# BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

| | |
|---|---|
| **SOP Title:** | **Walk-Through Inspections** |
| **SOP Number:** | **21925** |
| **Revision:** | **01** |

## TABLE OF CONTENTS


1. PURPOSE ..... 1
2. SCOPE ..... 1
3. BACKGROUND ..... 1
4. RESPONSIBILITIES ..... 1
5. DEFINITIONS ..... 2
6. PROCEDURE ..... 3
7. DOCUMENTATION AND RECORDS ..... 4
8. REFERENCES AND RELATED DOCUMENTS ..... 5


## 1. PURPOSE

This SOP outlines the procedure for scheduling, performing, and reporting the results of walk-through inspections of the Biopharmaceutical Development Program (BDP) areas.

## 2. SCOPE

This SOP applies to the BDP personnel responsible for the facilities management, inventory control, manufacture, and testing of material for clinical trials.

## 3. BACKGROUND

As part of the overall audit program at the BDP, Quality Assurance (QA) conducts walk-through inspections to ensure that the areas, processes, systems, and procedures comply with CGMP regulations (21 CFR 211, 21 CFR 610, 21 CFR 1271) as appropriate for the manufacturing and testing of Phase I/II clinical products.

Inspections are performed on areas involved in the production and testing of products as well as those areas that have a supportive function [Materials Management, Inventory Control (MMIC), Process Analytics/Quality Control (PA/QC), Sterilization, etc.].

QA conducts scheduled inspections. Inspections may involve a single auditor or group of auditors who will audit a predefined area by touring the area of inspection.

## 4. RESPONSIBILITIES

### 4.1 Director Regulatory Compliance

- Defines the overall audit program.

### 4.2 QA Management

- Schedules the inspections.

- Defines the areas and the frequency of inspections.
- Alerts BDP Management of any observations or findings that could possibly impact product safety, identity, strength, quality, or purity.
- Trends observations and findings

4.3 QA or Other Trained Auditor

- Conducts inspections.
- Identifies observations and findings.
- Completes the checklist and reports in the eQMS.
- Reports observations and findings
- Assigns Action Items based on responses.
- Follow-up and closeout identified corrective actions.

4.4 Auditee Management (Area Owner or Audit Contact)

- Reviews the audit report.
- Responds to observations and findings with recommended Action Items
- Completes Action Items
- As needed, implements corrective and preventative actions (CAPA), documenting CAPA activities, and updating QA as to CAPA and related progress.

## 5. DEFINITIONS

- **Observation Rating** – Observations are given a rating of Critical, Major, Minor, Recommendation, or Comment. See **SOP 21101 – Internal CGMP Compliance Auditing** for definitions of Critical, Major, and Minor ratings.
    - **Recommendation** – Used to capture ideas for improvements in the future and do not require any actions to be taken for audit closure.
    - **Comment** – Used for observations, that after discussion, was determined to not be a finding.
- **Containment/Correction** – An action taken to immediately control or correct a detected deviation or issue. These items are identified on the Immediate Actions tab in the eQMS.
- **Corrective Actions** – An action that is performed to eliminate the root cause of a deviation, issue, or undesirable situation to prevent its recurrence.
- **Corrective and Preventative Actions (CAPA)** – A quality system that includes a structured approach to an investigation to determine the root cause of a deviation and implements corrective and/or preventive action.

- **Walk-Throughs** – An informal walk through of an area designed to assess the compliance status at a specific moment in time. Walk-throughs provide a BQA presence to give other personnel an opportunity to ask compliance-related questions and discuss ideas and issues in an informal setting. Significant non-compliant observations are brought to the attention of the area management outlining the non-compliance and requesting corrective action. These are relayed through observations and action items in eQMS as appropriate. Minor observations are discussed with relevant personnel during the walk-through. These audits allow for a snapshot type check on the compliance level of any given area.

## 6. PROCEDURE

6.1 Following required gowning practices, tour the selected operational areas of the BDP with the designated area personnel as available. Areas include:

- Buffer Prep
- Fermentation and Cell Banking
- Purification
- Cell Therapy
- Virus Production
- Fill / Finish
- Quality Control/Accessioning
  - QC Microbiology
  - QC Raw Material Sampling
- Freezer Farm and MMIC
- CUP & Tech Spaces

6.2 Use the audit checklist, as needed, to aid in the review of the areas.

6.3 Should operations be dynamic in the area, observe personnel practices in these areas.

6.4 Observe the condition of the building and equipment being used in the area.

Random sample equipment to confirm calibration dates found on the equipment matches the calibration documentation.

6.5 Review a random selection of documentation (logbooks, lab notebooks, cleaning logs, etc.) and review the degree of completeness, accuracy, and good documentation practices.

6.6 Review a random selection of reagent/raw material expiration dates to confirm materials remain within expiry.

If materials are outside of their expiry, confirm that they are designated for R&D use per **SOP 20401 – Handling Rejected and Expired Materials.**

6.7 Discuss observations with relevant personnel. Report significant concerns to the area and QA management.

6.8 Record the date of the walk-through inspection, the area observed, and the name of the auditor in the eQMS Audit Workspace

## 7. DOCUMENTATION AND RECORDS

7.1 Complete the audit checklist within the eQMS for any applicable categories.

The checklist includes the following categories for inspection.

- Facility
- Warehouse and Storage Areas
- Raw Materials
- GMP Facility
- Safety
- Equipment
- SOP Manual
- Documents and Records
- Personnel
- Training

7.2 Final audit and any supporting documents are records are maintained in the eQMS using the Audit Workspace.

7.3 Observations and responses are documented with action items as appropriate.

Action Items will be linked to the audit InfoCard.

7.4 The final report is sent to management and any attendees of the inspection for completion of responses to observations.

Responses are expected within 30 days of the final report date.

7.5 Final report responses are reviewed by QA.

To signify acceptance of the responses, QA digitally signs the PDF and attaches the file to the audit InfoCard.

## 8. REFERENCES AND RELATED DOCUMENTS

| Document Number | Title |
|---|---|
| 10301 | Pest Control for the Biopharmaceutical Development Program |
| 12188 | Labeling and Storage of CGMP Raw Materials, Samples, and Equipment |
| 14150 | Labeling of cGMP Purification Equipment for Cleaning Status |
| 20302 | Receipt and Inspection of Materials |
| 20401 | Handling Rejected and Expired Materials |
| 21101 | Internal CGMP Compliance Auditing |
| 21104 | Pre-Production Clearance |
| 21409 | Good Documentation Practices |
| 21508 | Equipment Calibration Program |
| 21520 | Equipment Management and Control |
| 21531 | Equipment Logs |
| 21554 | GMP Area Status Management |
| 21706 | Personnel Health Restrictions in Product-Contact Environments |
| 21907 | Access Control for BDP Areas [redacted] |
| 21CFR211.42 | Design and construction features. |
| 21CFR211.44 | Lighting. |
| 21CFR211.46 | Ventilation, air filtration, air heating and cooling. |
| 21CFR211.50 | Sewage and refuse. |
| 21CFR211.56 | Sanitation. |
| 21CFR211.58 | Maintenance. |
| 21CFR211.67 | Equipment cleaning and maintenance. |