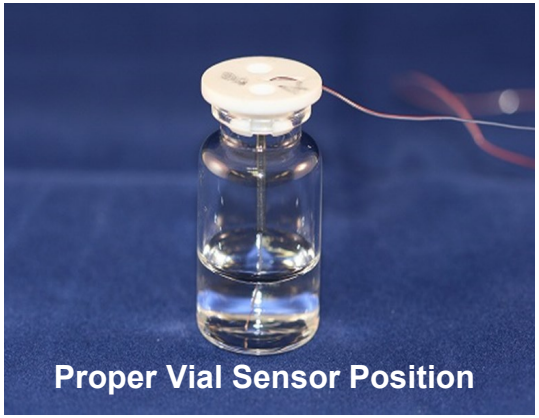

Proper Vial Sensor Position

Thank you to our LyoHUB industry members:

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DOWNLOAD

You can download the full Best Practices Report on Process Instrumentation in Freeze Drying at

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Special acknowledgement to Steve Nail PhD for exemplary leadership on this collaborative paper.

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Best Practices

Process Instrumentation In Freeze Drying

2016

PURDUE UNIVERSITY · NIST National Institute of Standards and Technology · University of Connecticut

Recommendations
product temperature measurements in vials

Thermocouples are preferred to other current methods because of the ability to measure temperature at a precise point. The most appropriate point to measure product temperature is in the center of the vial, with the tip of the thermocouple touching the bottom of the vial.

Use fine wire (e.g. 32 gauge) thermocouples because of the flexibility of the wire and the ability to place the tip of the thermocouple in a precise location.

Use a guide tube to hold the thermocouple in place within a monitored vial. Open area of this device should be very close to that of a partially stoppered vial.

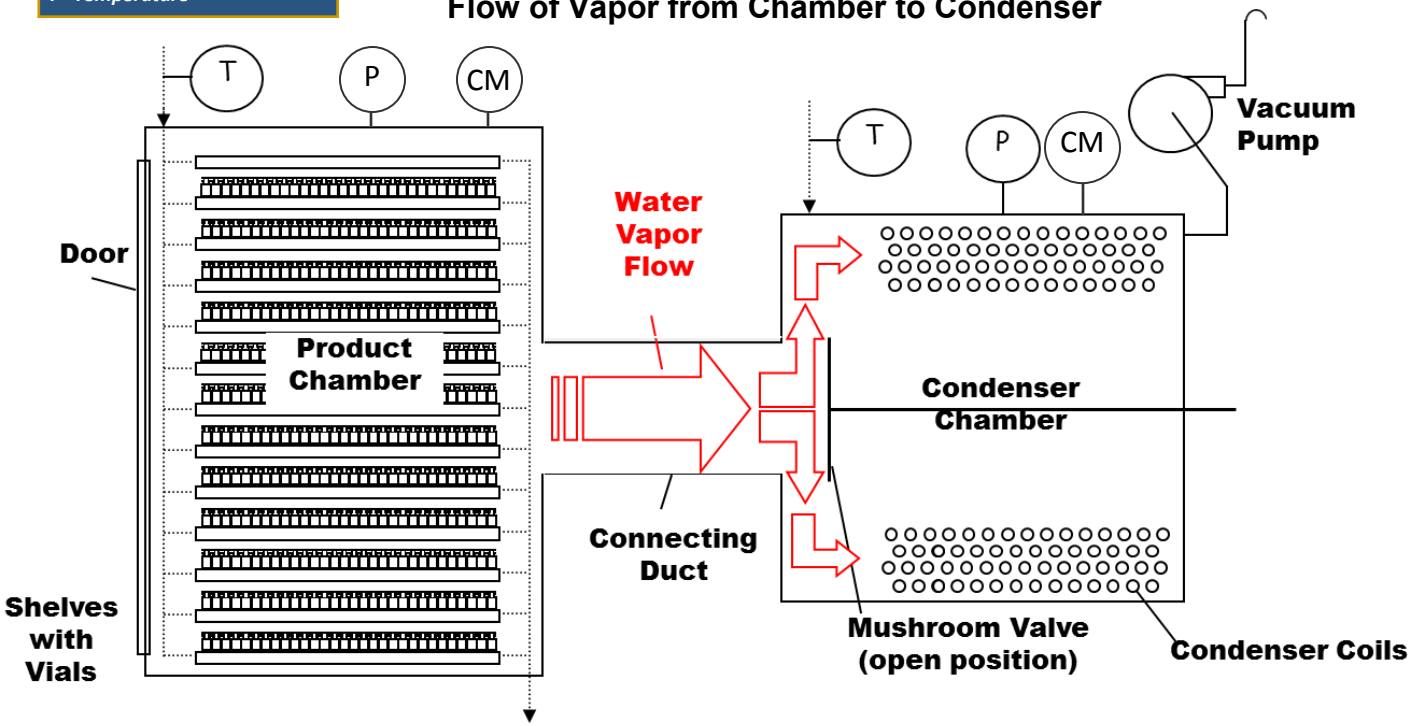
Be aware of the sources of uncertainty associated with product temperature measurement in a manufacturing setting, and don't over-interpret such data.

Be aware of the bias in freezing and freeze-drying behavior caused by any gauge. Recognize that monitored vials may freeze dry significantly faster than the rest of the batch.

The same best practices that apply at the laboratory scale should also apply in a manufacturing environment.

P= Pirani Gauge
CM= Capacitance Manometer
T= Temperature

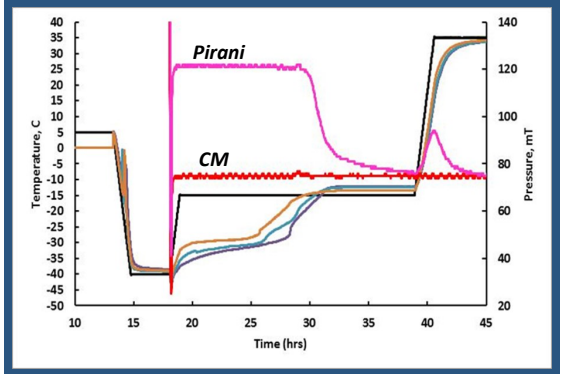
Flow of Vapor from Chamber to Condenser



Recommendations
pressure measurements

Include both a capacitance manometer and a Pirani gauge on both the chamber and the condenser.

Comparative Pressure Measurement



Use capacitance manometer with temperature-controlled sensing head for pressure measurement and control in a pharmaceutical freeze dryer.

Use Pirani *vs* capacitance manometer gauge comparative pressure measurement as a process monitoring tool to determine the end point of both primary and secondary drying.

Both repeated exposure to atmospheric pressure and repeated steam sterilization tend to shorten the interval between calibrations of a capacitance manometer. Historical records should be used to establish appropriate time interval between calibrations. In situ calibration is not recommended.