Frederick National Laboratory for Cancer Research, Frederick, MD

Biopharmaceutical Development Program

Standard Operating Procedure

Title: Calibration of Differential Pressure Gauges

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Table of Contents

1.0 Purpose
2.0 Scope
3.0 Authority and Responsibility
4.0 Test Apparatus
5.0 Test Setpoints
6.0 Procedure
7.0 Frequency
8.0 Documentation
9.0 Definitions
10.0 References and Related Documents

1.0 Purpose

This SOP describes the calibration of differential pressure gauges for the Biopharmaceutical Development Program (BDP).

2.0 Scope

This document covers the testing of "differential pressure" type gauges by in-house or contractor personnel. In the [redacted], most differential pressure is measured by digital devices. Calibration is then reviewed per ***SOP 21523 – Calibration Data Review***.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

3.0 Authority and Responsibility

3.1 The Director, Biopharmaceutical Quality Assurance (BQA), BDP, has the authority to define this procedure.

3.2 BQA Engineering is responsible for implementing or designating implementation of this procedure and for maintenance of equipment records.

3.3 The individual performing this work is responsible for following this procedure and completing the appropriate documentation.

3.4 BQA is responsible for quality oversight of this procedure (***SOP 21101 - Internal CGMP Compliance Auditing***).

4.0 Test Apparatus

4.1 Low pressure test standard**.**

4.2 Plumbing pieces (tubing, adapter, and connectors)

5.0 Test Setpoints

5.1 The level of calibration of the device determines test setpoints. The Calibration Master and History Records in The Blue Mountain Regulatory Asset Manager (BMRAM) will indicate the level of calibration. The calibration range and tolerance are listed in BMRAM; refer to manufacturer's literature or manual for any specifics for the test procedure. Specific requirements from the manufacturer may then be placed in BMRAM. Refer to the Equipment Calibration Procedure, ***SOP 21508 - Equipment Calibration Program***, for the appropriate test setpoints.

5.2 Where not specified by the manufacturer, test setpoints shall follow the guidance of ***SOP 21508 - Equipment Calibration Program*** to ensure that the entire calibrated range is represented. Critical devices should use five (5) measurements. All differential pressure devices used to monitor GMP areas are considered critical unless otherwise noted in BMRAM. Check instruments in ascending and descending setpoint order. This means that critical instruments will have at least ten (10) associated measurements.

6.0 Procedure

6.1 Gather together the test apparatus.

6.2 Locate the device to be tested and expose the pressure connections. Whenever possible, devices shall be tested in the position and at the location where they are used.

6.3 If using an external pressure source, a source other than the standard, connect the pressure source to a "T." To the other ends of the "T," connect the "high" side of the Standard and the Instrument. Make sure that the tubing from the Standard is the same length as the tubing from the Instrument or connect standard and UUT with equal length tubing with connections High-High and Low-Low.

6.4 Using the pressure source, apply pressure or vacuum slowly.

6.5 Record the pressure of the standard for "As-Found for Standard" and the temperature of the instrument for "As-Found for Instrument" in the Calibration History.

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6.6 Repeat Step 6.5 for the required test setpoints. Refer to Section 5.0 of this procedure.

6.7 If the device requiring calibration is within the calibration tolerances at all setpoints As-found, as determined per ***SOP 21508 - Equipment Calibration Program***, it is considered to be in calibration. If the instrument is in calibration, adjustment may still be required depending on the degree of drift per ***SOP 21508***. If adjustment is not required, record the "As-Found" values for the corresponding "As-Left" values, and proceed to Step 6.10. If the instrument is not in calibration or needs adjustment, proceed to Step 6.8.

6.8 Determine from the manufacturer's manual if the instrument requiring calibration can be adjusted. If the instrument can be adjusted, proceed to Step 6.9. If it cannot be adjusted, seek assistance from the BDP Process Engineer. The BDP Process Engineer shall assign disposition of these instruments on an individual basis.

6.9 Adjust the instrument requiring calibration per the manufacturer's directions and repeat Steps 6.4 through 6.6. Record the standard and instrument values for "As-Left" in the Calibration History. If after repeating this Step several times, the operator is still unable to achieve calibration, seek assistance from the BDP Process Engineer who will assign disposition of these instruments on an individual basis.

6.10 Attach the appropriate level of calibration sticker to the instrument in a visible place (reference ***SOP 21508 - Equipment Calibration Program***).

7.0 Frequency

7.1 All pressure-measuring instruments requiring calibration will be calibrated per intervals established per ***SOP 21508 - Equipment Calibration Program***. Default intervals are annually but may be shortened or extended based on performance and criticality.

8.0 Documentation

8.1 The individual performing this procedure shall record pertinent information in the Electronic Calibration History per ***SOP 21555 – Use and Management of Blue Mountain Regulatory Asset Manager***. Include service information, including the vendor's field service report, if applicable, with the Equipment Calibration Record.

8.2 The data file should be kept for a period of five years after the instrument is removed from service. Data in the file need not be maintained for more than ten years after the recording date.

9.0 Definitions

9.1 For calibration definitions, see ***SOP 21508 - Equipment Calibration Program***.

10.0 References and Related Documents

10.1 **SOP 21101** *Internal CGMP Compliance Auditing*

10.2 **SOP 21508** *Equipment Calibration Program*

10.3 **SOP 21523** *Calibration Data Review*

10.4 **SOP 21555** *Use and Management of Blue Mountain Regulatory Asset Manager*

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