QC / Microbiology Equipment`s / Calibration

We perform the validation of Incubators, BOD Incubators, CO2 Incubator, Stability, Chambers, Orbital Shakers, Refrigerators, Deep Freezers. Ultra-Low Deep, Freezers, Water Baths, Hot Air Ovens, Muffle Furnace, Vacuum & LOD Ovens, Cold Chambers. The reporting format consists of diagram indicating sensor location, min & max. temperature for all location's Graphical presentation of temperature v/s Time, Hot & Cold spots identification.

Ware House Mapping

Unique Cleanroom Technologies offers a complete temperature & RH Mapping service for any finished product, Raw material warehouse, production rooms, Cold facility in compliance with regulatory guidelines. Mapping of a warehouse must be conducted seasonally. We use small wireless sensors which have the capability to monitoring the temperature and RH simultaneously.

Cold Chain Management

Unique Cleanroom Technologies offers a complete temperature Mapping service: Cold Chain Management is a combination of multitude of activities to ensure that various temperature sensitive products such as Medicine, Vaccine Blood Samples, Tissues, Food etc. are stored and transported at the correct temperature from the point of manufacturer through transportation until it reached the end user or consumer through distribution channels. If the chain is broken at any point the product becomes inferior in its quality.

UNIQUE
CLEAN ROOM TECHNOLOGIES

Plot D-58, Phase V, Industrial Area,
Jeedimetla, Hyderabad - 500055
Mobile: 8341673333 | 9494694307
E-mail: uniquecleanroom@gmail.com,
validation.ucrt@gmail.com

CERTIFIED ISO 9001:2015 COMPANY

UNIQUE
CLEAN ROOM TECHNOLOGIES

VALIDATION & CALIBRATION SERVICES

ABOUT US:

Unique Cleanroom Technologies provides validation and calibration services to Pharmaceutical, Food, Biotech and other Microelectronic industries regulated standards such as ISO-14644, ISO-8573, EU-GMP, WHO, USFDA. Unique Cleanroom Technologies is a Pan India Company with the most competitive focus in the field of Validation of Cleanroom / HVAC activities. Established in the year of 2014, We have the capability to offer our customers localized support and services when and wherever required. We have been certified by ISO 9001-2015.

Services:

- Clean Room / HVAC Validations
- Compressed Air / Breathing Air Validations
- Nitrogen Gas Validations
- Pure Steam Validations
- Thermal Validations
- Calibrations

HVAC Validations

Cleanroom Validation/HVAC Validation is performed for various reasons. To ensure that the design of the facility is fit for its intended purpose; to ensure that the facility, equipment and environment meet to ensure that the facility function together as a system to meet defined standards.

Unique Cleanroom Technologies performs the Cleanroom/HVAC validation as per ISO-14644, ISO-8573, EU-GMP, WHO, USFDA, Schedule M (National Regulatory Body) guidelines for all cleanroom classifications.

Air Velocity & Air Changes Test, Air Balancing & Pressure Balancing Test

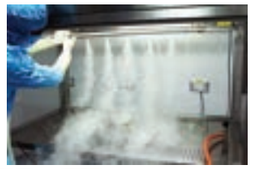
We Conduct Air Velocity Measurement to determine the average filter face velocity and uniformity and the average room airflow velocity and uniformity within a cleanroom. These tests can be conducted by using Anemometer or Air Capture Hood.

Filter Integrity Test

We conduct complete HEPA/ULPA filter integrity testing services. These are offered for both the Pharmaceutical, Food, Biotech and other Microelectronics industries. All filter integrity tests performed as per ISO 14644.

Non-Viable Particle Count and Recovery Test

We conduct Non-Viable Particle Count test and recovery test for Cleanroom/HVAC Validation Services. Our particle count test identifies particle count basis of As-Built, At-Rest, or in operational condition as per clients requirement. These tests demonstrate the ability of the cleanrooms.



Air Flow Visualization / Air Flow Pattern Test

We conduct Air Flow Visualization / Air Flow Pattern Test for client's cleanroom facility. The test is carried to demonstrate that Air Flow Directions.

Light Intensity/Sound Level Measurement

Light Intensity Measurement Test: The Purpose of the test to determine the lighting levels to verify the installed light levels and uniformity meet the specified requirement in cleanrooms. We make use of modern testing instruments for assessment of lux levels.

Sound level Measurement Test: We perform noise level test that measures the sound pressure. The measurements will vary based on the occupancy state-of-the-art cleanrooms. The purpose may vary but the procedures of testing are identical.

Compressed Air / Breathing Air & Nitrogen Gas Validations

The Quality of Compressed Air/Breathing Air & Nitrogen Gas is important to ensure that product is safe. The most important parameters in specifying quality are: Carbon monoxide • Carbon dioxide • Oxygen Concentration • Total Hydrocarbon • Oil Mist • NVPC (Non-viable Particulate Count) • Dew Point • $NO+NO_2$ • SO_2 and Water Content. Pharmaceutical products is vital to assuring the quality and safety of those products. Compressed Air and Nitrogen Gas is a Critical Process Parameter (CPP) those variability has an impact on the Critical Quality Attribute (CQA) and therefore should be monitored and controlled to ensure the process procedures the desired quality.

An important international standard, ISO 8573-1, EP/BP/USP provides a variety of Purity Classes that can be incorporated into a robust quality assurance plan for this critical utility. Testing and monitoring of compressed air and other process gases such Nitrogen and Oxygen that come into direct contact with the product is vital to assuring the quality and safety of the product.

Bubble Point Test (FILTER INTEGRITY)

The objective of this test is used to determine the assurance of filter performance and whether meeting specification, and confirm to rating of the filter

Pure Steam Validations

Steam quality test equipment to quality plant/utility/clean/pure steam generators, steam distribution systems and steam supplies to autoclaves in accordance with cGMP (Orange Guide) HTM 01, HTM 2010 (replaced by CFPP01-OI): 1997, EN 285:2006, DIN 58950, ISO14937:2000, AAMIST79, ISPE Baseline Guide for steam and water, PDA Technical Reports No. I&48.

Steam quality test to qualify plant/utility/clean/pure steam generators, steam distribution systems and steam supplies to autoclaves in accordance with cGMP meeting the following parameters

- Non-condensable gas test
- Superheat test
- Dryness value test

Thermal Validation / Mapping Study

Sterilizers/Processing Equipment

We perform the validation of Autoclaves, Bung processes, Manufacturing Vessels, CIP & SIP SKID, Lyophilization, Dry Heat Sterilizers, Eto Sterilizers, Tunnels which includes Empty chambers and Load Pattern Heat Distribution and Heat penetration study.

Fo, Fh, min. & max. Span and Spread Temperature, Graphical Presentation of Temperature V/S Time, Standard Deviation, Equilibration/Lag Time Calculation, Identification of Hot & Cold spots and Schematic diagrams will be prepared as per customers specification.