). In addition to the above, documents cannot be destroyed until two years after shipment and delivery of the drug for investigational use is discontinued per 21 CFR 312.57.

7.2 If two or more of the record categories are interfiled and screening for disposition is not practical, the entire file will be retained for the longest period prescribed for any of the records contained in that file.

7.3 For GMP documents in the BDP, the retention period is at least ten years from the receipt of the document in BQA. This applies to any project-related document in the BDP, except for financial and related documents. Laboratory notebooks are the property of the NCI and kept for an indefinite period of time, unless directed otherwise by the NCI.

7.4 Refer to ***SOP 21402 - Document Storage and Archival Process***, for procedures on archiving documents off-site.

8.0 Definitions

8.1 **Destruction Date –** Represents the day, month, and year in which a record may be destroyed.

8.2 **Record –** Recorded information, regardless of medium or characteristics, made or received by the BDP that is evidence of its operations and has value requiring its retention for a specific period of time.

8.3 **Record Copy –** The official copy of a record that is retained for legal, operational, or historical purposes, sometimes the original.

8.4 **Records Destruction –** The documented disposal of records of no further value by incineration, maceration, pulping, or shredding. The definitive obliteration of a record beyond any possible reconstitution.

Note: The destruction details are recorded in a BQAD database for reference of the original document and on Form 21407-01 (Attachment 1).

8.5 **Records Inventory –** A detailed listing of the types, locations, ages, and volumes of records in the BDP.

8.6 **Records Protection –** Safeguarding records against intentional or unintentional destruction or damage.

8.7 **Retention Period –** The time period records must be kept according to operational, legal, regulatory, and fiscal requirements. The BDP retains records **for at least ten years**, unless specifically stated otherwise, in writing, for certain documents or categories of documents.

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9.0 References and Related Documents

9.1 **SOP 21402** *Document Storage and Archival Process*

9.2 **21 CFR 211.180 General requirements. (a)** Any production, control, or distribution record that is required to be maintained in compliance with this part and is specifically associated with a batch of a drug product shall be retained for at least one year after the expiration date of the batch or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for examination under 211.137, three years after distribution of the batch.

(b) Records shall be maintained for all components, drug product containers, closures, and labeling for at least one year after the expiration date or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under 211.137, three years after distribution of the last lot of drug product incorporating the component or using the container, closure, or labeling.

9.3 **21 CFR 312.57 - Recordkeeping and record retention. (a)** A sponsor shall maintain adequate records showing the receipt, shipment, or other disposition of the investigational drug. These records are required to include, as appropriate, the name of the investigator to whom the drug is shipped, and the data, quantity, and batch or code mark of each such shipment.

(c) A sponsor shall retain the records and reports required by this part for two years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until two years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified.

9.4 **21 CFR 312.62 (c) Record retention.** An investigator shall retain records required to be maintained under this part for a period of two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.

9.5 **21 CFR 600.12 - Records. (b) Records retention - (1)** General. Records shall be retained for such interval beyond the expiration date as is necessary for the individual product, to permit the return of any clinical report or unfavorable reactions. The retention period shall be no less than five years after the records of manufacture have been completed or six months after the latest expiration date for the individual product, whichever represents a later date.

21 CFR 606.160 (Biologics). (d) Records shall be retained for such interval beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of unfavorable clinical reactions. You must retain individual product records no less than ten years after the records of processing are completed or six months after the latest expiration date for the individual product, whichever is the later date. When there is no expiration date, records shall be retained indefinitely.

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9.6 Good Laboratory Practices

21 CFR 58.195 Retention of Records

b. (2) A period of at least five years following the date on which the results of the nonclinical laboratory study are submitted to the Food and Drug Administration in support of an application for a research or marketing permit.

(3) In other situations (e.g., where the nonclinical laboratory study does not result in the submission of the study in support of an application for a research or marketing permit), a period of at least two years following the date on which the study is completed, terminated, or discontinued.

9.7 FNLCR Standard Operating Procedure, Records Management, Document 110.

10.0 Attachments

10.1 **Attachment 1** Form 21407-01, Authorization and Documentation of Records Destruction

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

Attachment 1
Authorization and Documentation of Records Destruction

FNLCR, BDP
Form No.: 21407-01
SOP No.: 21407
Revision 05: SEP 15 2016

Authorization and Documentation of Records Destruction

Document Number (if any)	Title of Document	Type of Media (use code)	Reason for Destruction (use code)	Method of Destruction (use code)	Is Secure / Witnessed Destruction Necessary? (Yes/No)

Codes: Media – "P" Paper, "CD" CD or DVD, "B" Blueprint, "E" Electronic; **Reason –** Expired, Obsolete; **Method –** "S" Shred, "B" Burn/Incinerate, Other – list method

Listed by: _____ Date: _____

Authorization for Document Destruction

Project Scientist, COTAR, or Document Owner: _____ Date: _____

BDP Management: _____ Date: _____

BRB/NCI Management: _____ Date: _____

Documentation of Document Destruction

Documents listed above destroyed by: _____ Date: _____

Witness/Verifier (if necessary): _____ Date: _____

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