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1.0 Purpose

This Standard Operating Procedure (SOP) describes how a negotiated Quality Agreement is established with an individual subcontractor who will perform GMP/GLP work supporting Biopharmaceutical Development Program (BDP) projects.

2.0 Scope

This procedure applies to outsourced subcontracted activities supporting GMP/GLP projects.

3.0 Authority and Responsibility

3.1 The BDP Director of Regulatory Compliance and the Program and Technical Director are jointly responsible for indicating, “Quality Agreement required,” as appropriate, on each Statement of Work issued for GLP/GMP-related subcontract activities.

3.2 The Leidos Biomedical Research, Inc. Research Subcontracts Representative is responsible for including the Quality Agreement Template with any requests for solicitation when the Statement of Work indicates that a Quality Agreement is required.

3.3 The BDP’s Contracting Officer Technical Representative (COTR) is responsible for:

3.3.1 Assisting in the determination as to whether a Quality Agreement is needed for subcontractor activities.

3.3.2 Assisting in the negotiation of an individualized Quality Agreement with the subcontractor (when needed).

3.3.3 Facilitating technical communication between the subcontractor and appropriate staff of the BDP.

3.4 The BDP Director of Regulatory Compliance, or designee, is responsible for:

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

3.4.1 Determining whether a Quality Agreement is needed for subcontractor activities. See 3.1 above.

3.4.2 Negotiating an individualized Quality Agreement with the subcontractor, when necessary.

3.4.3 Approving the negotiated Quality Agreement.

3.4.4 Distributing the approved, negotiated Quality Agreement to involved parties. (See section 3.5.3).

3.5 The BDP Quality Assurance Department is responsible for:

3.5.1 Assigning a tracking number to customized, vendor-specific Quality Agreements.

3.5.2 Scanning the customized Quality Agreement onto the BDP Public Server.

3.5.3 Alerting appropriate BDP staff to the existence of the Quality Agreement.

3.5.4 Maintaining the original signed Quality Agreement on file.

4.0 Overview of the Process

4.1 The BDP of Leidos Biomedical Research, Inc. manufactures materials for clinical trials. Subcontractors are solicited by the BDP to perform some of the manufacture of these products.

4.2 The BDP is also responsible for the compliance of its selected subcontractors to applicable product and establishment standards as they relate to BDP-specific projects. As a result, auditing, access to the subcontractor's Quality System records, effective communication with the subcontractor, and a clear understanding of expectations, limitations, and responsibilities are critical to assuring appropriate safety, identity, strength, quality, and purity.

4.3 The Quality Agreement is negotiated with each project subcontractor and formalized to establish and document the expectations that the BDP and the subcontractor have for each other when conducting the activities that support BDP projects.

4.3.1 Subcontractors performing GLP/GMP activities in support of BDP projects are provided a standard Quality Agreement Template prior to or at the time a solicitation is initially presented.

4.3.1.1 If a Subcontractor requests the use of their Quality Agreement Template, then both templates should be compared to determine which template will be selected to start negotiations.

4.3.2 The subcontractor may accept the provisions stated in the Quality Agreement Template or negotiate with BDP Quality Assurance to develop a modified Quality Agreement.

4.3.3 The BDP's expectation is that contractors design their systems and conduct activities in compliance with the Good Manufacturing Practice Regulations and Biological Standards appropriate for the manufacture of a clinical drug product, and that communication between the subcontractor and the BDP is timely and effective.

5.0 Procedure

5.1 During the development of a Statement of Work (SOW), the BDP Director of Regulatory Compliance and the Program and Technical Director, with assistance from the COTR, will make a decision regarding the need for a Quality Agreement with the subcontractor.

5.1.1 Work that supports GLP/GMP activities usually requires a Quality Agreement with the subcontractor.

5.2 The Leidos Biomedical Research, Inc. Research Contracts Representative prepares a formal document that describes the proposed work to be performed by the subcontractor. If this work has been identified as requiring a Quality Agreement, the Research Contracts Representative will include the Quality Agreement Template in the formal solicitation to the subcontractor.

5.3 As needed, the Director of Regulatory Compliance, or designee, with assistance from the BDP COTR, will negotiate with the subcontractor to make changes/modifications to the Quality Agreement. Points for negotiation will be based on product impact, stage of product (GLP, GMP), capabilities of the subcontractor, alternate mechanisms that could provide acceptable control, etc. These decisions are documented and approved in a "customized" Quality Agreement with the subcontractor.

5.3.1 Customized Quality Agreements will be traceable to the vendor from a tracking number that will appear in the footer of each page of the Quality Agreement. This tracking number will follow the convention:

5.3.1.1 *Vendor name (or vendor abbreviation)/ revision #(revision date).*

5.4 The BDP Director of Regulatory Compliance, or designee, will arrange to have the customized Quality Agreement signed by the subcontractor's Quality Contact. A signature from the Quality Contact of the BDP and the subcontractor are required to approve the Quality Agreement.

5.5 The original, signed Quality Agreement is forwarded to the BDP Quality Assurance Department.

5.5.1 The document is scanned.

5.5.2 The scanned file is named according to the tracking number at the footer of the document and electronically filed.

5.5.3 The tracking number is documented in the Quality Agreements log

5.5.4 Appropriate BDP/Leidos Biomedical Research, Inc., staff is alerted (e-mail) to the existence of the completed Quality Agreement. Appropriate staff include at a minimum:

5.3.1.1 BDP Director of Regulatory Compliance

5.3.1.2 BDP Program and Technical Director

5.3.1.3 BDP Program Manager

5.3.1.4 BDP COTR

5.3.1.5 Leidos Biomedical Research Contracts Representative

5.3.1.6 BDP Quality Assurance Audit Manager.

5.5.5 The original document is filed.

5.6 **Revising Quality Agreement**

5.6.1 Existing Quality Agreements may be revised at any time by following steps 3.3 through 3.5, above. The tracking number in the document footer must be updated to reflect a new revision level.

5.7 **Record**

5.7.1 Original Quality Agreements are filed in the Quality Assurance Department.

5.7.2 Records are maintained per ***SOP 21407 – Records Retention.***

6.0 References and Related Documents

6.1 Quality Agreement Template – Attachment to the infocard

6.2 Original Quality Agreements are filed in the Quality Assurance Department and electronically

6.3 **SOP 21407 –** *Records Retention*

6.4 **SOP 21109 –** *Supplier Qualification Program*

7.0 Change Summary

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