Musculoskeletal Clinical Regulatory Advisers, LLC

EXECUTIVE SUMMARY

Company Profile:

Name: MCRA

Founded: 2004

Headquarters: Washington, DC
New York, NY
Manchester, CT

Team: >100

- **Vision:** Create the market leading medical device services franchise recognized as the #1 in clinical, regulatory, reimbursement, quality, and healthcare compliance worldwide
- **Mission:** To leverage the existing platform to help expand the company franchise by creating & developing multiple service offerings in orthopedics & other healthcare niches
- **Focus:** Medical device professional service outsourcing

Market Opportunity:

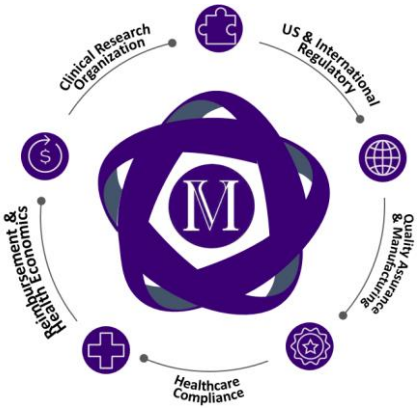
CRO Clinical Research
A leading full service CRO successfully executing medical device and medical device combination products studies through the full development lifecycle from pre-clinical testing, to FDA submission, study execution market approval, and post commercialization.

Regulatory
MCRA's integrated team of scientists, engineers, and biostatisticians leads the neuro-musculoskeletal industry through the device life cycle from strategic regulatory assessments of PMA approvals, advisory panel meetings, 510(k) clearances and post-marketing labeling and design considerations.

Reimbursement
Through day-to-day planning, integrated strategy development and operational execution, MCRA helps companies navigate coding, coverage and healthcare economic pathways at various stages in the product's lifecycle from technology development and clinical research through to product commercialization.

Quality Assurance
The Quality Assurance team helps companies bring devices to US and international markets, and keep them there, by ensuring compliance with regulations and standards.

Healthcare Compliance
An effective healthcare compliance program is an essential component to any medical device company.



Service Life Cycle Continuum:

Pre-clinical

- Draft pre- and non-clinical protocols (bench, animal, biocompatibility)
- Consolidate and summarize test reports and statistical analyses
- Regulatory pathway and landscape assessments
- Audit internal quality systems and external suppliers for regulatory compliance
- Conduct due diligence targeting completion of pre-clinical portfolio
- Perform landscape assessment

Clinical/CRO

- Proprietary medical device clinical trial execution
- Development of study protocol and documentation (CRF, TMF, etc.)
- Vast surgeon relationships for site identification & qualification
- Clinical Trial Agreement development & negotiation
- Data management support
- Abstract & manuscript for clinical study report writing
- Audits & FDA Inspection preparedness training
- Integrated regulatory, reimbursement, and healthcare compliance expertise

Regulatory/Quality

- Regulatory strategy
- Regulatory submissions & approvals (PMA, 510(K), IDE, IND, BLA, & IND)
- Preparation for FDA meetings
- PMA response services
- CE Mark
- Labeling
- Marketing compliance
- Quality Systems / GMP

Commercialization

- Reimbursement strategy execution
- Payor education/coverage (policy development)
- Clinical trial reimbursement services
- Post-market study design and support
- Case-by-case coverage support
- Call center programs
- New code applications
- Health economic analyses

Select Company Facts:

Total Clientele
>500
Clients in the past 10 years

Annual Clientele
≈150
Annual clients

Repeat Clientele
≈ 85%
2017 repeat client rate

Employee Retention
90%
Employee retention 2014-2017

Clinical Surgeon & Provider Site Relationship:

>200 Sites Over the Last 10 Years