The Mesa Advantage

-Validation Services-
-Cold Chain Packaging-
-Data Loggers-
-Biological Indicators-
-Continuous Monitoring-
-Contract Studies-
-Custom Indicator Development-

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MesaLabs

MesaLabs

Mesa Validation Services

Solutions to meet your every validation need

Mesa will develop a testing protocol based on the standards that most impact your processes, tailored to meet your specific requirements

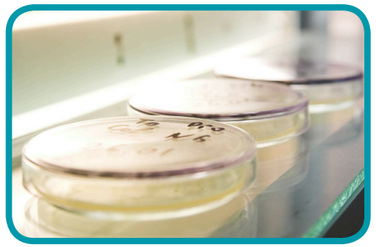
www.mesavalidation.com

Validation Expertise

Mesa stands at the forefront of the standards that govern manufacturers today, backed by a strong corporate presence with the PDA, ISO and AAMI. Our expertise, full-time validation expert, and in-house services offer our clients complete and customized validation solutions with a uniquely qualified Global Services team to bring it all together. Whether you need equipment repair, IQ/OQ/PQ, calibration, or process validation, our fully trained consultants will provide you with specialized service, expert protocol development and execution, and complete validation services, every step of the way. They will consult with you and develop a testing protocol specifically tailored to meet your needs and requirements based on the standards that have the most impact on your processes. These protocols will be carried out by our professional technicians, with over 30 years of combined validation and qualification experience.

Temperature Control Units

When it comes to Temperature Control Units, verifying that environmental conditions are maintained under normal operations and that the environmental conditions are recoverable when normal operation is disrupted, are both of critical importance.



IQ/OQ will:
- Verify system documentation.
- Identify and verify any critical control instruments.
- Verify system control/alarms operate as specified by the customer.
- Verify the environmental conditions are maintained in an empty chamber under normal operations.
- Verify environmental conditions in an empty chamber can recover when normal operation is disrupted.

PQ will:
- Verify the environmental conditions are maintained in a loaded chamber under normal operations.
- Verify environmental conditions in a loaded chamber can recover when normal operation is disrupted.

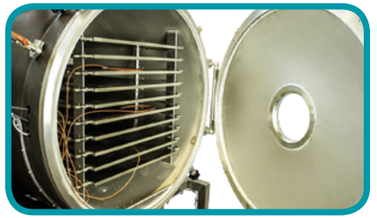
Types of Units
- Incubators
- Freezers
- Refrigerators
- Stability Chambers
- Product Storage Rooms

Depyrogenation Ovens & Tunnels

For Depyrogenation Ovens and Tunnels, it is critical to verify and reproducibly demonstrate the system can meet, maintain and control different temperature and biological indicator population reduction/ endotoxin removal/reduction requirements during cycles.

IQ/OQ will:
- Verify system documentation.
- Identify and verify any critical control instruments.
- Verify system controls/alarms operate as specified by the customer.
- Verify the system is able to meet and maintain the specified temperature during the cycle(s) to meet the customer requirements.
- Develop cycles to meet the customers' needs/requirements for duration, temperature, and load configuration.

PQ will:
- Reproducibly demonstrate the ability to maintain the required temperature and biological indicator population reduction/ endotoxin removal/reduction during the cycles.



Lyophilizer/Freeze Dryer

During normal operation for Lyophilizers and Freeze Dryers, it is important to verify that the system can meet and control different temperature requirements during cycles. For sterilize-in-place (SIP) systems, we want to reproducibly demonstrate the ability to maintain required temperatures, sufficient lethality and biological indicator population reduction during cycles to meet specified industry standards. We also want to demonstrate the ability of the system to successfully perform clean-in-place (CIP) cycles.

IQ/OQ will:
- Verify system documentation.
- Identify and verify any critical control instruments.
- Verify system control/alarms operate as specified by the customer.
- Verify the system is able to meet and maintain the required temperature during the cycle(s) to meet the customer requirements.
- Develop cleaning cycles to meet the customers' needs/requirements for duration, temperature, and cleaning efficiency.
- Develop sterilization cycles to meet the customers' needs/requirements for duration, temperature, and load configuration.

PQ will:
- Reproducibly demonstrate the ability to maintain the required temperature, sufficient lethality and biological indicator population reduction during the cycles to meet the customer and/or industry standards.

Clean Rooms/Controlled Environments

To meet regulatory requirements, it is essential to ensure that the design of the Clean Rooms and Controlled Environments are correct for the type of operation they will be used for. It is incredibly important to monitor the Area(s) for temperature, humidity, differential pressure, non-viable particulates and viable particulates to ensure that all ISO, EU, and FDA guidelines are able to be met.

IQ/OQ will:
- Verify system documentation for the rooms meet the customer and/or industry requirements.
- Verify room controls/alarms operate as specified by the customer.
- Verify the environmental conditions (temperature, humidity, differential pressure, non-viable particulates and viable particulates) are maintained under normal operations.
- Verify environmental conditions can recover when normal operation is disrupted.

PQ will:
- Verify the environmental conditions (temperature, humidity, differential pressure, non-viable particulates and viable particulates) are maintained under normal operations over an extended period of time (6 months to 1 year).
- Verify that the controlled areas are able to maintain the required environmental conditions during the change of seasons.

Autoclaves/Steam Sterilizers

For Autoclaves and Steam Sterilizers, it is critical to verify that the unit/ system is able to meet and maintain specified temperatures. In addition, it must be reproducibly demonstrated that the system is able to meet and maintain required temperatures, sufficient lethality and biological indicator population reduction during cycles to meet specified industry standards.

IQ/OQ will:
- Verify system documentation.
- Identify and verify any critical control instruments.
- Verify system control/alarms operate as specified by the customer.
- Verify the system is able to meet and maintain the specified temperature during the cycle(s) to meet the customer requirements.
- Develop sterilization cycles to meet the customers' needs/requirements for duration, temperature, and load configuration.

PQ will:
- Reproducibly demonstrate the ability to maintain the required temperature and biological indicator population reduction during the cycles.