



# BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

**SOP Title:** Documentation of Maintenance Work in cGMP Pharmaceutical Production Facilities  
**SOP Number:** 11121  
**Revision:** 08

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### 1. PURPOSE

This SOP describes the method to capture and document work performed in facilities associated with the Biopharmaceutical Development Program (BDP).

### 2. SCOPE

This procedure applies to personnel who perform, coordinate, and review maintenance work in BDP cGMP Facilities.

**Overview:** In typical situations, repair/maintenance activities are planned. During the planning process, issues of change control are addressed and, when needed, approved. Work is performed by FME staff or by contracted vendors. Maintenance/repair technicians document work, especially as it documents potential changes.

In emergency situations, FME staff responds to stabilize the emergency. At the earliest opportunity, the BDP Facility Manager and BQA Engineering Manager or designee are updated on the situation and participate in planning any needed additional actions created by the emergency (for example, failure notification, change control issues, requalification, revalidations, etc.). Actions are documented and reviewed by the BDP Facility Manager and BQA Engineering. Documentation becomes part of the Engineering Event or equipment/facility's MEF.

### 3. RESPONSIBILITIES

#### 3.1 Biopharmaceutical Quality Assurance Engineering, (BQAE)

- Defines the procedure.
- Reviews maintenance/repair paperwork from outside vendors and work completed as planned or appropriate for the situation.
- Determines if change control is necessary for requested repairs to validated facilities and equipment before the work order is executed.

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- Assists BDP Facility Manager with decisions regarding changes to facilities and equipment in emergency situations.
- Forwards any paperwork to BQA Documentation for filing.

### 3.2 FME

- Notifies the BDP Facility Manager and/or BQAE prior to commencement of any activities.
- Follows facility gowning and flow SOPs as applicable.
- Completes maintenance or repair activities in a manner that does not create a change in the construction or operation of the facility or equipment.
- In an emergency, when possible, obtains approval for any repair or maintenance that may cause a change to a validated facility or equipment.
- Documents work in the equipment log per **SOP 21531**.
- Cleans up the work area.
- Communicates with the Facility Manager regarding the nature of the repair to ensure no undocumented changes are made and provide needed updates.

### 3.3 The BDP Facility Manager, or designee

- Assists FME staff and vendors to contact appropriate BDP personnel within the areas where they will be performing work.
- Notifies BQAE of all emergencies.
- Reviews the physical work done in a timely manner in cases where documentation/testing alone do not provide all details. (Will typically apply to utility systems.) .

### 3.4 BQA

- Provides quality oversight.

## 4. PROCEDURE

### 4.1 Notification/Scheduling of Work

- 4.1.1 **Routine:** Notification of pending schedules for work described on Maintenance Service Requests (MSR) will be coordinated through the BDP Facility Manager, or designee, prior to work beginning. The BDP Facility Manager will address special conditions, safety tag clearances, authorization numbers, et cetera.

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4.1.2 **Emergency:** During business hours, the operator of the validated utility or equipment will place a trouble call to the BDP Facility Manager, or designee, by phone or by email. Provide the Facility Manager with the MEF#, NIH#, and location of the emergency. Once the BDP Facility Manager, or designee, has been informed, they will notify the FME Trouble Desk.

**NOTE:** FME will provide after-hours response to utility and equipment issues related to the BDP on a case-by-case basis and depending on the severity of the situation, by using alarm notification, remote access, or the ATRF Security Personnel to monitor and report anomalies to the BDP Facility Manager or designee. The BDP Facility Manager will work with the FME On-Call person to assess the situation and determine what level of FME response will be performed after- hours.

4.2 The BDP Facility Manager must notify BQAE of all emergencies.

4.3 Repairs do not need BQAE approval unless they require shutdown of the utility/system or supporting utilities/systems or involve replacement parts that are not the same as what is installed or involve other modifications.

4.4 Performing Planned Repair/Maintenance Work

4.4.1 Vendor representatives or outside service personnel must check in at the ATRF security desk.

4.4.2 The BDP Facility Manager or designee will assist FME or the vendor representative in locating the Area Contact for the work and confirming that the area/equipment is available for the repair/ maintenance work to be performed.

4.5 Managing Repairs and Controlling Change

4.5.1 When possible, maintenance and repairs should be executed in a manner that does not create a change in the construction or operation of the facility or equipment (or associated facilities or equipment). "Like-for-like" replacement is not considered a change.

4.5.1.1 If a repair/maintenance activity CANNOT be completed without a change to the facility or equipment, approval must be obtained from the BDP Facility Manager or designee.

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- 4.5.1.2 BDP staff will initiate an Engineering Event as per **SOP 21526 Engineering Event Management** to document the change control process when required.
- 4.5.1.3 FME or the vendor representative will document the repair/maintenance activity on the work order and/or the equipment logbook to the extent that any change or like for like replacement made to the equipment or facility is evident.
- 4.5.1.4 If any newly installed component from the service/repair is different from the manufacturer's original component, the BDP Facility Manager, or designee, must be contacted before the work is performed to determine if a change control is required.
- 4.5.1.5 If a change was made, a short description of the change will be included. The vendor representative will leave a copy of the repair order that should be first reviewed by the equipment owner and then given to BQAE.
- 4.5.2 FME or the vendor representative will clean the work area.
- 4.6 BQAE will determine the return to service activities based on the repair.
- 4.7 After hours alarms may be noted by BDP staff who get SCADA notifications or by ATRF Security Personnel contacting the BDP Facility Manager or FME directly.
  - 4.7.1 Alarms are assessed for criticality and unless critical, work is delayed until the next business day.
  - 4.7.2 FME will provide after-hours response by on call staff to critical utility and equipment issues related to the BDP.
- 4.8 Equipment or utilities, which have been validated and considered to be CGMP, will require BQAE approval according to change control standard operating procedures.

## 5. DOCUMENTATION AND RECORDS

- 5.1 Vendor Rendered Services
  - 5.1.1 The vendor contact shall obtain all documentation related to the work performed from the vendor. It is acceptable for documents to be mailed or emailed later; however, it is the responsibility of the equipment owner to ensure that required documents are received.



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- 5.1.2 Equipment owner ensures logbook entries are made per **SOP 21531 Equipment Logs** including any relevant work order numbers.
- 5.1.3 Documentation should be provided to the BDP Facility Manager or the Quality Engineering and Validation Manager for review to verify work was performed in compliance with governing SOPs.
- 5.1.4 Documentation will then route for filing in the MEF.
- 5.2 For FME Rendered Services
  - 5.2.1 Make logbook entries per **SOP 21531 Equipment Logs** including any relevant work order numbers.
  - 5.2.2 FME also tracks work and issues work order numbers for both preventive maintenance (PM) and trouble calls via their Maximo system.

### 6. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21526	Engineering Event Management
21531	Equipment Logs