1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Quality System Requirements for Vendors Manufacturing Investigational Product Policy. The Policy defines the procedures for planning, establishing, and overseeing the requirements and implementation of the vendor and/or company collaborator Quality System to meet all applicable agreements and regulations.

2. Scope

2.1. OSRO in the Center for Cancer Research (CCR), National Cancer Institute (NCI) shall establish and control the policy.

2.2. Investigators, research team members, other departmental personnel, and external NIH collaborators and contractors when they are working on studies conducted under a CCR-held Investigational New Drug application (IND), Investigational Device Exemption (IDE), or supported by a CCR-held Master File under OSRO oversight shall comply with the policy.

2.3. The policy applies to final products for human use, or intermediaries for products for human use for which the CCR is the actual manufacturer, or for which the products are manufactured to CCR specifications. Products that are covered under a quality agreement with NIH manufacturers are outside the scope of this policy; the requirements for vendor qualifications will be covered under the quality agreement with the NIH manufacturers.

2.4. Limitations

2.4.1. The policy applies to agreements governing the supply of products which became effective on or after January 1, 2022.

2.4.2. Personnel are not bound to this policy when working on non-IND or IDE studies and/or no interdepartmental collaboration with OSRO as Sponsor is required.

2.4.3. Nothing in this policy will supersede NCI, National Institutes of Health (NIH) or Health and Human Services (HHS) requirements.

3. Responsibilities

3.1. The Center for Cancer Research Management is committed to providing resources to meet the requirements for implementing a Quality System Requirements for Vendors Manufacturing Investigational Product Policy within OSRO and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding and using the Quality System Requirements for Vendors Manufacturing Investigational Product Policy.

3.3. The OSRO Director is responsible for establishing and maintaining the Quality System Requirements for Vendors Manufacturing Investigational Product Policy.

3.4. OSRO Sponsor and Regulatory Oversight Support (SROS) contractor staff assist OSRO Functional Groups as needed.

4. References

4.1. ICH E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018

4.2. 21 CFR Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General

4.3. 21 CFR Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals

4.4. 102 Audit Policy

5. Definitions

5.1. Refer to the OSRO Lexicon.

5.2. Vendor shall mean vendor and/or company collaborator.

6. Policy

6.1. Vendors who manufacture final product(s) or intermediary product(s) intended for use in a clinical trial conducted in CCR will be required to have a Quality System.

6.2. For every IND/IDE for which OSRO is the Sponsor, an agreement with the vendor will exist and require that

6.2.1. Product(s) will be manufactured under current Good Manufacturing Practices (cGMP) conditions.

6.2.2. Products will be tested under Good Laboratory Practice conditions.

6.2.3. A Certificate of Analysis or Certificate of Conformance will be provided with each product shipment to CCR.

6.3. For products for which the manufacturing process is described in a CCR-held IND/IDE or CCR-managed Master File:

6.3.1. An agreement will exist with each vendor supplying an intermediary or final product as outlined in Section 6.2.

6.3.2. The vendor will provide a copy of its Quality Manual to OSRO.

6.3.3. The vendor will be qualified prior to the IND or IDE submission to the FDA.

6.3.3.1. The qualification process may be handled by OSRO, the Office of Research Support and Compliance (ORSC) or other NIH entity.

6.3.4. The vendor will share all processes and procedures related to product manufacture with OSRO prior to manufacturing the product lots intended for the clinical trial.

6.3.5. The vendor will not change any of the processes and procedures related to product manufacturing without OSRO approval.

6.3.6. The vendor will provide a Quality Summary Report at least every 3 months during the vendor and/or company collaborator's support of the clinical trial.

6.3.7. At the request of OSRO, the vendor will provide a complete set of manufacturing batch records, Quality Control test records and relevant SOPs for the supplied product lots.

6.3.8. If deficiencies are found in supplied records, then:

6.3.8.1. OSRO will determine whether the product can be used.

6.3.8.2. OSRO may audit the vendor.

6.3.8.3. A written response addressing the deficiencies will be required from the audited vendor within 30 days of audit report receipt.

6.3.8.4. Responses will include a statement of the corrective action(s) completed or planned and the date by which the corrective action(s) was or will be completed.

6.3.8.5. Responses shall be reviewed for acceptance by OSRO.

6.3.8.6. OSRO shall communicate all or in part the acceptance or rejection of the response(s) to the vendor in writing.

6.3.8.7. Verification that corrective actions have been implemented shall be documented by OSRO after one or more of the following:

6.3.8.7.1. Next routine audit,

6.3.8.7.2. Additional follow-up measures depending on the severity of the issues (i.e., requiring further evidence of corrective action, moving up the next scheduled audit date, etc.).

6.3.9. OSRO will audit the vendor according to reference 4.4.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	04JUN2021	New Document
2	04MAY2023	Biennial Review Step 2.3 – added Step 2.4.1 – revised Step 3.4 – added Section 4 – added hyperlinks Section 6.2 – updated Step 6.3.1 – added Step 6.3.2.1 – removed "as determined by ORSC" Step 6.4 – removed