MEDICEPT

Trusted Solutions, Rapid Response

200 Homer Ave
Ashland, MA 01721
www.MEDIcept.com

OUR MISSION

MEDIcept strives to provide our clients with proven, trusted, and cost-effective solutions

ABOUT US

MEDIcept is an international medical device and IVD compliance consulting firm. For 25 years, our unique consulting practice has assisted thousands of companies of all sizes with cost-effective Regulatory, Quality, and Clinical 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 are 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.

BY THE NUMBERS

MEDIcept was founded in **1996**

Combined, our Partners have over **125 years** experience in the medical device industry

32% of our current clients are international

Our Regulatory consultants have been involved with over **625** regulatory submissions

Our Quality consultants have been involved with responses and/or remediation activities for **7** Consent Decrees, **15** Warning Letters, **2** CE Mark/ISO decertifications, and over **100** FDA 483s and Notified Body Major findings

Our Clinical team has been involved with over **40** clinical trials, involving close to **1400** sites and more than **12,000** subjects

TYPES OF SERVICES PROVIDED

Quality Management

- QMS development and support
- Quality System and Compliance Audits
- FDA 483, Warning Letter, Consent Decree
- QMS Remediation
- Interim Quality Professionals
- Post-Market Surveillance
- Training and Education

Regulatory

- Global Regulatory Strategy and Registration
- Regulatory Agency Communication and Meetings
- US Regulatory Submission: Pre-sub, 513(g), 510(k), DeNovo, PMA
- EU-MDR/IVDR Technical Documentation
- Clinical Evaluation Report
- Regulatory Due Diligence
- Interim Regulatory Professionals

Clinical Research

- Study Design and Protocol Development
- IDE and IRB Communication
- Site Selection and Management
- Clinical Trial Management
- Clinical Site Monitoring
- Clinical Audit
- Clinical Trial Report

Engineering Support

- Risk Management ISO 14971
- DHF Remediation and Development
- Medical Device Software Compliance IEC 62304
- Usability IEC 62366
- Process Validation
- Cyber Security
- IEC 60601
- Design Control

OUR TEAM

F. David Rothkopf, President, Founding Managing Partner
Brian Markham, Managing Partner
Susan Reilly, Managing Partner
L. Adelina Paunescu, Ph.D., VP of Clinical Services, Managing Partner
Jennifer Almy, Director of Quality System Services, Partner
Scott Blood, Director of Regulatory Services
Jason Gromek, Sr. Business Development Director, Partner
Dawn Ross, Director of Staff Development and Training
Jerika Acosta, Director of Clinical Operations
Henry R. Hidalgo, Sr. Quality Consultant
Natalie Vollrath, Sr. Regulatory Consultant
Stephen Gilbert, Sr. Quality Engineering Consultant
Sharyn Orton Ph.D., Sr. Regulatory Consultant
Jose Reyes-Marquez, Quality Consultant
Cheron Legault, Consultant
Terry Gower, Regulatory Affairs Engineer
Lisa Wagner, Director of Human Resources
David Martin, Quality Systems Consultant