

Leidos-Enabled Antibody Production Platform (LEAP²)

Enabling a One-Stop Monoclonal Antibody Development Solution from Bench-to-Clinic

Production of biopharmaceuticals is a core expertise at Leidos, and process development and current Good Manufacturing Practices (cGMP) production are a key function that we offer in support of our clients.

Leidos Life Sciences now offers this expertise as a service solution! Applying our Virtual Pharma approach, we assembled a team of leading scientists and biotechnology innovators that developed an integrated platform for turnkey monoclonal antibody (mAb) production to rapidly develop and test effective mAb products. With our value-added, low-risk approach to product development, we can markedly increase project feasibility and fundability, as well as identify potential drug candidates. Over the last 30 years, Leidos Life Sciences has been providing the experience, expertise, and management often needed by investigators and organizations when embarking on product development projects. Leidos is exceptionally experienced in managing large, complex, federally funded medical product development programs that address the needs of the global health community and the Warfighter. Our ability to create solutions and integrate subcontractors and technologies into a cohesive, efficient team is a core competency. We now bring this experience together with a key team of vetted service providers to offer the Leidos-Enabled Antibody Production Platform (LEAP²). This platform covers:

- ▶ Cell line development
- ▶ Research, master, and working cell bank (R/M/WCB) generation and testing
- ▶ Production process development
- ▶ Analytical method development and qualification
- ▶ Formulation development
- ▶ GMP manufacturing and fill-finish
- ▶ Good laboratory practice (GLP)-compliant nonclinical testing
- ▶ Investigational new drug (IND) application content and submission
- ▶ Clinical testing in human subjects



About Leidos: Leidos is a Fortune 500[®] information technology, engineering, and science solutions and services leader working to solve the world's toughest challenges in the defense, intelligence, homeland security, civil, and health markets.

Leidos Life Sciences executes a diverse portfolio of medical science, biopharmaceutical, and grant/program review contracts with services that span the full spectrum of the biomedical product lifecycle, from discovery through post-marketing surveillance. We deliver customized solutions that support groundbreaking medical research, optimize business operations, and expedite the discovery of safe and effective medical treatments.

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LEAP² can be used for à la carte services or full-spectrum support to move your product candidate from benchtop to clinic with a single point-of-contact. All services are coordinated by a Leidos project manager, with support from in-house manufacturing, nonclinical, and clinical personnel. Regulatory submissions are written, reviewed, and packaged according to long-standing standard operating procedures (SOPs) for electronic transmission through Leidos' FDA Electronic Submissions Gateway. Cost, schedule, and technical performance are monitored and managed to control scope and cost. Biweekly meetings and monthly progress reporting are provided to keep you up to date on development activities. →



Adherence to FDA Quality Requirements

Leidos performs audits and site visits at our FDA-regulated subcontractors' facilities. We review processes, procedures, SOPs, and other deliverables to ensure our subcontractors maintain high quality standards throughout the contract's life. By establishing predefined specifications and performing qualification site visits and audits, as well as document reviews, we ensure that each subcontractor maintains regulatory compliance (good clinical practices [GCP], GLP, and GMP), follows written protocols or production records, completes the appropriate documentation, meets quality criteria, and adheres to project schedules. Each subcontractor must have a quality department and associated quality systems that are appropriate for their scope, and each must ensure the quality of its vendors. The quality clauses in our subcontracts define the scope and number of audits and reports, procurement of services or materials, and general specifications for deliverables. Additionally, we establish Quality Agreements with our critical subcontractors; for LEAP², we have a draft Quality Agreement already in place with one contract manufacturing organization and more are in the works. To ensure project-specific compliance during execution, we schedule regulatory compliance (GCP, GLP, and GMP) annual, biannual, and risk-based audits or person-in-the-plant visits, depending on the Quality Agreement and the type of work performed.

Leidos also has an established Product Development Plan (PDP) template that can be easily tailored for any LEAP² mAb candidate. Our PDP addresses required manufacturing assays and documentation; nonclinical toxicology, safety and efficacy data; and clinical requirements for fielding mAb products – providing you a proven development path toward FDA licensure.



Leidos Life Sciences – your one-stop shop for clinical development of antibody products