TECHSOL
LIFE SCIENCES

MEDICAL DEVICE CLINICAL DEVELOPMENT AND REGULATORY AFFAIRS SOLUTIONS

CAPABILITIES OVERVIEW

- 20+ Years of MedTech Experience
- Technology-driven Scientific Processes
- Broad Therapeutic Area Expertise
- Focus on 100% Quality & Compliance
- End-to-end Professional Services
- Global Trial Conduct Experience

OUR QUALITY CERTIFICATIONS

- ISO 9001: 2015
- ISO 14155:2011
- ISO 13485:2016
- ISO 27001:2013

Trusted Partner for Medical Devices Clinical Research

How We Help Sponsors

Techsol specializes in offering value-focused medical device clinical research services powered with innovative GxP technology solutions to global sponsors who develop different classes of medical devices across therapeutic areas.

Our MedTech team has extensive domain knowledge and practical experience in handling of end-to-end complex global trials and working with US FDA, EMA, PDMA, SFDA, Health Canada, DCGI and ROW for regulatory approval submissions.

With an unwavering focus on quality, patient safety and regulatory compliance, we deliver end-to-end Clinical Trial Services, Pharmacovigilance, Medical Device MDR Compliance and Regulatory Services to multi-national medical device organizations.

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Medical Device Clinical Services

- Clinical Investigation Plans
- CER (Clinical Evaluation Reports)
- Feasibility Studies / Pilot studies
- Clinical Development for Pivotal Studies
- PASS (Post Authorization Safety Studies)
- PMS Plans / PMCF Plans
- Post Marketing / Observational Studies
- PMCF (Post Marketing Clinical Follow-up Studies)
- Biometrics Services (Clinical Data Management, Biostatistics & SAS Programming, Medical Writing)
- Literature search / Reviews
- Publications

Audit And QMS Services (ISO 13485:2016)

We can carry out audits as per the requirements of ISO 13485:2016

- Product & Process Risk Assessment
- Estimation & Control of Risk
- Premises Cleanliness Requirements
- Personal Hygiene Requirements
- Product Sterilization & Premises Fumigation Requirements
- Product Installation & Servicing Requirements
- Product Re-call procedures & Need of Improvements
- Technical Testing & Analysis of Medical Devices including Biocompatibility
- Evaluation of Design Parameters & Validation

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Product Certification Support: CE Marking

- Identification of EU MDR compliance requirements applicable to the Product
- Preparation of Product Technical File
- Provide guidance for Technical testing of Product as per Harmonized Standards.
- Identify the Conformity Assessment Process for CE marking of Product as per Risk Category
- Risk Assessment of Product
- Creation and Submission of Technical Documents to Notified Bodies for CE Marking

EU MDR / IVDR Support

- Gap analysis of existing Product Dossier
- EU MDR / IVDR Compliance Strategy
- Changes in Notified Bodies
- Labelling Review and Updates
- Tech File Remediation
- Design Dossiers and Renewals
- EUDAMED Database Management
- EU UDI implementation
- Regulatory strategy & Project Deliverables US/EU/CA/ROW
- Marketing Strategy Support
- Due Diligence

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Medical Device Regulatory Services

- US Regulatory Submissions (510(k), PMA, 180 Day, 30 Day Notices, RTR, IDE, Compassionate Use, HUD, HDE, CFG)
- International STED Development
- Health Canada License Amendments
- EU Technical Files, Design Dossiers, CE Renewals and Change Notifications
- Clinical Evaluation Reports (CER)
- ROW Market Support

Post Market & Regulatory Agency

- FDA-483 and Warning Letter Responses
- Consent Decrees
- Recall Support
- Liaison between Company and Regulatory Agencies
- US Agent Services & Establishment Registrations
- Preparation of internal team for agency meetings

EU PMS - FSCA Reporting

- Determine if a FSCA (Field Safety Corrective Action) and Field Safety Notice (FSN) are necessary and report to appropriate Competent Authorities.
- Complying FSCA reporting timelines as per MEDDEV 2.12/1 based on the severity of the incident.
- Inform your Notified Body of any incidents or FSCAs unless your device is Class 1 self-certified.
- Query responses to Competent Authorities regarding devices involved and design changes.
- Submit a Final Incident or FSCA Report to Competent Authorities.
- Provide vigilance reports along with any correspondence with Competent Authorities as per ISO 13485 quality system standards

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Medical Device Labelling & Branding

Labelling System Implementation

- Working on Client's Network
- Label Creation and Revision
- Change Management Documentation
- Reports on all Labelling Related Activities
- All data management handled off-site by Medical Device Labelling Professionals

Revising Labelling

- Revisions to labels, cartons and IFUs
- Updates for MDR Changes, Notified body, Numbers, EU Authorization Rep., etc.
- Creating space on Cartons and Labels for Multiple Languages
- Changes to Adobe Illustrator and InDesign Files

Rebranding

- Graphics artists develop and implement new branding on all forms of packaging
- Update cartons, labels, and IFUs to meet current standards
- Revisions to graphics after mergers and acquisitions
- Management of artwork files

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About Us

Techsol Life Sciences specializes in offering value-focused clinical development functional services powered with innovative GxP technology solutions to global pharmaceutical, life sciences, and healthcare companies.

We provide full-range of Clinical Trial Services, Pharmacovigilance, Medical Device MDR Compliance and Regulatory Services by strictly adhering to ICH-GCP, US FDA, EMA and comply with national and international regulations; dedicated to a high level of protocol compliance and proactive communication.

Our functional teams have extensive experience in handling of end-to-end complex global trials. Our clinical operations team, project management and quality teams constantly strive to ensure that study requirements, regulatory compliance and study timelines are met without comprising quality.

Office Locations

United States

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