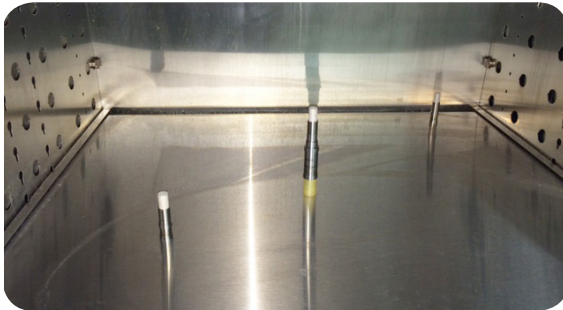


Benefits of Temperature Mapping

Current Good Manufacturing Practices (21CFR Part 211) require that raw materials, in-process materials, finished products, stability samples, and components are stored at the correct environmental conditions to maintain the integrity of the products and components.

To meet these requirements, temperature mappings of the areas and equipment used to store products must be completed before they are used. The areas and equipment must also be remapped on a defined schedule so that customers can rest assured that all the areas and equipment used for storage are being maintained at the required environmental conditions.

If it is discovered during an audit that temperature mapping has not been completed and it is determined that the raw materials, in-process materials, finished products, and components are not being stored in the correct environmental conditions, a company could be exposed to FDA Form 483 observations, and even potential product recalls.



By using Mesa's Compliance and Validation Services to complete the temperature mapping of product storage areas and equipment customers will know the environmental conditions in the areas or equipment, can determine the optimum storage locations for temperature sensitive products, and select the best locations to place the Continuous Monitoring System sensors.

Trained Mesa Labs service technicians will place data loggers throughout the product storage locations, which will capture temperature and relative humidity readings, and provide a detailed map of the environmental conditions in the critical product storage areas. The mapping data will then be used to determine the locations of any cold or hot spots, and the ideal locations for the placement of the Continuous Monitoring sensors so that customers will be aware if the storage conditions go out of specification, and can prevent damage to products and components.

By having Mesa Labs complete temperature mappings of product storage areas and equipment, customers will:

- Know the locations of any hot and cold spots in the storage areas
- Have documented records of the environmental conditions of the product storage areas and equipment
- Determine the optimum storage locations for temperature sensitive products
- Ensure that all requirements for the storage of the raw materials, in-process materials, finished products, stability samples, and components are meeting Current Good Manufacturing Practices (cGMP) requirements
- Save time and resources