MEDICEPT

Trusted Solutions, Rapid Response

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www.MEDIcept.com

Our Value Statement

MEDIcept's relationships are built on Integrity and Communication to provide customized Innovative and Quality solutions in a Collaborative manner.

MEDIcept is an international medical device, IVD, combination product, and biotechnology compliance consulting firm. For over 27 years, our unique consulting practice has assisted thousands of companies of all sizes with cost-effective Regulatory, Quality, Clinical, Auditing, and Educational services. Our experienced team of former FDA, Notified Body, and industry experts will work with you to efficiently develop or remediate a quality system, create a regulatory strategy, or establish a clinical trial to meet your specific needs.

MEDIcept will help you navigate the complex FDA and international regulatory pathways, reduce business risk, and increase time-to-market while maximizing your potential for success. Every client and every issue is unique. We customize our solutions to fit your needs. With a retention rate of over 90 %, we can promise that you will benefit from working with us.

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By The Numbers

MEDIcept was founded in **1996**.

Our Clinical team has been involved with approximately **50** clinical trials, almost **1,500** sites and almost **20,000** patient subjects.

Our Regulatory consultants have been involved in over **625** regulatory submissions. They have helped with hundreds of Regulatory Agency responses.

Our Quality consultants have been involved with **hundreds** of Regulatory Agency responses and/or remediation activities for Consent Decrees, Warning Letters, CE Mark/ISO Certification activities, FDA 483s and Notified Body findings. In addition, we have performed thousands of audits i.e., QMS, Compliance, Mock, Supplier, and Due Diligence.

32% of our clients are International, stretching across **6** continents.

Types of Services Provided

Clinical

- Clinical Study Design and Protocol Development
- Clinical Regulatory Submissions
- Clinical Trial Management
- Data Management & Statistics
- Medical Writing
- Clinical Audits
- Clinical Trial Reports
- Clinical Evaluation Reports/Performance Evaluation Reports

Regulatory

- Global Regulatory Strategy and Registrations
- Regulatory Agency Communication and Meetings
- US Regulatory: Pre-sub, 513(g), 510(k), DeNovo, PMA, BDD, STeP, and eSTAR
- EU-MDR/IVDR Technical Documentation
- CERs/PERs
- Due Diligence, Labeling, Marketing Material, & Social Media Reviews
- Reimbursement Strategy
- Interim Regulatory Professionals

Quality Management

- QMS development and support
- Audits: QMS and Compliance (MDSAP, QSIT, EU, Due Diligence)
- Responses for FDA 483s, Warning Letters, Consent Decrees, NB Observations
- QMS Remediations
- Retrospective Record Protocols and Reviews
- Post-Market Surveillance Reports
- QMS and Audit Prep Training and Education
- Interim Quality Professionals

Quality Engineering

- Risk Management (ISO14971) development and support
- Design Control: DHF Development and Remediation
- Medical Device Software Compliance (IEC 62304)
- Cybersecurity
- Usability (IEC 62366)
- eQMS Validation
- Process Validation
- Interim QE Professionals

Our Core Consulting Team

To view our growing consulting team, visit the Our Team section on our website at www.medicept.com/team/.