

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

MCRAs 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.

MCRAs 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.

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