ViewPoint Monitoring System

ViewPoint

Regulatory:

With the vast range of regulations and laws that are required to ensure your assets remain viable, Mesa Labs' ViewPoint Continuous Monitoring System is the reliable, secure system to meet your needs. We can provide peace of mind on various regulations, no matter what your industry.

Mesa's ViewPoint CMS is compliant with:

- **CDC's Vaccines for Children (VFC)**

  o The CDC purports requirements for VFC storage which include temperature and storage best practices for all vaccines. The CDC will also require NIST-certified calibrated probes in the center of storage units by your vaccines. For proper environment monitoring, you will be required to:

  -Review and record storage unit temperature readings at least 2 times a day, and minimum and maximum temperatures once each morning.

  -Use the digital data logger to store and record temperatures at regular intervals for 24-hour monitoring.

  -Have a digital display for the data logger for reading outside of the storage unit.

  -Maintain temperature data and document any malfunctions or outages.

- **FDA 21 CFR Part 11- Electronic records and signatures**

  o The FDA 21 CFR Part 11 regulation dictates how records should be kept and reported. The scope includes operational areas of a pharmaceutical, biotechnology or medical device company such as:

  -Manufacturing (e.g. production records)

  -Maintenance (e.g. asset management or calibration records)

  -Laboratory (e.g. sampling results or product development)

- **The Joint Commission (TJC)**

  o The Joint Commission evaluates and accredits hospitals and other health care organizations. To earn and maintain TJC's Gold Seal of Approval®, an organization undergoes an on-site survey by a Joint Commission survey team at least every three years. (Laboratories are surveyed every two years.)

- **Clinical Laboratory Improvement Amendments (CLIA)**

  o CLIA regulates laboratory testing and requires clinical laboratories to be certificated by their state as well as the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing.

  o CLIA confirms the integrity of a product and helps organizations maintain patient samples and those products that may be used in testing, such as reagents and test kits. This includes transportation to the diagnostic labs, which can impact results.

- **CAP – Part 11 compliance, close to CLIA CAP is broader**
- **United States Pharmacopeia (USP) <797> Pharmaceutical Compounding – Sterile Preparations**

  o This regulation requires the sterility of any compounded human or animal drug. Temperatures must be controlled not only in the designated areas but also when transporting media to a microbiological incubator. The regulation also requires total particle counts of all ISO-classified areas must be conducted during typical operations every 6 months.

Mesa's ViewPoint system is designed to provide coverage of all regulations that may affect your precious assets. ViewPoint is reliable, effective, and versatile – all to help meet your needs. Contact us today for a specialized consultation and demonstration of this powerful system!

Mesa Laboratories, Inc.
12100 W. 6th Avenue
Lakewood, CO 80228 USA

MesaLabs

Tel: 303-565-2724
Fax: 303.987.8989
monitoring.mesalabs.com

Rev. 12.20.2016