ab initio pharma

OzUK

MANUFACTURING

GMP MDI SERVICES

Seamless Transition from R&D to cGMP Manufacture of MDIs for Clinical Trials

A Collaborative Approach by OzUK and Ab Initio

Streamlined MDI Development Partnership

Ab Initio advantage

In the rapidly evolving pharmaceutical landscape, the journey from research and development (R&D) to commercialization is pivotal. Particularly in the respiratory care sector, the development of metered dose inhalers (MDIs) requires not only innovative R&D but also rigorous compliance with Good Manufacturing Practice (GMP). Two notable companies in this field, Ab Initio Pharma and OzUK, have emerged as leaders, offering comprehensive services that ensure a seamless transition from R&D to cGMP manufacturing of MDIs for clinical trials.

OzUK: Pioneering MDI R&D and Support for Clinical Trials

OzUK's cutting-edge R&D services are focused on the formulation of MDIs. With a facility based in the UK, OzUK specializes in both the development of generic MDIs and the formulation of new products using NCEs. Their approach integrates rigorous testing and validation processes, which are crucial for ensuring the efficacy and safety of the inhalers.

OzUK's ***MDISprint™*** service exemplifies their commitment to accelerating the commercialization process of MDIs. By optimizing product development through lean methodologies and concurrent execution of chemistry manufacturing and controls (CMC) modules, OzUK significantly reduces time-to-market for

their clients' products. Moreover, their strategic collaborations enhance the selection and validation of critical components, such as canisters, valves, actuators, and propellants, facilitating a smooth transition to commercial scale-up and manufacturing.

Ab Initio Pharma: A Hub for GMP Services

Located in Sydney, Australia, Ab Initio Pharma excels in GMP manufacturing for early phase clinical trials. This facility is not just a cornerstone for compliance but is equipped with state-of-the-art technologies that support both conventional and novel pharmaceutical endeavours. Ab Initio provides a full spectrum of GMP services essential for the development, scale-up, and commercialization of MDIs. This includes the capability to handle a variety of propellants, such as the traditional hydrofluoroalkane (HFA) and the newer, environmentally friendly low global warming potential (GWP) propellants like HFA1234ze and HFA152a.

Ab Initio is able to handle existing approved molecules as well as potent new chemical entities (NCEs) and scheduled molecules including canabinoids, psychedelics and therapeutics for pain management.

Ab Initio's GMP services are comprehensive, covering everything from preclinical testing and analytical services to quality control and logistics. This ensures that every stage of MDI development, whether for generic formulations or NCEs, adheres to stringent regulatory standards.

A Synergistic Approach to Clinical Trials and Beyond

The partnership between Ab Initio and OzUK offers pharmaceutical companies a unique advantage by providing an end-to-end solution from product concept to market entry. Ab Initio's GMP-certified manufacturing capabilities ensure that products developed by OzUK's innovative R&D processes can be seamlessly transitioned into clinical trials and subsequently to market with full regulatory compliance. This collaboration not only streamlines the development process but also enhances the capacity to fill both conventional HFA propellant formulations and new low GWP propellants.

This integrated approach ensures that all phases of MDI product development, from the initial R&D to final GMP manufacturing, are handled with precision, efficiency, and adherence to global regulatory standards.

Government Support and Incentives

Australia's government offers substantial financial incentives for R&D activities through the R&D Tax Incentive program. Eligible companies working with Ab Initio can benefit from up to 43.5% refundable tax offset. This incentive is designed to reduce the cost of undertaking R&D, enhancing the overall feasibility and appeal of conducting research in Australia

Conclusion

The strategic collaboration between Ab Initio Pharma and OzUK sets a new standard for the pharmaceutical industry, particularly in the development and manufacturing of MDIs. By combining Ab Initio's robust GMP services with OzUK's innovative R&D capabilities, they provide a comprehensive pathway for bringing both generic and novel MDI products to market efficiently and effectively. This partnership not only accelerates the delivery of critical respiratory solutions to the market but also ensures they are produced to the highest standards of quality.

ABOUT AB INITIO PHARMA

Ab Initio Pharma, is a licensed GMP manufacturer (TGA Licence: MI-2012-LI-02662-3, APVMA Licence: 3016), specialising in formulating and manufacturing pharmaceutical goods. Ab Initio can take molecules from initial discovery to clinical trial products and commercialisation.

CONTACT

www.ab-initio-pharma.com
67-73 Missenden Road,
Camperdown, NSW, 2050, Australia
enquiries@ab-initio-pharma.com
+614 0377 1606