Biomedical Product Life-Cycle Development Support

Fostering research, discovery, and development to improve human health

WHY LEIDOS LIFE SCIENCES?

- Ability to support all phases of manufacture, evaluation, and regulatory affairs for biologics, drugs, and medical devices
- Experience with spectrum of federal agencies, biotechs, commercial pharma, CMOs/CROs, academia, and non-profit research institutes
- Large existing network of subcontractors and collaborators ready to execute drug development contracts from proof of concept through manufacture and clinical testing
- Strategic IR&D projects, a seedling patent portfolio, and a growing publication record

The Leidos Life Sciences team executes a diverse portfolio of medical science, biopharmaceutical, and grant/program review contracts that encompasses a spectrum of infectious diseases, cancers, and neurological disorders. Our virtual pharma approach involves production and testing of vaccines and biotherapeutics for use in human clinical trials, and utilizes a proven operating model that leverages the technical expertise of multiple Contract Manufacturing Organizations (CMOs), Contract Research Organizations (CROs), biotech firms and academia. This strategy supports the broad requirements of our customers and helps to ensure our success in three prime markets:

- Global Health: Emerging, neglected, and tropical infectious diseases
- Defense Medical: Products designed to protect and treat our warfighters
- Threat Reduction: Biodefense vaccines, biotherapeutics, and diagnostics

Our specific expertise is in biopharmaceutical concept prototyping, regulatory strategy, and product development. Leidos scientists currently manage a large malaria biologics pipeline and have developed four experimental malaria vaccines for inclusion in government clinical studies. Other ongoing or previous vaccine and therapeutic projects are related to Anthrax, West Nile Virus, HIV, Polio, Candida, and influenza. We also maintain a collection of internally funded feasibility studies for novel candidates to feed future drug development opportunities.

Successfully managing diverse science and technology platforms, the Leidos Life Sciences team has established itself as a corporate leader by filling a market niche that unites sponsor mission and operational necessities with regulatory requirements and technical expertise. Our solid experience has led to tremendous proficiency in the identification, qualification, and oversight/coordination of current Good Manufacturing Practices (GMP)/Good Laboratory Practices (GLP)/Good Clinical Practice (GCP) operations for the development, manufacture, and testing of pharmaceutical products, including multiple novel biopharmaceuticals (primarily monoclonal antibodies).

Helping to ensure continuity across a distributed network of lifecycle contributors is an attribute that distinguishes our Life Sciences team from CMOs and CROs throughout the industry. As we have learned from 18 years of networked and collaborative biopharmaceutical development, there is a definite and crucial need to unite the procedural and quality practices of contract entities that perform each step in the overall process. There are also gaps in the general service offerings of the CMO/CRO community that we seek to bridge in our effort to cover the full spectrum of lifecycle requirements.

Integration: The Life Sciences team understands the importance of integrating diverse scientific entities into a functioning virtual pharma development team, and this integration occurs at three levels: organizational, quality, and regulatory. Our role in medical product development programs helps to ensure that the science and development path are thoroughly planned in advance, and that collaborators maintain quality and regulatory compliance without losing efficiency. This combination of technical and managerial oversight provides our client with a turn-key drug development solution that relieves their burden of facilitation while helping to maintain open communication with all stakeholders.

Evaluation: Our project team evaluates ongoing preclinical study data, process development activities, risk assessments, and vendor/collaborator deliverables against project requirements and U.S. Food and Drug Administration regulations and guidance. We assess the history, evolution, and current status of the product, the production process, and intended use, as well as the intended route of administration, and estimated dosing requirements. This preliminary information provides an idea of the total amount of product required for nonclinical, clinical, and stability studies, and whether or not the current process/platform has the capability to produce the quantities needed to complete clinical trials.

Communication: Leidos communicates to our customer what to expect during the development process, and we clarify various aspects of the gap analysis such as ongoing and planned studies, manufacturing sites, adequacy of production documentation, and clinical and regulatory risks.

Leidos Life Sciences' virtual pharma approach is innovative, efficient, and collaborative with proven results.

Services

Strategy Development

- Integrated development plans
- Risk management plans
- Economic analyses
- Strategic planning

Critical Decision-Point Management

- Integrated project timelines
- Product team meeting management
- Project prioritization

Preclinical and Clinical Scientific Support

- Preclinical program and study design
- Scientific peer review
  - Toxicology, immunology, microbiology, virology
- Preclinical findings extrapolation
- Clinical data analyses
- GCP audits

Regulatory Affairs Support

- Regulatory agency meeting and submission preparation
- Clinical protocol development and final study report preparation
- Annual report preparation
- Regulatory documentation authoring

Chemistry, Manufacturing, and Control Support Services

- Process development and validation
- Production planning
- Batch production record development
- Current GMP, Quality System Regulation, and International Conference on Harmonisation audits
- Person-in-the-plant visits

FOR MORE INFORMATION

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