NAVITAS LIFE SCIENCES

A TAKE Solutions Enterprise

Regulatory Services

Process Outsourcing Enhanced by Technology

Knowledge process outsourcing and technology capabilities to support our customers across the entire value chain of drug and device regulatory environment.

Submissions & Report Publishing

Navitas Life Sciences offers document, report and submission level publishing for simple and complex submission applications including life cycle management. Navitas Life Sciences also provides invaluable subject matter expertise in evolving electronic submissions standards, health authority specific guidelines and processes.

Licence Maintenance

Licence maintenance activities for marketed products can be effort intensive and difficult to manage at optimal costs. Navitas Life Sciences provides continuous and cost effective support to Regulatory Operations in authoring and submitting variations, renewals and annual reports for marketed products across the world.

Labeling & Artwork Services

Navitas Life Sciences has more than a decade of experience in Labeling & Artwork management. We provide support to the industry's thought leadership in Labeling through LabelNet. We provide cost effective labeling document review, alignment with company core data sheets, labeling maintenance, coordination and proof reading expertise from our delivery centre in Chennai.

Regulatory Information Management

Regulatory information technology is often a range of point solutions that are not well integrated. The ability of these tools to work together plays a major role in the effective maintenance of Regulatory information, user confidence in the data integrity and the overall usefulness of the RIM system. Our experts can provide integrated RIM solutions or utilize our technology partnerships to meet your specific needs.

Regulatory Strategy and Support

Working with partners in the US and Europe, we provide high quality strategic regulatory advice throughout the lifecycle of your product. Advisory services range from regulatory requirements and strategy for early clinical studies to the optimal regulatory pathway to market for new products, generics and line extensions balancing speed-to-market, optimal market access and ultimate commercial success.

Why Navitas Life Sciences?

Expertise

Case Study: Global Publishing and Submission Management for Top 5 Pharma

Business Need

- Global submission volumes between 45,000 and 55,000 per annum
- Mandate to accommodate growth without increasing cost while maintaining quality and timelines

A client-facing Navitas Life Sciences team was set up to compile, format, publish, and submit Regulatory compliant submissions to support new applications and also maintain current marketing authorizations.

Delivery

- Delivery from Navitas Life Sciences Delivery Center in Chennai, India. Additional support to LATAM through the Navitas Life Sciences regional hub in Colombia.
- Trained and dedicated resources function as an extension of the client's publishing group in their Citrix environment
- Well-defined metrics and measurements
- Unit based pricing approach

Results

- Delivery of around 15000 -18000 submission per annum
- 45+ trained publishers who can publish submissions across global requirement
- 24 x 5 coverage
- Trained buffer resources to manage surge in workload

Delivery model

- Navitas Life Sciences becomes an extension to our clients own Regulatory function as a true partner
- Our Functional Service Provider model enables us to be highly flexible and respond rapidly to customer requirements
- Our state of the art Global Delivery Centre in Chennai, India enables us to deliver process outsourcing at scale and cost effectively
- Our unit pricing approach enables the client to reliably forecast costs and drives a partnership approach to continuous improvement

Technology

Our technology capability has helped us develop PharmaReady™: PharmaReady™ is a web-based electronic Document Management and eSubmission Solution suite specifically designed for both emerging and large Life Science organizations where ease of installation, ease of use, regulatory compliance, and affordability are the primary business drivers.

www.pharmaready.com

We endeavour to bring our technology capabilities to all our outsourcing contracts to increase efficiency and effectiveness of the processes outsourced.

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About Navitas Life Sciences

As a partner for the industry, Navitas Life Sciences leverages industry insights, consulting and technology capabilities to deliver full service clinical, regulatory and safety solutions and desired outcomes to clients. As the dedicated life sciences brand of TAKE Solutions, Navitas harnesses the combined knowledge and experience of three legacy brands—Ecron Acunova, Navitas, and Intelent—to provide end-to-end services and solutions. Navitas helps clients address their most critical problems by bringing together the capabilities of a full-service CRO, a technology-led life sciences services provider across clinical, regulatory and safety, and a life sciences big data services and analytics provider. Operating from 7 countries across the globe, Navitas works with over 150 customers in Life Sciences.

For more information

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