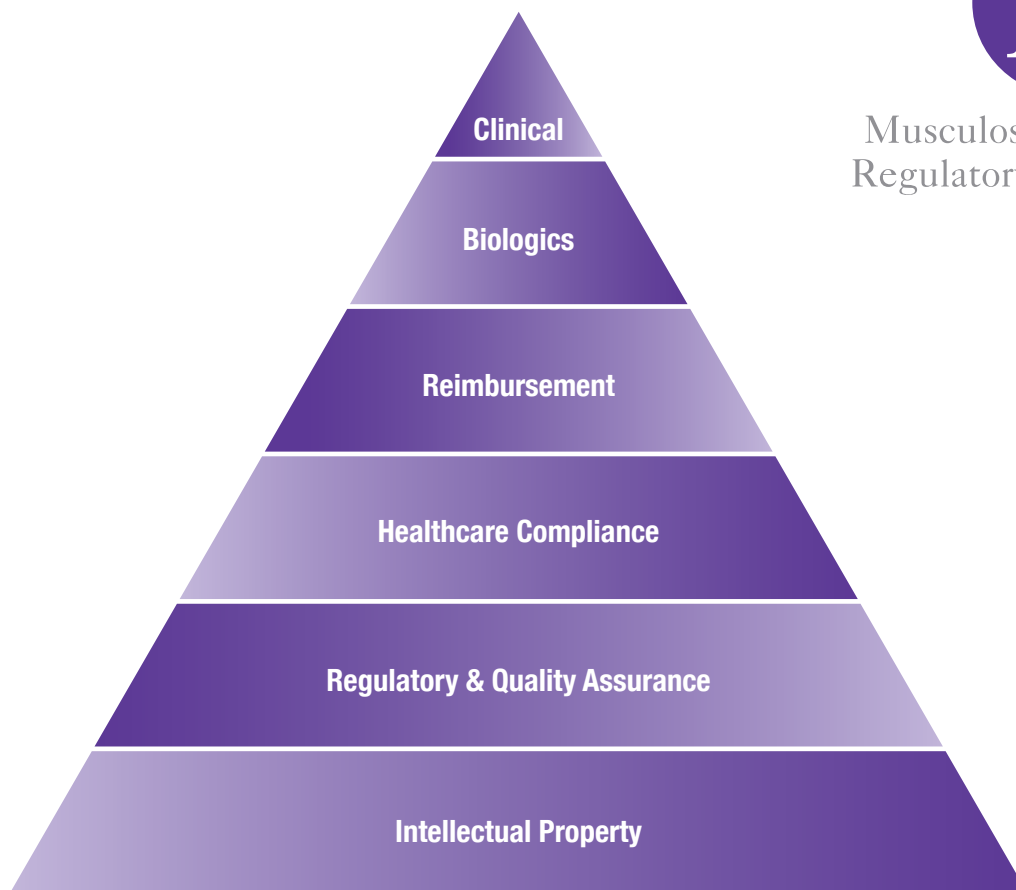




Musculoskeletal Clinical
Regulatory Advisers, LLC



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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Washington, DC 20005
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New York, NY 10022
Phone: 212.583.0250
Fax: 212.750.2112
www.mcra.com

REGULATORY (US & International)

> 1,000 Protocols Written, Submitted & Reviewed*

Key Personnel

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



Glenn Stiegman

Vice President Clinical and 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.

CLINICAL

>100 Written, Advised & Monitored Studies*

Key Personnel

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



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Abigail Allen

Clinical Trials Manager

Ms. Allen is responsible for running the day-to-day activities of the Clinical Department as well as ensuring the department's standard operating procedures (SOPs) are being upheld and maintained. During the course of a clinical trial, Ms. Allen is the point of contact for sponsors, sites, vendors, and monitors. In addition, she is in charge of managing the clinical project team and their activities to ensure project timelines and client expectations are being met. Previously, Ms. Allen worked on multiple spine IDE's along with their PMA submissions. She has also worked on more than 35 clinical trials as both a clinical manager and a study coordinator.

* all numbers include both MCRA & past experiences

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.



Steven Mounts

Sr. Director, Quality Assurance

Mr. Mounts brings over 20 years of experience from the medical device industry in the fields of quality assurance, regulatory affairs and logistics. Having held positions in nearly every area of Quality Assurance, Mr. Mounts has obtained practical, working knowledge of how to create, implement and maintain effective, compliant quality systems. Mr. Mounts is an ISO 9000 lead auditor of quality systems and has conducted over 100 supplier and internal audits. He has hosted and/or participated in over 40 FDA, notified body and regulatory agency audits/inspections. He also has extensive experience in S/W validation and electronic records compliance, responsible for overseeing the validation of over 900 S/W applications.



Patrick Biggins

Director, Quality Assurance

Mr. Biggins has over twenty years of experience in the area of Quality Systems and Manufacturing beginning as a Quality Engineering Manager. Mr. Biggins is an expert at Quality Management Systems, specifically in the areas of Corrective and Preventive Action (CAPA), Customer Complaints, Design Control (including Design Change) and Production and Process Control, including process validations based on the GHTF guidance. Mr. Biggins has assisted organizations in creating and implementing a QMS based on the FDA QSR. He has completed reviews of DMRs, process validations and instituted DHR systems at a number of small, medium and large, including multi-site and multi-national, firms. Mr. Biggins has planned and implemented systems to meet MEDDEV guidance and MDD requirements. He has implemented multi-site registrations for ISO 13485 since 2002.

HEALTH ECONOMICS, REIMBURSEMENT & PUBLIC POLICY

> 1,200 Healthcare Economic-Related Activities*

Key Personnel

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



Tim Hunter

**Director, Health Economics,
Reimbursement & Public Policy**

Mr. Hunter has over 13 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.



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.



Jeffrey D. Zigler, JD

**Director, Health Economics,
Reimbursement & Public Policy**

Mr. Zigler has over 5 years of experience assisting orthopedic and cardiovascular medical device companies achieve reimbursement goals for commercialized products, as well as for those technologies undergoing clinical research. His competencies include health economic outcomes research development and execution; clinical trial agreement development and negotiation, study site selection and reimbursement protocol review; as well as Medicare and commercial carrier repayment management. Mr. Zigler also performs coverage and market gap analyses, which are integral to sponsor organizations' business decision making platforms. Mr. Zigler works closely with medical device industry representatives, professional societies and the payor community to advocate for the adoption and appropriate reimbursement of new technologies.



Joseph "Chip" Thomas, MD

Director, Reimbursement Strategy

Dr. Thomas joined MCRA in 2011 and is responsible for development and implementation of payor strategies. Prior to joining MCRA, Dr. Thomas served as a Medical Director at Aetna Health Plans, Bravo Health, Lincoln Financial Group, Blue Cross Blue Shield Tennessee, and Unum.

Dr. Thomas is a board certified orthopaedic surgeon who has practiced in the US Air Force and private practice prior to working in the insurance industry. He has practiced in the United States and Great Britain, and more recently has worked with various insurance companies in utilization management and provided orthopaedic expertise for utilization, technical and reimbursement issues.

* all numbers include both MCRA & past experiences

HEALTHCARE COMPLIANCE

Key Services

- Compliance Program Development
- Compliance Program Assessment
- Compliance Program and Business Ethics Training
- Sanction Screening
- Hotline Management
- Audits & Investigations
- Patient Privacy
- Conflict of Interest Management
- Compliance Program Outsourcing

Team Experience:

- Fifteen Years Experience
- Compliance Program Implementation
- Business Ethics Training
- Auditing and Monitoring Expertise
- Patient Privacy Knowledge
- Provider, Payor and Pharmaceutical Experience

Key Personnel



Christopher Gingras, FACHE, CFE Vice President, Compliance

Mr. Gingras joined MCRA in 2011 and is responsible for assisting clients in identifying potential opportunities to enhance their overall compliance efforts, thereby reducing business risk, and assuring the effectiveness of the compliance program. We help organizations develop, implement and assess healthcare compliance programs with a particular focus on medical device companies and companies involved in clinical trials.

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
- Prior Orthopedic Industry Experience

Key Personnel



Andy Riutta Patent Analyst

Mr. Riutta guides companies and individuals to leverage the full value of their intellectual property. He combines his experience with medical devices and intellectual property to deliver actionable portfolio management systems, practical analyses and meaningful searches, including landscape, patentability, prior art and clearance.

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 200 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.

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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