



Expert consultants in Regulatory, Biotechnology, Medical Technology and Pharmaceuticals. We serve the needs for global life sciences in:

Surgical innovation	Immunology	Diagnostics	Financing Options
Infectious Disease	Gene Therapy	Digital Health Apps	Reimbursement
Oncology	Cell Therapy	Medical Software	Business Development
Cardiology	Precision Medicine	Telemedicine	Grant Development

REGULATORY and CLINICAL TRIAL/EVALUATION SERVICES

- Global regulatory strategy for biotech, device, diagnostic and pharma products
- Regulatory submission development for international health authorities
- Clinical trial and clinical evaluation studies for biotech, device, and pharma products
- Coordination with FDA, Health Canada, MHRA, ANVISA, PMDA, CFDA and KFDA
- Clinical trial design and clinical site setup and coordination for all stages of development

SCIENTIFIC and ENGINEERING DEVELOPMENT SERVICES

- Basic scientific research feasibility and data studies for early candidate screening
- Grant proposal writing and submissions to NIH, NSF, DoD, BARDA, DARPA, NASA
- Technical and CMC documentation for design, patent and regulatory submissions
- Pre-clinical evaluation and safety study development for drugs, devices and biologics
- Human factors and usability evaluations for medical devices, diagnostics and software

BUSINESS SERVICES

- Team development, project management and resource acquisition
- Financing options and connections to financiers for startups and mature firms
- Entrepreneurial fundraising and asset valuation options and reimbursement analyses
- Strategic partnerships and global supply chain support for life science clients
- US Agency and coordination services for international life science and med-tech firms
- Soft landing services for innovators in multiple regions



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