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1.0 Purpose

This procedure describes the performance and documentation of routine laboratory/plant duties in the production areas for the Biopharmaceutical Development Program (BDP).

2.0 Scope

This SOP applies to routine duties for personnel working in all GMP areas of the ATRF.

3.0 Authority and Responsibility

3.1 The Technical Operations Lead for manufacturing (BDP) has the authority to define this procedure.

3.2 The Technical Operations Managers (BDP) is responsible for training personnel in this procedure and for documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 BDP Production personnel are responsible for the implementation of this procedure.

3.4 The Area Manager/Supervisor or designated alternate is responsible for designing data collection forms, reviewing the documentation recorded, and responding to any comments or items outside of the established limits for their respective areas.

3.5 BQA is responsible for quality oversight of this procedure.

4.0 General Instructions

4.1 Complete checklists for each production area by writing the requested information in the appropriate spaces when work is performed at the specified interval.

4.2 Return forms to a designated place in each area at the end of each shift.

4.3 At the end of the week, or as indicated, return the completed forms to the Area Supervisor or designated alternate.

4.4 Notify the Area Supervisor when equipment deficiencies are found (leaks, noises, etc.) or out of parameters stated on the RPD Form or other governing SOPs.

4.5 If an area surface finish is observed to be damaged (e.g., dent in wall) such that it could potentially compromise the integrity of a GMP area that is in active use, the damaged area should be temporarily repaired using a suitable patching material (e.g., released adhesive tape) while processing is underway, and repair should be made at the earliest available opportunity.

4.6 Note any problems and corrective action taken in the comment section of the form.

4.7 Any inactive manufacturing area does not require completion of these forms. Inactive areas should be indicated at either the entrance to the manufacturing space or at the entrance to the suite. Portable eyewashes may be placarded as inactive until area is in service. Charts may continue to be submitted to BQAD for any operational equipment within the area.

5.0 Documentation

5.1 Each area shall perform and document routine lab/plant duties on the appropriate form for the area.

5.2 The Area Supervisor or designated alternate shall review the completed forms and submit them to BQA Documentation.

6.0 References and Related Documents

SOP 19102	Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, Centrifuges, and Biovest Bioreactors
SOP 19401	Use of Flexible Tubing at WFI Sites
SOP 19407	Flow of Personnel, Materials, Equipment, and Waste in the CGMP Areas of the ATRF
SOP 19500	Operation and Maintenance of the BMT Steam Sterilizers
SOP 19503	Flow of Personnel, Materials, Equipment, and Waste in B2310 of the ATRF
SOP 19506	Flow of Personnel, Materials, Equipment, and Waste for B3 GMP Areas of the ATRF
SOP 21507	Monitoring Temperatures with Chart Recorders
SOP 21531	Equipment/Facility Logs
SOP 21533	Policies for Operation, Cleaning, and Routine Maintenance of Controlled Temperature Equipment
Form 12113-01	Upstream Production Daily / Weekly Plant and Laboratory Duties Checklist
Form 12113-02	Upstream Production Monthly Plant and Laboratory Duties Checklist
Form 12113-03	LPS Process Analytics Daily / Weekly Routine Plant and Laboratory Duties Checklist
Form 12113-04	LPS Process Analytics Monthly Plant and Laboratory Duties Checklist

Form 12113-05 Purification Daily / Weekly Routine Plant and Laboratory Duties Checklist

Form 12113-06 Purification Monthly Plant and Laboratory Duties Checklist

Form 12113-07 Virus Production Facility Daily / Weekly Plant and Lab Duties Checklist

Form 12113-08 Virus Production Facility Monthly Laboratory Duties Checklist

Form 12113-09 Fill/Finish Daily / Weekly Routine Plant and Laboratory Duties Checklist

Form 12113-10 Fill-Finish Areas Monthly Laboratory Duties Checklist

Form 12113-11 B2 Cell Therapy Area Daily / Weekly Plant and Laboratory Duties Checklist

Form 12113-12 B2 Cell Therapy Area Monthly Laboratory Duties Checklist

Form 12113-13 B3 Cell Therapy Area Daily / Weekly Plant and Laboratory Duties Checklist

Form 12113-14 B3 Cell Therapy Area Monthly Laboratory Duties Checklist

7.0 Change Summary