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1.0 Purpose

This SOP describes the policy for visitors to enter facilities and areas in the Biopharmaceutical Development Program (BDP).

2.0 Scope

This SOP applies to the Biopharmaceutical Development Program (BDP) administrative and other personnel who arrange for visitors to tour the GMP facilities.

This SOP does not apply to FME and service personnel who are going to provide service or maintenance to the BDP, which is covered in ***SOP 11121 - Documentation of Maintenance Work in cGMP Pharmaceutical Production Facilities***, nor to inspections by the FDA or other regulatory agencies, which is covered in ***SOP 24301 - Inspections by Regulatory Agencies***.

3.0 Authority and Responsibility

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

3.2 The Director, Biopharmaceutical Quality Assurance (BQA), or designee, is responsible for providing quality oversight for this procedure.

3.3 It is the responsibility of the tour lead to ensure that this procedure and any other applicable SOPs are followed, depending on the context of the tour and the areas being toured.

3.4 The BDP Program Coordinator (or designee) is responsible for processing BDP visitor requests for non-government employees. If a tour for government employees is requested by the Director of the NCI/BRB, a visitor's request is not required per NCI Management Operations & Support Branch (MOSB).

4.0 Procedure

4.1 Frederick National Laboratory for Cancer Research (FNLCR) and/or BDP management has the authority and responsibility to deny entrance to any group or individual that may compromise compliance with cGMP or other Federal, State, NCI, or BDP regulation or policy. This is dependent on the nature of the activities scheduled to occur in BDP facilities at the time of the tour.

4.2 Persons who are not employees of the BDP, or one of its contractors, are considered visitors. Visitors who are not employees of Leidos Biomedical Research, Inc., are required to report to Protective Services to obtain a visitor's pass.

4.3 EHS Procedure EHS-PS-2, Access and Identification for Visitors to NCI at Frederick Facilities will be strictly followed. (The current version of this procedure is available online or from EHS upon request.) The BDP Program Coordinator (or designee) will process visitor requests.

4.4 Visitors wishing to enter the GMP facilities must contact the Director's office of the GMP Production Facility to arrange for the feasibility and logistics of a tour. The Director's office will coordinate with BQA, the BDP Program Coordinator, and the NCI Project Officer to obtain approval to tour the buildings. It is the responsibility of the Program and Technical Director of the GMP facility, or designee, to manage the tour of the visitors through the GMP facilities.

4.5 Visitors may not enter areas where active cGMP processing is occurring unless they have successfully completed the gowning certification specific to the area.

4.6 A cGMP-trained BDP employee must lead any tour of cGMP-compliant areas.

4.7 All SOPs relevant to general cGMP operations and/or the specific area(s) being toured must be followed.

4.8 Any exceptions to this procedure or any other relevant procedures for the area(s) being toured require the written permission of the area head, or designee, and the Director of Quality Assurance, or designee, prior to the tour/visit.

5.0 Documentation

5.1 BDP Administrative Staff will be responsible for the adherence to the policies specified in EHS Procedure EHS-PS-2, Access and Identification for Visitors to NCI at Frederick Facilities.

Form 21001-01 can be used to provide the requested visitor information needed for the BDP Program Coordinator (or designee) to complete the on-line FNLCR Report of Visitor Form. Alternatively, this information can be provided to the **BDP Program Coordinator (or designee) in an email.**

6.0 References and Related Documents

6.1 **SOP 11121** *Documentation of Maintenance Work in cGMP Pharmaceutical Production Facilities*

6.2 **SOP 24301** *Inspections by Regulatory Agencies*

6.3 EHS Procedure EHS-PS-2, Access and Identification for Visitors to NCI at Frederick Facilities.

6.4 **Form 21001-01** *BDP Visitor Registration*

7.0 Change Summary