stefatos
Engineering
Contracting and Trading

Clean Room – HVAC
GMP & ISO 14644
Validation Services

Stefatos offers full Clean Room Qualification/Validation testing and documentation to EU GMP and ISO 14644-1 requirements.

- Design Qualification (DQ)
- Preparation of protocols (IQ, OQ, PQ)
- IQ , OQ, PQ Execution
- Temperature (T) and Relative Humidity (%RH) checks
- HEPA filter integrity testing (DEHS test)
- Airflow Particle Count analysis
- Room Differential Air Pressures (DP)
- Room Air Change Rates (ACPH)
- Sound Level (db) and Light Intensity (Lux) Testing
- Airflow Visualization Display Analysis
- Submittal of completed IQ, OQ, PQ protocols
- Support services during audits

Absolute Filter (HEPA) Efficiency & Integrity Testing

➲ GMP & ISO 14644 Requirements
➲ EN 1822 Test Method
➲ DEHS Test Media
➲ Laser Particle Counter
➲ Calibrated Particle Generator
➲ Calibrated 1:100 Dilution System
➲ Preparation of Test Protocols

ENGINEERING & DQ | PROCUREMENT | INSTALLATION | COMMISSIONING | OQ | PQ

Stefatos S.A. – Head Office: 538,Vouliagmenis Ave., 174 56 Alimos, Athens, Greece
Tel.: +30 2 10 9929773 - Fax.: +30 2 10 9955660
e-mail: info@stefatos.gr - Website: http://www.stefatos.gr

INSTALLATION QUALIFICATION

Installation Qualification provides documented evidence that the Clean Room premises, supporting utilities and the equipment have been built and installed in compliance with their design specification and in accordance with EU GMP & ISO 14644 requirements.
Installation Qualification includes, but is not limited to, verification of the following:

- Installation of equipment, piping, services and instrumentation checked to current engineering drawings and specifications
- As-built drawings
- Collection and collation of supplier operating and working instructions and maintenance requirements

OPERATIONAL QUALIFICATION

The Operational Qualification is an essential part of the Validation Program of any EU GMP Pharmaceutical facility. Operational Qualification provides the documented verification that the Clean Room HVAC System, as installed or modified, performs as intended throughout the anticipated operating ranges, in accordance with the design specifications.
Operational Qualification includes tests that will prove that the environmental conditions (i.e. Temperature, Differential Pressure, Relative Humidity, Room Air Particulate Quality, etc.) during production are in accordance with the User Requirement Specification.

HEPA TERMINAL FILTER EFFICIENCY & INTEGRITY TESTING

HEPA filters are an essential component in any Clean Room design. In fact, their use is dictated by GMP regulations. In a properly designed HVAC system for a Pharmaceutical facility, HEPA filters are essential for maintaining the cleanliness (classification) of an area. Therefore, GMP regulations and ISO 14644 guidelines dictate that HEPA filters shall be periodically tested to verify their efficiency and integrity. HEPA filters will lose their efficiency over time due to clogging, they may be ineffective due to improper installation or they could be damaged (holes, rips) during installation or plant maintenance activities.

STANDARDS / REGULATIONS

The preparation of the OQ protocols and the execution of the OQ testing are in accordance with the following guidelines, as a minimum:

- EU-GMP
- PICS/S
- ISO 14644
- ISPE Baseline, Vol.5

All testing and measurements are accomplished by the use of special calibrated equipment.

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