Validation

- **Generation and Execution of IQ/OQ Documentation**
- **Cleanroom Validation in line with ISO 14644 and FED Standard 209E**
- **Cleanroom Validation Feasibility Studies**
- **Validation of Laminar Flow Devices**
- **HEPA Filter Integrity / Leak Testing**
- **Airborne Particulate Count Analysis**
- **Environmental Testing**
- **Airflow Visualisations**

KES Validation specialise in providing independent cleanroom validation services and our in-house team can develop site specific IQ / OQ documentation.
KES have been involved in a wide range of cleanroom testing with clients in the pharmaceutical, medical devices, semi-conductor and heathcare industries.

King Environmental Services Limited
Documentation | TAB Commissioning | Water Treatment | Validation | Heat Load Testing
www.kingenvironmental.eu

Validation

Airborne particulate analysis

This test determines the quality of the client's cleanroom. We can test for the relevant sized particles in rooms of ISO Class 9 to ISO Class 4. Test reports are generated in the format of the relevant standard (EU GMP, FED 209E, ISO 14644). KES use the most up-to-date particle counters on the market.

- Ensures the cleanroom is operating within design parameters and relevant standards.
- This test will document any emerging contamination trends. (Cleaning personnel can be guided to these areas)

Environmental testing

KES carry out the following environmental testing in clean-rooms:

- Noise levels
- Temperature / humidity mapping
- Luminance levels
- Air volumes / air change rates.
- Room pressure differentials
- Room recovery rates

Generation and execution of IQ / OQ protocols

KES have generated and executed numerous IQ /OQ protocols for new cleanrooms. These protocols provide documented evidence that the installed cleanroom meets and operates within the design specification and regulatory standards. During execution of these protocols site SOPs, maintenance procedures and equipment manuals are also reviewed to ensure best practice is met.

- Ensures that the system has been installed in line with the design drawings.
- Ensures that the system operates in line with the design specification.
- Ensures that the cleanroom meets the relevant regulatory standards and client specifications.

Cleanroom validation

KES carry out cleanroom validation on a quarterly, bi-annual or annual basis to ensure client compliance with relevant standards. Cleanroom validation gives a complete overview of how well the cleanroom is operating. We issue a comprehensive validation report following each visit which will include confirmation that all testing equipment used by KES is maintained and calibrated to international standards.

- Ensures cleanroom continues to meet client design specifications and relevant standards.
- Regular validation minimizes product defects, equipment downtime and inefficiencies
- Ensures any changes can be addressed before they become a source of contamination
- This documentation will be required for cleanroom audits.

Cleanroom validation feasibility studies

KES feasibility studies outline any changes required to an existing cleanroom ensure regulatory compliance is met. Prior to a new cleanroom being installed, design data can be reviewed to ensure the system can be easily validated on an ongoing basis.

- Ensures Cleanroom is designed to be accessible to testing in line with ISO 14644 and FED 209E.
- Ensures appropriate access available to adequately test supply and extract HEPA filter integrities
- Ensures aerosol injection ports fitted in appropriate locations

Validation of laminar air flow devices, microbiological safety cabinets and isolators

KES carry out annual or bi-annual validation of laminar airflow devices, microbiological safety cabinets and isolators. Tests carried out on these devices include HEPA filter integrity testing, airflow velocity and airflow visualisations. Ongoing validation of these devices is critical to protect both personnel and product.

- Ensures initial and continued equipment compliance to required standards.
- Ensures safety of personnel operating the equipment.
- Ensures the product remains uncontaminated.

King Environmental Services
Mullenstown, Ardee
Co. Louth, Ireland
P: +353 41 6858773
F: +353 41 6858578

KES ENGdoc
The Innovation Centre
Ballinode, Sligo, Ireland
P: +353 71 9141564
F: +353 71 9141572

www.kingenvironmental.eu
info@kingenvironmental.eu