

**SOP Title: Policy for Visitors to the GMP Facilities**

**SOP Number: 21001**

**Revision: 07**

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#### 1. PURPOSE

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

#### 2. 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. BACKGROUND

Tours for non- government employees are processed by the BDP. 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. RESPONSIBILITIES

##### 4.1 Program and Technical Director

- Defines this procedure.

##### 4.2 Director of Regulatory Compliance

- Provides quality oversight to this procedure.



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### 4.3 Tour Lead

- Ensures that this SOP and any other applicable SOP are followed depending on the context of the tour and the areas being toured.

### 4.4 BDP Program Coordinator / Program Manager

- Processes BDP visitor requests for non-government employees.

## 5. SAFETY

Access and Identification policy on the NCI at Frederick website (EHS section) for Visitors to NCI at Frederick Facilities is strictly followed. (The current version of this procedure is available online or from EHS upon request.)

## 6. PROCEDURE

- 6.1 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.
- 6.2 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.
- 6.3 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 QA, 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.
- 6.4 Visitors may not enter areas where active cGMP processing is occurring unless they have successfully completed the gowning certification specific to the area.
- 6.5 A cGMP-trained BDP employee must lead any tour of cGMP-compliant areas.
- 6.6 All SOPs relevant to general cGMP operations and/or the specific area(s) being toured must be followed.
- 6.7 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 Regulatory Compliance, or designee, prior to the tour/visit.



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### 7. DOCUMENTATION AND RECORDS

- 7.1 BDP Administrative Staff adhere to the policies specified for Access and Identification for Visitors to NCI at Frederick Facilities. The current guidelines are listed on the NCI Frederick website.
- 7.2 **Form 21001-01** can be used to provide the requested visitor information for EHS. Alternatively, this information can be provided to the BDP Program Coordinator / Manager in an email.

### 8. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
11121	Documentation of Maintenance Work in cGMP Pharmaceutical Production Facilities
24301	Inspections by Regulatory Agencies
21001-01	BDP Visitor Registration
N/A	Access and Identification for Visitors to NCI at Frederick Facilities, current version on the NCI at Frederick website (EHS section)