BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title:	**Management of Project-Related Documentation**
SOP Number:	**21410**
Revision:	**07**

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1. PURPOSE

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

2. SCOPE

This SOP applies to project-related documents generated internally or received by the BDP 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 22009 Quality Control Test Request Scanning, Verification, and Adobe File Archiving.**

3. RESPONSIBILITIES

3.1 Director / Regulatory Compliance

- Defines procedure.

3.2 Biopharmaceutical Development Program (BDP) Employee

- Provides hard copy project related documents upon receipt to Biopharmaceutical Quality Assurance Documentation (BQAD) upon receipt.

3.3 Project Scientist

- Ensures that hard copies of project related documents are forwarded to BQAD to be filed and electronic copies of project related documents to be placed on the BDP network in appropriate project files, according to number/name.

3.4 Contract Officer's Technical Representative (COTR)

- Forwards contract-related hard copy documents to BQAD.

3.5 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight.

3.6 BQAD

- Ensures that forms provided by external sources are maintained and that current revisions are available for BDP use.

4. DEFINITIONS

- **Historical Documents** – Project-related documents whose origin preceded acceptance of the project by the BDP, that provide the rationale for or information concerning constructs,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.
- **Subcontractor Reporting Deliverables** – Progress and Final reporting requirements defined under a subcontract and submitted by the subcontractor as contract deliverables.
- 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.
- **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. 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.

5.1.3 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].

5.1.4 QC Test Reports are received through a different process. Refer to **SOP 22009 Quality Control Test Request Scanning, Verification, and Adobe File Archiving.**

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
- 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, failed or aborted product runs are filed in orange binders.

NOTE: R&D, issued (not used) and / or aborted runs filed before the effective date of Rev 07 of this SOP were previously filed in yellow, red, green or orange folders. After the implementation of Rev 07 these are filed in orange folders.

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. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21402	Document Storage and Archival Process
22009	Quality Control Test Request Scanning, Verification, and Adobe File Archiving
22907	Sample Accessioning and Trafficking