

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 is 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.