YR = Present year

Scope:

This procedure defines the responsibilities and main activities for the Maintenance department of the Pharma A/S production plant in Lyngby, Denmark.

Summary

The Maintenance department has the responsibilities of minor repairs and maintenance of the Pharma A/S production and utilities units.

The Maintenance department operates the plants utility systems.

Maintenance executes and maintain the plants calibration program for relevant instruments and systems. The calibration program is based on Risk Management principles.

General maintenance

The Maintenance department does repair and preventive maintenance of equipment and systems registered in the maintenance data file. Equipment or systems not included in the maintenance data file must be serviced from outside companies typically the supplier of the equipment.

Utilities

The Maintenance department runs the equipment and utility systems of the Pharma A/S site to supply: High pressure steam, cooling water, pressurized air, sterile air for the fermentation and the water system including; Tap water, demineralized water and Purified Water.

Calibration program

All instruments and relevant systems have been evaluated of their calibration frequency according to a Risk Management principle for impact on final product quality. The Risk Management principles are based on the production needs, the maintenance departments knowledge and experience about the equipment and the specific suppliers recommendations.

Based on the Risk management the instruments and systems have been divided into 3 categories:

Critical. These equipment and systems have direct impact on product quality and must have a calibration frequency and a preventive maintenance program corresponding to the specific risk assessment.

Indirect critical: These equipment and systems do not have direct impact on product quality and should have a calibration frequency and a preventive maintenance program corresponding to the specific risk assessment.

Non critical: These equipment and systems do not have any impact on product quality and should have a calibration frequency according to the manufacturers recommendation.

Calibration records for all relevant components including their type of criticality, calibration frequency and calibration procedure, are maintained in the Maintenances deps preventive data management system.

Any deviation from a specified calibration result must be registered as a CAPA register.

Responsibilities:

This document: Maintenance Engineer
Calibration program: Maintenance Engineer

Change Log

Version	Description	Initials	Date
1	This is first version	Maint Eng	01.05.(YR-1)
2	Implementation of calibration program	Maint Eng	01.07.(YR-1)