

VEEDA'S EXPERTISE IN HANDLING INHALATION STUDIES

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Inhalation products belong to the topical drug delivery system. They are delivered through the pulmonary route. It is mainly formulated for the treatment of asthma and Chronic Obstructive Pulmonary Disease (COPD). DPIs are an alternative to the aerosol based inhalers commonly called metered-dose inhaler.

VEEDA'S INFRASTRUCTURE

- State of art negative-pressure room for dosing activity for respiratory medications at Vedant Facility of Veeda.
- A uniform environment with relatively consistent temperature, humidity, air flow, oxygen content and other major environmental factors for all respiratory dosing.
- Better respiratory dosing compliance.
- Specifications of Negative-pressure room.
 - Change Room 1 (at 25 PA, 3 people can be accommodated at a time).
 - Dosing Room 1 and 2 (at 10 PA, 3 people can be accommodated at a time).
 - Change Room 2 (at 25 PA, 3 people can be accommodated at a time).
- Advantages of Negative-pressure room.
 - Provides a uniform environment with relatively consistent temperature, humidity, air flow, oxygen content, and other major environmental factors for all respiratory dosing.
 - Eliminates any chance of cross contamination from one dosed subject to another during dosing procedure.
 - Better regulatory acceptance due to assured well-controlled dosing procedure.

VEEDA'S EXPERIENCE FOR INHALATION STUDIES

Veeda had Completed 20 inhalation bio-studies and few more are in pipeline:

| Completed Studies | | |
|--------------------------------|------------------------|----------------------|
| pMDI | Dry Powder | Nasal Spray |
| 13 studies | 6 studies | 1 study |
| Volunteers dosed – 640 | Volunteers dosed – 200 | Volunteers dosed –36 |
| Total Studies | 20 | |
| Total approx. volunteers dosed | 876 | |



TRAINING OF VOLUNTEERS

Veeda provides training to the volunteers for these studies.

Monitoring is done to see the inhalation flow with respect to time and translate this into turbulent energy, acceleration rates and inhalation volumes. It is important to train volunteer before study participation for.

- To have required uniform inhalation rate
- Training of co-ordination between actuation of pMDI and inhalation.
- Proper inhalation technique without any leakage during inhalation.

WHY PARTNER WITH US?

- Proper understanding of Inhalation and its challenges, for clinical development phase.
- Highly skilled & Excellent scientific expertise: focused on client's special requirements & capable of handling challenging studies.
- · Skilled project management with Robust and Proactive communication.
- Start of Art infrastructure for Inhalation studies e.g.
 - Excellent compliance volunteers database for complex studies.
 - Full temperature and humidity control clinical facility.
 - Adequate facility for IMP storage.
- · Focused on volunteer training for smooth execution of inhalation.
- · Past experience of conducting Inhalation study with large no of volunteers.
- Well trained Physicians and Nurses, avaliable round the clock during clinical execution phase, capable of handling any emergency.
- Good understanding of regulatory requirements.
- Management focus on training of staff for complex and challenging studies.









