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1.0 Purpose

This Standard Operating Procedure (SOP) describes the procedure for calibration of pressure-measuring devices for the Biopharmaceutical Development Program (BDP).

2.0 Scope

This document covers pressure-measuring devices used by the BDP in the Current Good Manufacturing Practice (CGMP) facilities and calibrated "on-site." This procedure is to be performed by Facilities Maintenance and Engineering (FME) calibration staff or calibration contractors for the BDP. Calibration is then reviewed per ***SOP 21523 – Calibration Data Review***.

3.0 Authority and Responsibility

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

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

3.3 The individual performing the 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 Pressure test standard

4.2 Pressure Test Station

4.3 Plumbing pieces (tees, adapters, and nipples)

4.4 Teflon® Tape

4.5 Wrenches

5.0 Test Setpoints

5.1 The level of calibration of the device determines test setpoints. The Calibration Master and History Records in Blue Mountain Regulatory Asset Manager (BMRAM) and the present calibration sticker will indicate the level of calibration. The calibration range and tolerance are listed in BMRAM; refer to manufacturer's literature or manual for manufacturer's specifications and any specifics for the test procedure. Specific requirements from the manufacturer may then be placed in BMRAM for convenience. 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 be located, at least one each, in each third of the scale of the device and covering at least 70% of the range.

5.3 Check instruments in ascending and descending setpoint order unless otherwise specified.

5.4 When the tolerance of a compound gauge is stated in percent of full scale there are two approaches that may be used. Approach 1, the scale may be split with vacuum displayed in Inches of Mercury (INHg) and pounds per square inch (PSI) for the pressure section provided that the tolerance followed is stated in this format. Approach 2, the scale shall be considered continuous and converted into PSI, for the vacuum and pressure section provided that the tolerance followed is stated in this format.

6.0 Procedure

NOTE: Calibrate pressure-measuring devices in the system/loop in which they are to be used, whenever possible.

The system/loop shall contain a readout device.

6.1 Gather the apparatus necessary to complete the calibration of this system/gauge.

6.2 Isolate the utility pressure source and remove or verify removed residual pressure in the system. When pressure measuring devices are removed the piping must be capped or plugged to render the system safe. Otherwise secure the system per the Environment, Health and Safety approved "lockout/tagout" procedure.

6.3 Remove the pressure device, leaving it attached to any associated readout device. The unit under test (UUT) may be left connected to the piping when the test standard can be added to the system such that pressure is applied to both units simultaneously. In this case, be sure that the pressure can be controlled over the range of the device without harm to equipment or personnel.

6.4 Place the UUT in the pressure test setup. The pressure test station must be connected such that pressure is applied to the UUT and the pressure standard simultaneously.

6.5 Apply pressure to the UUT slowly.

6.6 The pressure applied shall cover a minimum of 70% of the range or as specified by the level of calibration selected (reference ***SOP 21508 - Equipment Calibration Program***).

6.7 Record the pressure of the standard “As-Found for Standard” and the pressure of the instrument “As-Found for Instrument” in the Measurement Data form for the History.

6.8 If the instrument calibration is within the calibration tolerances at all setpoints, as determined per ***SOP 21508 - Equipment Calibration Program***, it is in calibration. If the instrument is in calibration, adjustment may still be required depending on the degree of drift per ***SOP 21508 - Equipment Calibration Program***. If adjustment is not required, record the “As-Found” values for the corresponding “As-Left” values, and proceed to step 6.12. If the instrument is not in calibration or needs adjustment, proceed to step 6.9.

6.9 Determine if the instrument requiring calibration can be adjusted. If the instrument can be adjusted, proceed to step 6.10. If it cannot be adjusted, seek assistance from the BQA Quality Engineer. The BQA Quality Engineer shall assign disposition of these instruments on an individual basis.

6.10 Adjust the instrument requiring calibration per the manufacturer’s directions, and repeat steps 6.4 through 6.7. Record the standard and instrument pressure values for “As-Left” in the Calibration History. If after repeating the step several times the operator is still unable to achieve calibration, seek assistance from the BQA Quality Engineer who shall assign disposition of these instruments on an individual basis.

6.11 Pressure Switch Testing

When testing pressure switches, record the pressure at the start of the test and the state of the switch at this point.

NOTE: The start pressure should be at normal operating pressure.

Record the point at which the switch changes state and the direction of the applied pressure (ascending or rise) or (descending or fall). Continue to apply pressure until at least 10% past the trip point. Change the direction of the applied pressure. Return to the starting pressure and record the state of the switch and pressure. The recorded data should follow the order of testing.

6.12 Generate the label report or manually complete the appropriate level of calibration sticker and attach to the instrument in a visible place (as per ***SOP 21508 - Equipment Calibration Program***).

7.0 Frequency

7.1 Calibrate all pressure-measuring instruments per intervals established per ***SOP 21508 - Equipment Calibration Program***, or as required.

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 An equipment calibration sticker shall be attached to the equipment or instrument in a visible area as per ***SOP 21508 - Equipment Calibration Program***.

8.3 The BQA Quality Engineer shall maintain calibration data for a period of five years after the instrument is removed from service. Data need not be maintained for more than ten years after the recording date.

9.0 Definitions

9.1 **Adjust** – To attempt to bring an instrument to a state of conformance with a set of specifications through instructions provided by the manufacturer of the instrument.

9.2 **Adjusted** – Having made an instrument conform to a set of specifications by adjusting it.

9.3 **As Found** – The condition of an instrument/equipment prior to having an adjustment made to it. This also pertains to the data taken form this instrument/equipment.

9.4 **As Left** – The condition of an instrument/equipment after having an adjustment made to it. This also pertains to the data taken from this instrument/equipment.

9.5 **Compound Gauge** – A compound gauge is one that has two scales in combination to measure two separate events. These events do not occur simultaneously and require different engineering units. However, the internal mechanism of the gauge is such that it can measure each engineering unit type.

9.6 **Stability** – An instrument is considered stable when the deviation of three consecutive readings obtained from the instrument at intervals of at least two minutes is less than or equal to the tolerance of the instrument or the range in the least significant digit is equal to or less than ± 2, whichever is greater.

10.0 References and Related Documents

SOP 21101 *Internal CGMP Compliance Auditing*

SOP 21508 *Equipment Calibration Program*

SOP 21523 *Calibration Data Review*

SOP 21531 *Equipment Logs*

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