

MCRA Services

The Most Experienced Team Guiding Technologies Through Regulatory, Reimbursement, Clinical, Intellectual Property, Quality Assurance and International Regulatory Affairs



Musculoskeletal Clinical
Regulatory Advisers, LLC

MCRA Services

The MCRA Difference

First-In-Class Team

- Industry, FDA (CDRH & CBER), CMS & US PTO
- Engineers, Attorneys, Scientists, Clinicians

Experts in All of Neuro-Musculoskeletal

- Bone; Skin, Muscle; Tendon; Ligament; Cartilage; Brain; Spinal Cord; Peripheral Nerves

Completely Integrated Strategy

- Regulatory, Clinical, Reimbursement, Intellectual Property & Quality Assurance

Unrivaled Competitive Landscape Knowledge

Our Experience

> 1,000 Regulatory Approvals

- IDE/PMA's; BLA's; 510(k)'s; HDE's
- Written, Submitted or Reviewed

> 100 Clinical Studies

- 510(k); IDE; PMA; Post-Marketing

> 1,200 Healthcare Economic-Related Activities

- Coding, Coverage/Policy Development & Studies

> 220 Patent Applications

- Written, Examined or Prosecuted

Integration of Services

The true value of MCRA is the integration of 5 business value creators (intellectual property, regulatory, clinical, reimbursement and quality assurance). MCRA prides itself on being a "one-stop-shop" for any company that would like to commence, continue or complete its technology's path to and beyond commercialization. The end result is a single source of responsibility, creating efficiencies in accountability and time management.

MCRA US FDA Regulatory Services

Core Regulatory Services

Submissions with Direct Knowledge of FDA's Mindset

- IDE; PMA; BLA; 510(k); HDE
- Pre-IDE/BLA, Day 100, & Panel Meetings

Strategy, Analysis & Development

- Predicate Landscape & Device Design
- Balancing Indications, Costs & Claims
- Leveraging Regulations, Competition & New Opportunities

Design, Review & Implement Pre-Clinical Testing

- Mechanical, Biocompatibility, Biomechanical & Animal

Other Services

- Annual Updates for PMA, BLA & HDE Devices;
- New Product Acquisitions & Transfer of Ownership;
- Adverse Event Reporting
- Site Registrations;
- Device Listing;
- US Agent for Foreign Companies

Integration with MCRA's Other Divisions

Clinical

- Customized Clinical Study Design
- Innovative & Unique Clinical Protocols
- IRB Approvals

Reimbursement

- Recommend Regulatory Pathway Based on Current Coding & Client's Financial Resources
- Healthcare Economic Data Included Within Regulatory Submissions for Future Coding Purpose

Intellectual Property

- Redesigns & Improvement of Implants & Instrumentation

MCRA's regulatory department is the most experienced team guiding technologies through FDA approval at any point of the device life-cycle: from pre-clinical testing, to FDA submission, to market approval, and post commercialization.

MCRA combines vast orthopedic industry knowledge with nearly 30 years of FDA experience. The result is that MCRA leverages data generated through mechanical, animal, or clinical testing, with unrivaled competitive knowledge, making MCRA the most experienced team to advise or execute the regulatory pathway of your technology.

MCRA's team will save your company both time and money, while creating optimal value for your technology.

MCRA Reimbursement Services

Core Reimbursement Services

Strategic Planning

- Evaluation of Current & Future Codes; Payment Assessments;
- Reimbursement Readiness Assessment

Coding & Add-On Payment Applications

- Prepare Applications for CMS, AMA & Others
- Represent Company In Front of Payors

Healthcare Policy Development

- Develop Request for Coverage Submissions with CMS, State Medicaid, TriCare, Kaiser, Federal Health System & Major Insurance Carriers

Utilization Analysis

- Assist with Health Economic Outcome Studies
- Demonstrate Cost Effectiveness, Quality of Life & Resource Utilization

Predictive Economic Utilization Modeling

Integration with MCRA's Other Divisions

Regulatory

- Recommend Regulatory Pathway Based on Current Coding & Client's Financial Resources

- Infusing Healthcare Economic Data Within

Regulatory Submissions for Future Coding Purposes Clinical

- Clinical Study Review & Recommendations

- Inclusion of Appropriate Measures in

Protocol Design to Demonstrate

"Substantial Clinical Improvement"

- Inclusion of Insurance-Required Sub-Populations

- Integration of Healthcare Economic Data

MCRA's reimbursement services guide companies throughout the multiple healthcare economic pathways: from technology development, to commercialization and beyond.

As regulatory and clinical endeavors are paramount to streamlined and successful reimbursement, MCRA's integration of our five services is both unique and effective. MCRA is the preeminent team for evaluating existing technologies' current coding, coverage and payment options. Further, MCRA's team can work to assist your company's desires to affect trends and changes in healthcare policy.

Companies with an early stage technology will find MCRA's integration imperative, while companies who have had complications in the past will find MCRA's first-in-class services invaluable.

MCRA Clinical Services

Core Clinical Services

Clinical Study & Regulatory Submission Preparation

- Study Protocol & Budget Development
- Retrospective Clinical Data Compilation
- Literature Searches & Analysis
- Investigator Selection
- Compile IRB Packets, Coordinate IRB Approvals, Compile Investigator Brochures, & Creation Consistent Case Report Forms

Clinical Study Management

- Manage Data Entry & Analysis Through Subcontract to a CRO
- Manage Site Trainings & Monitor Site Status Reports
- Negotiate IRB Approvals
- Perform Study Statistics Analysis
- Write Final Clinical Study Report for Submission

Post Clinical Studies

- “Ghostwriting” for Peer-Reviewed Medical Journals, Whitepapers, PowerPoint Presentations & Abstracts for US & International Medical Conferences

Integration with MCRA's Other Divisions

Regulatory

- IDE/PMA, IND/BLA, HDE and/or 510(k) Protocol Development

- Clinical Data & Literature Search Analysis

Reimbursement

- Integrating Healthcare Economic Data Within Clinical Study Protocols for Future Coding Purposes
- Sponsor Health Economic Outcome Studies

Intellectual Property

- Redesigns & Improvement of Implants & Instruments

MCRAs unique clinical services enable international and US-based companies of all sizes to successfully execute a clinical study. As clinical affairs should be integrated with regulatory and reimbursement initiatives, MCRA's integration is perfectly positioned to optimize quality, cost, and time.

MCRAs uses dedicated and experienced clinicians to actively manage CRO's, statisticians, investigators and IRB's, leading to faster enrollment and ultimate success. Furthermore, MCRA's clinical team is adept at writing whitepapers and other clinical publications.

MCRAs clinical expertise, coupled with our global surgeon relationships, makes MCRA a valuable clinical service addition to any company.

MCRA Quality Assurance and International Regulatory

Core Quality Assurance

Quality System Creation/ Modification/Implementation

- Compliance Assessment
- FDA QSR, ISO 13485, European Medical Device Directive; Canadian Medical Device Regulation
- Create Quality Manual; Standard Operating Procedures; Work Instructions
- Internal & Supplier Quality Audits

International Regulatory Affairs

- CE Mark Approval
- Create or Update Technical Files
- Design Dossiers
- Obtain & Maintain Device Licenses

Personnel Training

- MDD, QSR, ISO 13485, Risk Management

Other Services

Integration with MCRA's Other Divisions

Intellectual Property

- Design Control Process
- Labeling Development

Regulatory

- Uniform Approach for US & International Strategy
- Consolidated Testing Strategy
- Reports from International Submissions Utilized for US Submissions
- Design Controls to Meet FDA Requirements & Use in FDA Submissions

Clinical

- Clinical Paper Demonstrating Equivalence Based on Literature Search
- Approval with Competent Authority & Local Law
- Adherence to Harmonized Standards, Helsinki Accords, & Patient Privacy

MCRAs are the preeminent team, assisting orthopedic companies in achieving regulatory and standard compliance with U.S., European and Canadian agencies and organizations. MCRA's integration of services allows us to coordinate U.S. and international regulatory strategies to streamline the commercialization and validation processes.

It is imperative that companies understand the various nuances of U.S. quality system requirements versus those of Europe and other countries. A proper quality system is often overlooked by small companies and deemed cumbersome, but is critical for commercialization. Larger companies, on the other hand, could benefit from MCRA's services to streamline procedures and improve efficiencies.

MCRAs assistance in quality assurance and international regulatory affairs is just one of our service components necessary on the road to commercialization.

MCRA Intellectual Property

Unmatched Experience

- Former USPTO Examiners in the Medical Art
- Registered Patent Agents
- Law Firm Experience
- Orthopedic Industry Expertise
- Advanced Degrees in Biomedical Engineering

Technology Expertise

- Orthopedic: Joint, Small & Large Bone
- Spine
- Cardiovascular
- Tissue & Nerve
- Surgical Methods
- Surgical Instruments

Featured Patent Services

- Clearance / Freedom-to-Operate Searches
- Competitive Patent Landscapes
- Patentability / Novelty Searches
- Product or Technology Due Diligence
- Invalidity Searches

Featured Patent Products

- Patent Landscape Maps
- Patent Databases
- Patentability Matrices
- Expert Analysis Reports

MCRA's Intellectual Property department provides highly relevant and context-specific patent searches and IP analyses for law firms, companies, and independent surgeons and inventors, with an exclusive focus on the medical device field.

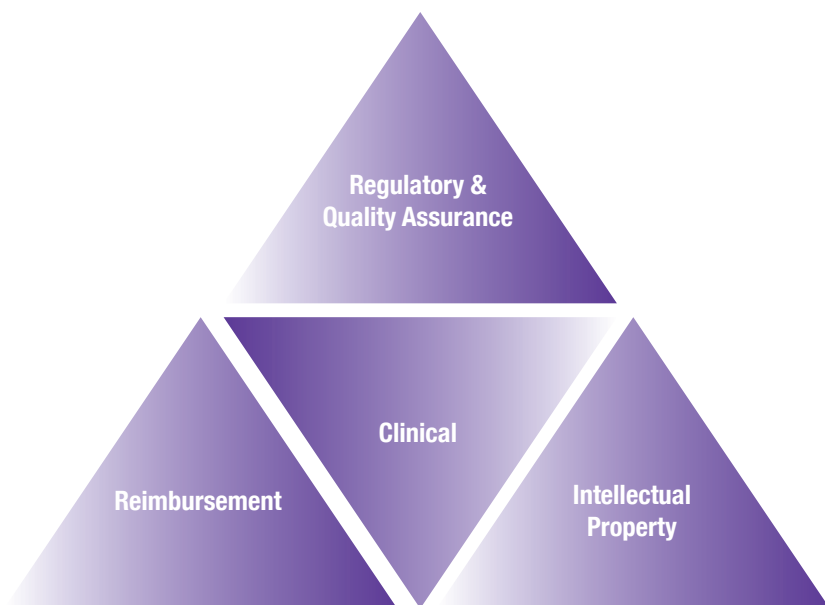
MCRA's highly qualified Intellectual Property team has years of USPTO patent examination, law firm and industry experience related to the medical device field, and we bring our expertise to every service offered. Because of our specialized educational and professional backgrounds, we afford our clients a familiarization with their medical technology, an understanding of their specific product market and the skills necessary to successfully help develop, protect, and optimize their intellectual property. Our in-depth industry knowledge gives us insight into what IP information constitutes valuable corporate intelligence, allowing us to present relevant search results in meaningful deliverables that facilitate smart business decisions.

MCRA's Intellectual Property suite of specialized services and products are particularly designed for the medical device industry, and they cannot be matched by a general search firm. We can work with you at any point during your product lifecycle to develop and execute the most appropriate, timely and cost effective strategies necessary to get your product protected and cleared for marketing. Additionally, we can assist you to build and optimize your patent portfolio to maximize its value to your company, based on short and long term goals. We can help you develop and navigate the competitive patent landscape surrounding your product or technology to identify potential infringement risks, patent trends in the relevant technologies, and/or opportunities for value creation through detailed searches of the related field. Our expertly designed interactive patent landscape databases are customized to your needs to provide you with a powerful tool that can guide your R&D efforts and streamline the patent process. We can also prepare product clearance or product patentability searches for you. Additionally, we can assist you at any stage of a due diligence process, including assessing the current health and potential value of a product or technology's intellectual property.

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Experts in All of Neuro-Musculoskeletal



Responsibility, Accountability & Execution

About MCRA

MCRA was founded in 2003 and provides “first-in-class” service to its clients through its superior knowledge, global surgeon relationships and deeply experienced management team. MCRA places particular emphasis on working with companies at all stages of development, whether they are single-technology companies or companies with several thousand technologies.

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