Leidos Life Sciences Case Studies

Life Sciences Translational Research Support

The Leidos Life Sciences team provides the experience, expertise, and management often needed by investigators and organizations when embarking on translational science projects. We markedly increase project feasibility and fundability, as well as drug candidate pedigree with our value-added, low-risk approach to product development. Our focused services (summarized below) bridge the gap between concept and clinical to help ensure compliance with cGMP/GLP requirements.

- Identification and acquisition of support technologies (e.g., adjuvants, formulations)
- Technical guidance for process development and production scale-up
- Coordination of manufacture, preclinical, and clinical evaluation of drug candidates
- Audit of vendor and Person-in-Plant to oversee vital operations
- Stability assay development, qualification, validation, and study management
- Regulatory document preparation and electronic submission to the FDA

Leidos facilitates control of the translational process and enables access to the leading contract services sought after by pharmaceutical and biotech companies—without tasking the investigator or organization to create a costly internal technical and administrative infrastructure. Our focused efforts help to limit the amount of time taken away from current projects, which relieves scientists of this burden and allows for greater opportunity to focus on accelerating discoveries towards application. A summary of our capabilities is presented in the figure below, followed by case studies describing services the Life Sciences team has provided to recent clients.
CASE STUDY 1: A research hospital with a novel biotherapeutic to treat glioblastoma required Leidos Life Sciences’ assistance to bring their concept to readiness for clinical testing.

- Assembled and archived all deliverables and project documents for upcoming IND
- Drafted a product development plan from current status through Phase 1 clinical trial
- Served as project management point-of-contact for preclinical studies, process development, and manufacturing activities
- Assisted with additional vendor and collaborator identification and evaluation
- Conducted cGMP compliance audits and site visits of vendors
- Developed a regulatory strategy that dovetailed with the product development plan
- Prepared the IND as well as associated documents and updates (electronic submission)
- Supported FDA interactions and meetings
- Supported clinical trial phase as requested

CASE STUDY 2: A non-profit vaccine development program requested project management and production support from Leidos for a challenging new product class.

- Developed timelines and a work breakdown structure (WBS) for an integrated product development plan that included a target product profile, translational research plan, translational development plan, near-term manufacturing plan, key assumptions, unanswered questions, as well as a risk assessment and associated mitigation plans
- Developed timelines and a WBS for formation and launch of a multilateral product development steering committee with a formal governance structure
- Provided project coordination, including but not limited to, scheduling meetings and teleconferences with project partners, and preparing meeting agendas, minutes, and progress reports
- Performed site visit(s) and maintained project-related documentation consistency

CASE STUDY 3: A biotechnology company sought our subject matter expertise to navigate cGMP manufacture and regulatory affairs associated with a federally funded vaccine development project.

- Audited CMOs contracted for manufacture of Bulk Drug Substance (BDS) and Final Drug Product (FDP)
- Reviewed all written methods including analytical methods (in-process, BDS release and FDP release), batch records, stability protocols, specifications, and bill of materials
- Reviewed technology transfer batch results, engineering batch results, and cGMP production batch results
- Reviewed any deviations, failure investigations, and corrective and preventive action plans
- Project management support
- Regulatory affairs consultative and operational support

For more information, please contact:

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To learn more about our expertise