Frederick National Laboratory for Cancer Research, Frederick, MD

Biopharmaceutical Development Program

Standard Operating Procedure

Title: Management of Project-Related Documentation

SOP Number: 21410

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Approval/Date:

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1.0 Purpose

This Standard Operating Procedure (SOP) describes the steps to follow when internal and external documents are received in the Biopharmaceutical Development Program (BOP).

2.0 Scope

This SOP applies to project-related documents generated internally or received by the BOP from external sources, such as principal investigators. This SOP does not apply to Business Operations, subcontract reporting deliverables, or financial documents. QCTRs are not covered by this procedure but are covered under ***SOP 22907 - Sample Accessioning and Trafficking.***

3.0 Authority and Responsibility

3.1 The Program and Technical Director, BOP, has the authority to define this procedure.

3.2 Upon receipt of hard copy project-related documents, the BDP employee who receives the document provides the document received to Biopharmaceutical Quality Assurance Documentation (BQAD).

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted]

3.3 The Project Scientist is responsible for ensuring that hard copies of project-related documents are forwarded to BQAD for filing and placing electronic copies of project-related documents on the BDP network in the appropriate projects file by project number/name.

3.4 BQAD is responsible for ensuring that forms provided by external sources are maintained and that current revisions are available for BDP use.

3.5 In support of documents received under a subcontract, the Contract Officer's Technical Representative (COTR) is responsible for forwarding received contract-related hard copy documentation to BQAD. Electronic files should be saved on the BDP network in the appropriate project file.

3.6 It is the responsibility of each Supervisor/Manager to train their personnel on this SOP and submit documentation of training to BQA.

3.7 BQA is responsible for quality oversight of this procedure.

4.0 Definitions of Project-Related Documents

4.1 **Historical Documents –** Project-related documents whose origin preceded acceptance of the project by the BDP, that provide the rationale for or information concerning constructs, R&D history, possible product indications, preclinical, and clinical plans, et cetera. This includes background information on the plasmid constructs and other vital project information.

4.2 **Subcontractor Reporting Deliverables –** Progress and Final reporting requirements defined under a subcontract and submitted by the subcontractor as contract deliverables.

4.3 Samples for testing by contract laboratories are submitted to Process Analytics following ***SOP 22907 - Sample Accessioning and Trafficking***. Each request receives a QC Test Request Number. The testing report is stored in the BQA Documentation archive, filed sequentially under the QC Test Request Number.

4.4 **Sponsor Required Forms** (e.g., chain of custody or rapid notification forms) - Completion of these project specific forms are required by the sponsor. The current revision of these forms is provided by the sponsor and maintained both electronically for use by BDP staff and in the project files.

5.0 Procedure

5.1 Receipt of Documents

5.1.1 The document is received at the BDP from an outside source or generated internally.

5.1.2 The recipient of the hard copy document provides the received document to BQAD for the project files. The recipient can recommend where the document should be filed within the project documentation files. Electronic files of a project related document should be saved by the recipient on the BDP network in the appropriate projects file.

5.1.2.1 In the event project required forms are received, a historical copy is maintained in the project files and an electronic copy for use by BDP is maintained in a project specific folder at [redacted].

5.1.3 QC Test Reports are received through a different process. Refer to ***SOP 22907 - Sample Accessioning and Trafficking***.

5.2 Identification and Filing

5.2.1 Once the hard copy document is identified with a specific project, BQAD files the document.

5.2.2 Documents by project may be grouped into individual folders (prepared by BQAD as needed). Some examples are listed below:

- General Project Folder - contains memos, e-mails, correspondence.
- Batch Records and Review Findings
- Master Specifications and Certificates of Analysis
- Development
- Deviation Folder
- Labels
- Project History
- BQA Release
- Stability
- MMIC Inventory
- In-Process Audits
- Distribution Forms

5.2.3 Batch Records from contract manufacturers for specific projects are filed with the project in binders as follows.

- Completed batch records, reviewed by BQA, are filed in blue binders.
- Batch records not reviewed are filed in orange binders.
- Batch records of failed or aborted product runs are placed in red binders.

5.2.4 Regulatory documents are filed with the associated projects.

5.2.5 There is a designated area in BQA for documents received related to contract testing vendors.

5.3 Storage and Archival of Project-Related Documents

5.3.1 Documents for ongoing projects are stored in the BQAD Document Control Room whenever possible.

5.3.2 Overflow documents may be transferred to the off-site archive. See ***SOP 21402 - Document Storage and Archival Process***, for more information.

6.0 References and Related Documents

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

6.2 **SOP 22907** *Sample Accessioning and Trafficking*

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