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## 1.0 Purpose

This SOP provides guidelines for the use of water in production processes in the Biopharmaceutical Development Program (BDP).

## 2.0 Scope

This procedure applies to BDP production staff that use water in production processes.

## 3.0 Authority and Responsibility

3.1 The Director, Late Process Sciences (LPS), Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

3.2 The Director, LPS, BDP is responsible for ensuring that manufacturing staff is trained in this procedure and for documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 Manufacturing staff is responsible for adhering to this procedure.

3.4 BQA is responsible for quality oversight of this procedure.

## 4.0 Guidelines

4.1 When drawing water for use or sampling, latex or nitrile gloves must be worn and operator must be gowned appropriately per the area classification.

4.2 Water drawn in advance of its use, for any purpose, must be stored in a container compatible with the temperature of the water being drawn.

4.2.1 The container must either be a released item obtained from Materials Management and Inventory Control or a piece of process equipment with an assigned equipment ID and accompanying usage log per **SOP 21531, *Equipment/Facility Logs***.

4.3 Water drawn in advance by aseptic 0.2 µ filtration into a closed sterile container, such as a sterile flex-bag with 0.2 µ filter attached, may be stored for up to one year prior to use.

4.4 Water drawn in advance by non-aseptic means may be stored for no more than one day prior to use.

4.5 Water that is not drawn in the area in which it is to be used must be sealed in a container per step 5.1.2 prior to removal from the area in which it was drawn. Once sealed, it must remain sealed during transport to the area in which it is to be used. The container or system must remain sealed until use.

## 5.0 Definitions

5.1 The following definitions apply throughout this text.

5.1.1 **Clinical Grade Product –** a product whose intended end use is in support of a Phase I, Phase II or Phase III clinical trial.

5.1.2 **Closed Or Sealed System Or Container –** a container (carboy, flexboy, etc.) or system (container with peripherals, interconnected multiple containers, etc.) which is configured to avoid incidental contamination from the environment exterior to the container or system. Such configurations may employ filters (≤ 0.2 micron), gaskets, etc.

5.1.3 **Downstream Purification –** the final steps of the purification process.

5.1.4 **Purified Water –** water from a validated system that meets the specifications defined for purified water as per the current United States Pharmacopeia (USP).

5.1.5 **Upstream Purification –** the initial steps of the purification process.

5.1.6 **Water For Injection (WFI) –** water from a validated system that meets the specifications defined for WFI as per the current United States Pharmacopeia (USP).

5.1.7 Subsequent references to the definition specified in 5.1.4 and appended with the phrase "or better" denotes that water meeting the specification(s) given in the definition(s) following the reference (5.1.6) may be used as well.

5.2 Water used in the initial cleaning and rinsing of equipment used in the manufacture of non-clinical products must be purified water or better.

5.3 Water used in the final rinse after cleaning or manufacture of non-clinical products must be purified water or better.

5.4 Water used in the cleaning and rinsing of equipment used in the manufacture of clinical grade products must be purified water or better, excluding the final equipment rinse.

5.5 Water used for final rinses of all equipment used in the manufacture of clinical grade products must be WFI.

5.5.1 If the water is to be used in an unclassified area, it must be kept in a clean closed system.

5.6 Water used in the manufacture of clinical grade products must be WFI.

5.6.1 If the water is to be used in an unclassified area, it must be kept in a clean closed system.

## 6.0 Documentation

6.1 Documentation of this procedure will be recorded on the batch record(s) and/or other appropriate forms that document the process in which the water is used.

6.1.1 Record the source, type of water, date drawn, expiration date, and process on the containers into which the water is drawn and into the documents that record the uses of this water.

## 7.0 References and Related Documents

**SOP 21531** *Equipment/Facility Logs*

## 8.0 Change Summary

[redacted]