Aspire Quali-tech

ASPIRE TO BUILD QUALITY SYSTEM

A COMPLETE ENVIRONMENTAL MONITORING SOLUTION FOR PHARMACEUTICAL INDUSTRY, FOOD INDUSTRY, HOSPITALS, LABORATORIES ETC.

Microbiological Environment Monitoring Services

- Real Time Viable and Non Viable Particle Count using RMM Technology.
- Microbial Environment Monitoring by Settle Plate.
- Microbial Environment Monitoring by Active Air Sampler.
- Microbial Personnel Monitoring by Surface Swab Testing and Finger Dab Testing.
- Microbial Surface Monitoring by Surface Swab Testing and Contact Plate.
- Microbial Monitoring of Compressed Air.

Clean Room and HVAC Validation

- Air Velocity (Flow) Test, ACPH Calculations.
- HEPA Filter Integrity Test.
- Particle Count Test.
- Recovery Test.
- Pressure Balancing Test.
- Air Flow Pattern Test.

Air Quality Monitoring (Indoor, Outdoor and Stack Monitoring)

Testing reports are based on following guidelines: OSHA regulations, EPA Guidelines, NIOSH, WHO, ASHRAE, ISHRAE, CPCB, NAAQS. The test parameters include:

- Particulate Matter 2.5 (PM2.5).
- Particulate Matter 10 (PM10).
- Formaldehyde (HCHO).
- Total Volatile Organic Compound (TVOC).
- Carbon Monoxide (CO).
- Carbon Dioxide (CO_2).
- Sulphur Dioxide (SO_2).
- Nitrogen Dioxide (NO_2).
- Air Velocity.
- Temperature and RH.

Compressed Air Validation

Aspire Quali-tech provide services for testing of Compressed Air, Breathing Air & Nitrogen Gas.
The Quality of Compressed Air / Breathing Air is important to ensure that product is safe and also to comply ISO 8573. The most important parameters in specifying Compressed air or Breathing air quality are:

- Dew Point
- Oil Content
- Particulate Matter
- Moisture / Water Content.
- Oxygen.
- Nitrogen.
- Gaseous Impurities Like, Carbon monoxide, Carbon dioxide, Hydrocarbons, Sulphur dioxide, Oxides of Nitrogen.
- Viable Count.
- Non-Viable Particulate Count.

Thermal Validation and Calibration

We provide temperature mapping services for equipment and facilities like Autoclave, Oven, BOD Incubator,Cold Storage,Stability Chamber, Warehouse.
Calibration services for process controlling devices.

Support to Microbial Environment Monitoring Services

- Protocol Development/Sampling Program Development for Microbial Environment Monitoring.
- Defining Procedures/SOPS for Microbiology Tests and Practices.
- Establishing Rationale for Cleaning Process, Evaluation of Disinfectant Solution.
- Documentation Support for Development of Protocols for Microbial Methods and Validation Studies.
- Training Related to Microbial Environment Monitoring and other Microbiology Aspects.

Consultancy Services

- Implementation of requirement of WHO-GMP, ICH Q7 and other regulatory authority and auditing services for pharmaceutical industries.
- Pre-inspection audits and compliance support.
- Gap assessment audits.
- Documentation support for SOP preparation and review, Validation/Qualification Protocol, Site Master File, Quality Manual etc.
- Implementation of system for compliance of ISO 9001:2015, ISO 13485:2016, ISO 45001:2018, ISO 14001: 2015, ISO 22000: 2018, FSSC, FAMI-QS, ISO 17025:2017 Standard Requirements.
- Internal Audit Management for the QMS, EMS, OHSMS, FSMS, FSSC, FAMI-QS,MD-QMS, Competence of Testing and Calibration Laboratories.
- Training for cGMP, ISO standards, customised training as per the customer requirement.

FOR MORE INFORMATION

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