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, IVD, combination product, and biotechnology compliance consulting firm. For over 25 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.

## BY THE NUMBERS

MEDIcept was founded in **1996**

Combined, our Executive Team has over **215 years** of 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, **16** 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 (MDSAP, QSIT, EU)
- FDA 483, Warning Letter, Consent Decree, NB Observations
- 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
- Reimbursement Strategy
- Regulatory Due Diligence
- Labeling, Marketing Material, & Social Media Review
- Interim Regulatory Professionals

### Clinical Research

- Study Design and Protocol Development
- Clinical Regulatory Submissions
- Clinical Trial Management
- Data Management & Statistics
- Safety
- Medical Writing
- Clinical Audit
- Clinical Trial Report
- Clinical Evaluation Report

### Engineering Support

- Risk Management (ISO 14971)
- Design Control; DHF Remediation and Development
- Medical Device Software Compliance (IEC 62304)
- Cyber Security
- Usability (IEC 62366)
- Medical Safety (IEC 60601)
- eQMS Validation
- Process Validation
- Interim QE Professionals

## OUR CORE CONSULTING TEAM

**F. David Rothkopf,** President
**Kim Trautman,** Managing Director and VP
**Susan Reilly,** VP Quality
**Brian Markham,** VP Quality Systems
**L. Adelina Paunescu, Ph.D.,** VP Clinical Services
**Scott Blood,** Director Regulatory
**Jennifer Almy,** Director Quality Systems
**Jerika Acosta,** Director Clinical Services
**Marion Cappadona,** Manager Software Systems

**David Martin, Ph.D.,** Quality
**Terri Armstrong,** Quality
**Sean Yohey,** Quality
**Henry Hidalgo,** Quality Engineering
**Stephen Gilbert,** Quality Engineering
**Taylor Dieringer,** Quality Engineering
**Samly Maat,** Software Quality
**Natalie Vollrath,** Regulatory
**Terry Gower,** Regulatory Engineer
**Cheron Legault,** Consultant
**Jean-Marie Toher,** Consultant