

# Research Development (R&D) Support Services

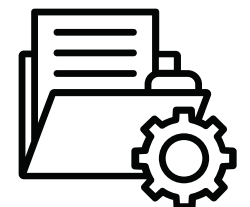
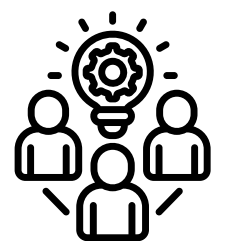
## *From Innovation to Regulatory Approvals – Driving Product Performance and Compliance*

### Why Do You Need Us?

At the Landrich Group, we support clients through the critical early stages of product development by providing strategic, regulatory-aligned R&D services. From design verification and validation planning to managing analytical and clinical studies, we help ensure your product meets the evolving expectations of the FDA and other National Competent Authorities (NCA). Whether you're preparing for an FDA submission—including IDE, IND, or NDA—seeking EU MDR/IVDR compliance or coordinating with other NCAs, our team ensures your study plans, data and documentation are complete, compliant, and defensible for pre-market review processes and regulatory inspections

### Services:

- Develop Design Verification & Validation (V&V) Plans, Protocols, and Reports
- Develop Clinical Plans, Protocols, and Reports
- Manage Clinical Trials and Performance Evaluations as a CRO
- Perform Quality Management System (QMS) Gap Assessments
- Support Regulatory Communications and Submissions
  - Develop Global Regulatory Plans to assure market access in multiple markets
  - Lead U.S. FDA Pre-Subs and NCA interactions
  - Prepare, compile and submit Regulatory Submissions
  - Ensure inspection readiness



### Aligned with Global Regulatory Standards:

#### Our services are designed to meet the requirements of:

- U.S. FDA – including design control, risk management, V&V, and submission readiness
- NCA – compliance with country-specific regulatory frameworks
- EU MDR/IVDR – medical device and In Vitro Diagnostic (IVD) compliance
- ICH Guidelines – pharmaceutical and diagnostics harmonized GCP
- CLSI Standards – analytical and clinical performance evaluations



With deep expertise across regulatory frameworks and technical development, we help R&D teams turn innovative concepts into submission-ready products—ensuring quality, traceability, and global market access from start to finish.

Contact us for a free consultation at [admin@landrichgroup.com](mailto:admin@landrichgroup.com)