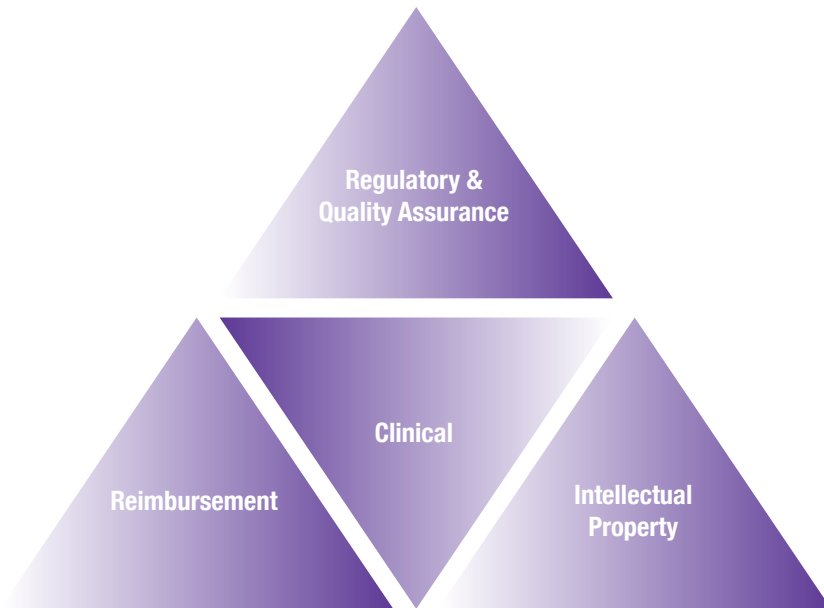




Musculoskeletal Clinical
Regulatory Advisers, LLC



Unparalleled Expertise & Experience

The Most Experienced Team, Guiding Neuro-Musculoskeletal Companies Through US and International Regulatory, Reimbursement, Clinical, Intellectual Property and Quality Assurance Affairs

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REGULATORY (US & International)

> 1,000 Protocols Written, Submitted & Reviewed*

Key Services

- FDA Submissions (510(k), IDE, PMA, IND, BLA, HDE)
- International Regulatory Affairs
- Strategy Analysis & Development
- Predicate Landscape & Device Design
- Design, Review & Implement Pre-Clinical Testing

Team Experience

- More than 50 years combined
- Currently Work on >100 Projects for >60 Companies
- Former FDA Reviewers
 - Experience on >1000 Submissions
 - Oversight on:
 - Guidance Documents
 - Reclassification Petitions
 - Integrity, Compliance & Monitoring
- Former Members of 3 FDA & Industry Panels

Key Personnel



Glenn Stiegman

Vice President, Regulatory Affairs

Mr. Stiegman manages and directs the regulatory affairs for MCRA and its clients and leads the firm's submission process, regulatory strategy, analysis, and development. Mr. Stiegman previously served as Chief of the FDA Orthopedic Devices Branch, overseeing all FDA guidance documents and FDA policy determinations for orthopedic devices marketed in the US, and has represented the FDA as a member of several Orthopedic leveraging groups.



Hollace Rhodes

Director, Orthopedic Regulatory Affairs

Ms. Rhodes is responsible for regulatory affairs relevant to general orthopedic devices (hip, knee, small bone, trauma, etc.) for MCRA's clients. Ms. Rhodes served as a lead reviewer in the FDA Orthopedic Devices branch and advised firms and inventors as they developed clinical protocols for new orthopedic technologies.



Justin Eggleton

Director, Spine Regulatory Affairs

Mr. Eggleton is responsible for regulatory affairs relevant to spine devices for MCRA clients, with experience writing FDA submissions and drafting test protocols. Mr. Eggleton served as a lead reviewer in the FDA Orthopedic Devices branch and contributed to guidance documents and ASTM technical committees regarding orthopedic device testing.

QUALITY ASSURANCE

>150 Different Companies, >350 Different Projects*

Key Services

- Quality System Creation, Modification & Implementation
- Pre-PMA Auditing
- Personnel Training
 - MDD
 - QSR
 - ISO 13485
 - Risk Management
- Prospective & Retrospective Validation

Team Experience

- More than 30 Years Combined
- Quality System Creation & Implementation
- Manufacturing Site Development & Relocation
- Compliance Auditing
- Design Engineering & Manufacturing Management
- Sterilization Validation Expertise

Key Personnel



Kevin Ladd

Vice President, Quality Assurance

Mr. Ladd manages and directs the quality assurance affairs for MCRA and its clients. Mr. Ladd creates, modifies, and implements quality systems for device manufacturers and developers. He also ensures compliance with FDA QSR systems, ISO 13485, European Medical Device Directives. Since 2000, Mr. Ladd has provided engineering quality system, and international regulatory consulting services to 17 companies, 9 of which were in the orthopedic field.



Aaron Lyon

Director, Quality Assurance

Mr. Lyon has extensive experience in manufacturing acquisitions, relocation, and full cycle manufacturing site development. Mr. Lyon has developed two manufacturing sites in China, two sites in Mexico together with a distribution center, and three manufacturing sites in the United States. In total, Mr. Lyon has relocated more than 450 Class I, II, and III medical devices to three countries with total net annual sales of more than \$600 million.

* all numbers include both MCRA & past experiences

REIMBURSEMENT

> 1,200 Healthcare Economic-Related Activities*

Key Services

- Strategic Reimbursement Planning
- Reimbursement Landscape Assessments
- Coding & Add-On Payment Development & Applications
- Healthcare Policy Development & Advocacy
- Utilization Analysis
- Predictive Economic Utilization Modeling
- Clinical Trial Reimbursement Planning

Team Experience

- More than 70 years in Health Care Policy & Finance
- Government Agency (DHHS, CMS)
- Direct Interface with:
 - DHHS, CMS, & State Medicaid
 - TriCare & VA/DoD
 - Commercial Carriers
- Direct Experience in Legislative Affairs
- Proven Track Record in Coverage, Coding, & Payment Development for New and Existing Technologies

Key Personnel



Charles Schneider

Vice President, Reimbursement

As a seasoned professional with more than 20 years of experience as an accomplished industry leader and author in reimbursement, health economics, and government affairs, Mr. Schneider directs MCRA's reimbursement department for its clientele. Mr. Schneider has held key positions with large and regional insurance carriers as well as holding leadership positions within the medical device community.



Gerald N. Rogan, MD

Executive Consultant

Dr. Rogan served for over six years as a Part B Medicare Carrier medical director. His experience includes work as a practicing physician and developing coding solutions for emerging technologies for California Medical Association and the Centers for Medicare and Medicaid Services.



Tim Hunter

Director, Reimbursement

Mr. Hunter has over 12 years of experience helping biotechnology, pharmaceutical, and medical device companies develop comprehensive and successful coverage and reimbursement strategies. Mr. Hunter has a proven record of working with payors at the national and local level to advocate for the adoption and appropriate reimbursement of new technologies.

* all numbers include both MCRA & past experiences

CORPORATE & SURGEON ETHICS & COMPLIANCE

Key Services

- Compliance Program Establishment, Implementation, & Monitoring
- Compliance Auditing
- Contract and Financial Activity Review
- Investigation of Inappropriate Activities
- Compliance Hotline Management

Team Experience

- More than 10 years Investigation, Compliance, & Healthcare Policy & Finance Experience
- Development & Implementation of Compliance Policies & Procedures
- Complex Investigation Expertise
- Clinical Trial Management Expertise
- Contract Management & Negotiation Expertise
- Reimbursement & Regulatory Strategy Expertise

Key Personnel



Robert Hoehn, JD

Director of Compliance

Mr. Hoehn joined MCRA in 2004 and is responsible for the development, implementation and execution of health care compliance strategies for MCRA's clients. Mr. Hoehn has expertise in the development and management of health care compliance programs with a particular focus on medical device manufacturers and companies involved in clinical trials.

CLINICAL

>100 Written, Advised & Monitored Studies*

Key Services

- Retrospective & Prospective Study Management
- Literature Searches & Analysis
- "Ghostwriting" for Publications & Presentations
- Case Report Form (CRF) Development
- Study Proposal & Budget Development

Team Experience

- More Than 25 Years Combined
- Clinical Study Management
 - IDE/PMA
 - Post-Market
- Peer-Reviewed Papers & National Grants
- Patient Data Analysis
- CRA & CRC Experience

Key Personnel



Teresa Schroeder

Director, Clinical Affairs

Ms. Schroeder is an experienced clinician with more than 15 years experience managing CRO's, statisticians, investigators, and IRB's and leads a team of clinical professionals executing clinical study and regulatory submission preparation, clinical study management, and clinical writing initiatives. Ms. Schroeder has worked on clinical studies for several large orthopedic medical device companies.



Aviva Barber

Director, Clinical Affairs

Ms. Barber has been with MCRA since 2005 and is responsible for the clinical affairs functions of MCRA. In her role, Ms. Barber manages clinical studies, writes clinical protocols, and ghostwrites peer-reviewed technical papers for publication. Prior to MCRA, Ms. Barber worked in both the hospital and private sectors. In the private sector, she managed the clinical development process and ran both large and small scale clinical studies.

INTELLECTUAL PROPERTY

Key Services

- Clearance Analyses
- Patentability Searches
- Invalidity Searches
- Competitive Patent Landscapes
- Product or Technology Due Diligence

Team Experience

- Former US Patent & Trademark Office Examiners
- Registered Patent Agents
- Prior Orthopedic Industry Experience

Key Personnel



Urmi Chattopadhyay

Director, Patent Affairs

Ms. Chattopadhyay assists MCRA's clients to develop, protect and optimize. Chattopadhyay was a Patent Examiner at the United States Patent & Trademark Office in the medical art.

GLOBAL MARKET DEVELOPMENT

Key Activities

- Client Contracting
- Proposal Development
- Continued Client Relations
- Internal Employee Coordination

Team Experience

- Pharmaceutical & Medical Device Sales Experience
- Surgeon Relations & Development
- Currently Coordinate more than 100 Clients

Key Personnel



Amanda Briscoe Tracy

Vice President, Global Market Development

With more than 14 years experience as an accomplished entrepreneur, reimbursement professional, and sales and marketing leader, Ms. Tracy manages and directs the Global Market Development departments of MCRA. Prior to joining MCRA, Ms. Tracy served as an executive with expertise in pharmaceutical and medical device sales and reimbursement.

* all numbers include both MCRA & past experiences



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Musculoskeletal Clinical Regulatory Advisers, LLC is the leading neuro-musculoskeletal consulting firm assisting established and emerging companies in the development and commercialization of their technologies. MCRA's consultants are industry leaders who support Clinical, Regulatory, Quality Assurance, Reimbursement, and Intellectual Property initiatives. MCRA's integration of these key value creating initiatives, as well as its focused specialization, creates unparalleled expertise to its clientele.

www.mcra.com