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Musculoskeletal Clinical
Regulatory Advisers, LLC

Company Profile:

Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA) is a highly specialized, independently operated consulting firm committed to executing regulatory, reimbursement, clinical, and intellectual property strategies to assist companies in successful value creation. Founded in 2003, the firm provides "first-in-class" service to its clients through its superior knowledge base, 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-product companies or companies with multiple technologies. The company has two locations (Washington, DC and New York), with > 25 employees worldwide.



Services:

1. **Regulatory (> 1,000 Regulatory Approvals)** – MCRA's regulatory department is the most experienced team guiding technologies through FDA approval at any point in the device lifecycle: from pre-clinical testing, to FDA submission, to market approval, and beyond commercialization. Key services include: FDA submissions (IDE/PMA, IND/BLA, 510(k), HDE, PDP); strategy, analysis and implementation; design and review pre-clinical testing; and other related services.
2. **Reimbursement (> 1,200 Healthcare Economic-Related Activities)** – MCRA's strength is in skillful execution of healthcare economic initiatives. 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. Key services include: strategic planning; coding and add-on payment applications; healthcare policy development; utilization analyses and predictive economic utilization modeling.
3. **Clinical (> 100 Clinical Studies)** – MCRA's clinical capabilities allow international and US-based companies of all sizes to successfully execute a clinical study. MCRA's competitive landscape knowledge, coupled with MCRA's global surgeon relationships, make MCRA the leading resource for a company commencing a clinical trial. Key services include: clinical study and regulatory submission preparation; clinical study execution; post-marketing studies; and other written materials.
4. **Quality Assurance / International Regulatory** – MCRA's constant vigilance of updated standards makes us a partner of choice when a company is ready to implement their international regulatory strategy and their quality system. While quality assurance is often an overlooked process, compliance with worldwide quality systems is imperative in order to gain US and international regulatory approval and ensure patient safety. Key services include: quality system creation, modification, implementation; international regulatory affairs; personnel training and other related services.
5. **Intellectual Property (> 220 Patent Applications)** – MCRA's direct experience as employees of the US Patent and Trademark Office allows us to guide and strategize with orthopedic companies throughout the different intellectual property pathways: from concept, to patent, to portfolio optimization. Key services include: evaluation and analysis of current IP portfolio; portfolio management; competitive patent landscape; and patent application preparation.

Integration:

MCRA believes in a full partnership between intellectual property planning, regulatory strategy, clinical study design, reimbursement and quality system initiatives, leading to elevated capabilities and increased company value. 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 and eliminating lapses in accountability often found during the value creation process of any technology.