JSK VALIDATIONS

79/1, Royal Park Apartment, 2nd Floor 205, Behind Sansera unit-7, Omax Circle,
Bommasandra - Jigani Link Road, Jigani Hobli, Anekal Taluk, Bangalore - 560105
Mob: +91 9845664627 | E : jskvalidations@gmail.com

INTRODUCTION

Clean Room Validation

If you have clean rooms, you need JSK Validations to ensure that they are truly clean and that they stay that way.

JSK Validations is started with a team having a minimum 6 Years of experience in HVAC Validations. JSK Validations helps you maintain control of your controlled environment. It's a proven resource for clean room testing needs arising from manufacturing of medical devices or Pharmaceutical production, as well as sterile compounding in hospital pharmacies and Microelectronics, Aerospace production, Semiconductor manufacturing plants.

JSK Validations investigates, identifies, locates, assess, and resolves contamination problems throughout your controlled spaces. Our work meets or exceeds applicable clean room testing requirements for regulatory regimes including the International Organization for Standardization (ISO), the European Union (EU) Annex, and the U.S. Food and Drug Administration (FDA).

Our staff comprises highly trained with long experience applying modern clean room validation technologies in all varieties of controlled environments. Along with our expertise and capabilities we continue to grow.

JSK Validations carries out following tests to validate clean rooms / clean zones.

To keep contamination risks in your controlled environment under control, call on JSK Validations for the following testing support:

- Air Flow Velocity & Volume testing of Equipment's/ Unidirectional & Non-Unidirectional Clean room
- Installed HEPA filter Integrity Testing along with possible repair or replacement
- Air Pressure difference Measurement & Pressure Balancing
- Airborne / Nonviable Particle count test
- Testing of clean-up Recovery
- Airflow visualisation Test
- Temperature and RH Monitoring & Data Logging
- Compressed Air Validation
- Illuminance (Light level) Test
- Sound Level Test

INSTRUMENT LIST

SL #	Instruments Name	Purpose	Make / Model	Range
1	Laser Particle Counter (3 No's)	To measure Non-Viable Particles	TSI / 9310-02	1 CFM
2	Laser Particle Counter	To measure Non-Viable Particles	TSI / 9500-01	100 LPM
3	Laser Particle Counter (2 No's)	To measure Non-Viable Particles	LASAIR III / 5100	100 LPM
4	Aerosol Photometer (4 No's)	To check HEPA Filter System Leakage	Tec Services / PH-5 & ATI / TDA 2H	0.0001 to 1000 µg/Ltr
5	Cold Aerosol Generator (5 No's)	To check HEPA Filter Leakage	TV / TAG SS6 & ATI / TDA 4B	50 to 8400 CFM
6	Hot Aerosol Generator	To check HEPA Filter Leakage	S & M Electronics / Compact	200 to 71580 CFM
7	Rotating Vane Anemometer	To measure Air-flow Velocity	TSI / 9565P- 995	0 to 9999 fpm
8	Hot Wire Anemometer	To measure Air-flow Velocity	TSI / 9565P- 966	0 to 9999 fpm
9	Hot Wire Anemometer	To measure Air-flow Velocity	TSI / 9535	0 to 9999 fpm
10	Hot Wire Anemometer (2 No's)	To measure Air-flow Velocity	Lutron / AM 4204	40 to 3500 fpm
11	Air Flow Capture Hood (2 No's)	To measure Accurate Air-flow volume	TSI / Accubalance 8380	25 to 2500 CFM
12	Air Cone kit	To measure Accurate Fresh air flow	TSI / 801749	0 to 9999 fpm
13	Air Flow Pattern Kit (3 No's)	To measure Air-flow direction	TV / FPT400	With WFI / Distilled / Normal Water
14	Air Flow Pattern Kit	To measure Air-flow direction	---------	Using Dry Ice
15	Digital Lux meter	To measure illuminance intensity	TQC / LU8500	0.01 LUX to 400 KLUX
16	Digital Sound Level meter	Sound Level measurement	KM 929 MK1	30dB to 130 dB
17	Temperature & Humidity Sensors (175 No's)	To measure & Datalog Temperature & Humidity	Testo 174H	-20° to +70° C 0 to 100% RH
18	B Type Thermocouple (1 No)	To measure & Datalog Temp & Rh for Furnace.	Linear Instruments	Upto 1800° C
19	RTD sensors (22 No's)	To measure & Datalog Temp & Rh	Linear Instruments	Upto 120° C
20	Paperless Datalogger (16 Channel) – 2 No's	To measure & Datalog Temp & Rh	Linear Instruments/ DL-35	NA

Our Documentation

We take pride in producing professional, well structured reports to ensure your audits are trouble free.

We JSK Validations are in pursuing/ developing a New Software for all Documentations.

Our reporting format is completely flexible and will include:

Concise summary of results.

Defined acceptance criteria for each test conducted.

Detailed, site specific test methods.

Layout drawings of the facility indicating location of test measurements.

Test certification with full results and raw data collected.

Calibration certificates for all test equipment used.

Report conclusion and recommendations.

Reports can be compiled, quality checked and issued whilst on site to speed the validation and approval process fulfilling utmost customer requirement.

We use the latest, high flow particle counting equipment and statistical analysis software to reduce sampling times.

Our testing will be tailored to each individual site's requirements and our reporting format is flexible to your needs and to those of the standards to be met. Minimising your production down time, we can compile, check and issue our reports while still at your site, hastening the validation and approval process for you.

Principles of Cleanroom Validations

A cleanroom is a modular environment in which the following environmental factors are kept under control; temperature, airborne particulates, relative humidity, differential pressure, and air flow.

Cleanroom Validation is performed for a variety of reasons. To ensure that the design of the facility is fit for its intended purpose, the User Requirement Specifications (URS), meet defined regulatory requirements, the facility, equipment, and its environment function together as a system to meet defined standards.

Cleanrooms are validated and then certified to a chosen class of ISO 14644. Each class of ISO14644 has its unique requirements that must be made for a facility to be classified in the specified classification.

Our Customers

1. M/s Lupin Limited (Goa)
2. M/s Unichem Laboratories (Ghaziabad)
3. M/s Strides Shasun Ltd (Bangalore)
4. M/s Ontop Research Pvt Ltd (Bangalore)
5. M/s Bal Pharma Limited (Bangalore)
6. M/s The Himalaya Drug Company (Bangalore)

7. M/s Auriga Research Limited (Bangalore)
8. M/s Robust Materials Technology Pvt Ltd (Bangalore)
9. M/s Beloor Bayir Biotech Ltd (Bangalore)
10. M/s Integrated Cleanroom Technologies (I) Pvt Ltd (Hyderabad)
11. M/s Green Leap Projects Pvt Ltd (Bangalore)
12. M/s S M Enterprises (Bangalore)
13. M/s Higher Pharma Pvt Ltd (Harohalli – Bangalore)
14. M/s Kewaunee Labway (I) Pvt Ltd (Bangalore)
15. M/s Cleanroom Technologies (Bangalore)
16. M/s Micro Labs Limited (ML 11, ML 26, ML 25, ML 14, ML01, ML02, ML03 & ML 05)
17. M/s Stelis Biopharma Pvt Ltd (Bangalore)
18. M/s Glenmark Pharmaceuticals Inc (NC – USA)
19. M/s KVK Life Science Inc (NJ – USA)
20. M/s Schneider Electric ITB India Ltd.
21. M/s NNE Focused Pharma Engineering
22. M/s Meher Advanced Materials Pvt Ltd.
23. M/s Archimedis Healthcare Private Limited
24. M/s Tenshi Kaizen Pvt Ltd
25. M/s Stelis Biopharma Pvt Ltd
26. M/s JAS Cal-Pro Pvt Ltd
27. M/s Zifam Pyrex Myanmar Company Limited (Myanmar)

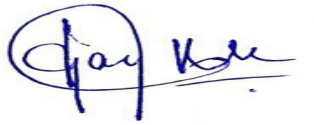
Our Strengths

We are in process in successfully completing clean room validations meeting international standards and our service personnel are trained and technically qualified.

To have close co-ordination with our customers, we have branches in all the major industrial hubs in India initially starting with in Bangalore and we have our Branch Offices at Hyderabad and Goa.

Finally we would expect a better support vice versa in your concern.

Yours faithfully
for JSK VALIDATIONS



Jaya Shankar.K
Mobile: 9845664627.