INHALATION CASE STUDY 02

Incorporation of a clinical delivery platform into a preclinical exposure device

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BACKGROUND

There is an increasing requirement to develop alternative aerosol delivery methodologies for the non-clinical testing of materials that are structurally delicate and unsuitable for delivery from standard aerosol generators.

Such materials may be sensitive to pressure, temperature, humidity, light and oxygen. Typically the client will be in the process of formulating their test article to suit an identified clinical delivery platform. This might take the form of lyophilized powder in vials or metered dose inhalers, or powder in foil blister packs or capsules.

Through a recent acquisition, Covance now has access to over 40 years of experience conducting programs using clinical delivery platforms that have been adapted in-house to suit animal exposure systems. These custom designed and built systems allow clients to provide test article in the exact packaging that will be used in the clinic, so mimicking human clinical exposure methods and reducing test article supply costs.

To replicate the proposed clinical delivery the client required that the test article aerosol was delivered primarily to the upper respiratory tract without changes in particle size or sedimentation in the animal exposure system.

THE CHALLENGE

The client approached the Covance inhalation study group to develop an inhalation exposure system that would deliver test particulate aerosol in the same particle size range (5+ µm) as that required clinically, so only targeting the upper airways of a large animal model. The test article was to be provided in capsules sealed in foil blister packs.

A clinical delivery platform had already been selected and if possible all future non-clinical work should be conducted on this platform. Prior studies had indicated increased toxicity if the test article was delivered to the deep lung. Therefore the inhalation study group also had to design a delivery system that would not generate or selectively deliver test article with a small particle size.

The challenge presented to Covance - to incorporate the selected clinical delivery platform into a large animal exposure system while maintaining particle size distribution within the clinical range and a high efficiency of test article delivery.

THE SOLUTION

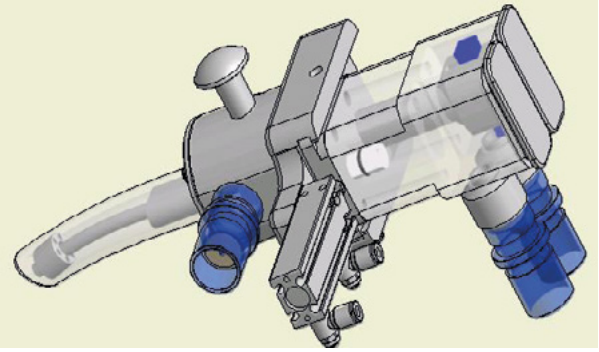
The Covance aerosol technology and inhalation engineering services groups designed and manufactured an oro-pharyngeal (OP) delivery system which included our clients selected clinical delivery platform.

Features of the design included:

- Continuous monitoring and display of the animals' respiratory pattern throughout dosing;
- Delivery of an operator triggered air pulse to coincide with the animals' inspiration, so optimizing the dose delivery;
- Encapsulation of multiple clinical devices within a single dosing unit avoiding the need to replace capsules during dosing.

CUSTOMER BENEFITS

Test article particle size maintained at the same mass median aerodynamic diameter as required for clinical administration. Study costs were reduced - a result of the high efficiency of test article delivery, in spite of the large particle size. Test article formulation handling costs minimized - by using the same capsule and foil blister pack for clinical and nonclinical studies. This 'test article specific' designed and built dry powder aerosol delivery system allowed our client to administer their test material via their selected clinical delivery platform by providing efficient delivery to the upper respiratory tract in this nonclinical study.



CAD DRAWING OP DELIVERY SYSTEM

OP dosing was recommended to ensure that the dry powder aerosol was presented close to the larynx to minimize the filtering impact of the nasal turbinates and the humidifying effects of exhaled air and mucosal membranes in the mouth and nose.

To find out more about how our unique approaches can save you time, money and resources in your development program contact us today

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