Regulatory Affairs Support

Facilitating the regulatory approval process to accelerate product development

WHY LEIDOS LIFE SCIENCES?

- Solutions that help accelerate time to market for vaccines, drugs, and biotherapeutics
- Ability to deliver support throughout the product development lifecycle
- Experienced regulatory affairs professionals that have deep knowledge of FDA and international regulatory agency requirements
- A broad understanding of regulatory document preparation and electronic submission requirements

Our Leidos Life Sciences team provides critical regulatory guidance at every step of the product development process. We collaborate with client integrated product teams to help them navigate the complex regulatory pathway from research and development to clinical trials and licensure. Leidos provides comprehensive regulatory affairs consulting services to foster the submission and approval of accurate, scientifically sound regulatory documents.

Our regulatory affairs professionals apply their expertise in the development of vaccines, drugs, and biotherapeutics. Their keen understanding of FDA and international regulatory agency requirements helps assure that investigational, marketing, and post-approval applications are compliant with stringent regulations.

Leidos Life Sciences offers a wide range of services, including regulatory strategy and planning assistance; regulatory authority interaction guidance; and document preparation and control. Since 2012, Leidos has been providing clients with a full scope of electronic Common Technical Document (eCTD) services, including preparation, hosting, training, management, and strategy. Our experienced team can assist clients with regulatory operations and help clients navigate the eCTD submission guidelines, ensuring that valid eCTD submissions will be delivered on time to the regulatory authorities.

www.leidos.com/health/life-sciences

The following project examples illustrate Leidos' regulatory affairs capabilities:

Document Preparation and Control for Regulatory Submissions

The Leidos Life Sciences team provides hands-on technical and administrative assistance for an infectious disease research institute. We support the preparation, review, assembly, archiving, distribution, and tracking of all pre-Investigational New Drug (IND) briefing documents, INDs, common technical documents (CTDs), investigational device exemptions, master files or equivalent submissions, and subsequent supplemental submissions to regulatory authorities. In addition, we maintain the database that archives and tracks all protocol registration documentation and enables orders for clinical trial materials. We offer a process-based approach to eCTD compilation and our regulatory affairs team ensures that electronic submissions are clear, thorough, and fully compliant. Leidos' eCTD submission management system results in improved quality for every eCTD submission and increased efficiency and thoroughness during the review process.

Regulatory Affairs Consulting and Compliance Support

Leidos personnel help vaccine, drug, biotherapeutic, and medical device product development teams at U.S. civilian and military medical research organizations develop regulatory rationale and strategies. We collaborate with principal investigators on clinical protocol development, help marshal protocols through the multitiered Institutional Review Board process, and draft investigator brochures. Our experts also manage the preparation of the pre-IND readahead documents; participate in meetings with the FDA; review all IND sections for accuracy, consistency, and regulatory compliance; and finalize each IND for submission to the FDA. Through our support of advance planning and strategy development, Leidos fosters regulatory compliance, which helps accelerate the development of new biomedical products.

Regulatory Affairs Consulting for Product Acquisition

Our Life Sciences team provides critical guidance on product development, from preclinical research to FDA market approval, for a government biomedical research organization that is responsible for the acquisition of drugs, vaccines, therapies, and diagnostic tools for public health emergencies. We apply our deep understanding of FDA regulations and practices to provide our customer with a realistic picture of manufacturers' regulatory strategies and timelines for FDA licensure and approval. Leidos also assesses the suitability of animal models, provides extensive reviews of essential IND documents, and evaluates and interprets FDA correspondence to the manufacturer. This support helps to ensure that, should a health emergency arise, public health organizations have an adequate supply of countermeasures to combat the threat.

Services

Regulatory Affairs Consulting

- Strategy and planning
- FDA premeeting package preparation, discussions, and panel participation
- Document preparation
  - IND, New Drug, and Biologic License Applications
  - CTDs
  - Drug Master Files
  - Investigator brochures
  - eCTD services
- Clinical protocol development and review
- Clinical study and annual report preparation
- Chemistry, Manufacturing, and Controls support and management

Regulatory Compliance Support

- Compliance plan development
- Audits and assessments
- Quality systems development
- Validation plan and protocol development and evaluation
- Warning letter response preparation
- Recall management consulting

Document Control

- Document control system development
- Document maintenance, tracking, and archiving
- Electronic database management systems support

Product Development Plans

- Strategy and target product profile development
- Integrated project timelines
- Risk management plans

Training

- Regulatory requirements education

FOR MORE INFORMATION

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