MRC Global, LLC offers a comprehensive solution for your regulatory, quality or clinical consulting needs with a focus on life sciences, including medical devices, biologics, and tissues. We are proud to offer tailored services to meet your project completion or strategic guidance objectives, regardless of company size or budget. We also offer access to transactional and physician leadership / Key Opinion Leader (KOL) advisory services and provide assistance with Sunshine Act reporting.

Device Experience

- Spinal, orthopedic, trauma and neurological implants and bone void fillers
- Biologic, tissue and human cellular based products
- Personal protection equipment (masks, gowns, drapes)
- Medical mobile applications
- Capital equipment with software (cardiac, infusion, imaging, navigation, light and laser- based devices)
- Dental devices

Christine's extensive regulatory background has made her a sought-after resource by established medical device manufacturers and product development teams, as well as new device starts-ups and investors evaluating market potential. Christine will assist in overseeing strategy and interfacing with governing bodies. With an extensive background in the medical device and biologics industry that includes VC funded startups to fortune 100 device manufacturers, Dawn's depth of expertise allows her to develop custom client solutions, go-to strategies for clinical studies and evaluations, and a risk based approach related to regulatory and quality systems. David is a trusted advisor for medical device/pharmaceutical companies, health systems, community/rural hospitals, specialty health service providers and single/multi-specialty medical groups. With our 65+ years combined experience in medical device and transactional and compliance consulting experience, we will put our depth of knowledge to work for you.

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Expert Services

- Global Regulatory assessment, planning and strategy
- U.S. traditional and special 510(k), Emergency Use Authorizations (EUA), Investigational Device Exemptions (IDE), Pre-Market Approval (PMA) and *de novo* preparation and submission
- European technical file and design dossier preparation
- Preparation for Medical Device Regulation (MDR) implementation in Europe
- FDA, Notified Body, and ISO 13485 registrar audit preparation and participation
- Quality Systems
  - Establish 21 CFR 820 and ISO 13845 (2003 & 2016) Quality System
  - Provide short-term or interim Quality System maintenance
  - Prepare and assist with Medical Device Single Audit Program (MDSAP)
- Tissue Auditing, Licensing and Registration
- Supplier and Internal Audits
- Design Controls implementation and completion of Design History Files
- Clinical Evaluation Reports and Literature Reviews
- Medical Device Reporting and Vigilance Reporting
- Labeling and Instruction for Use
- Promotional literature assessments including surgical techniques, brochures and websites
- Remediation resulting of audits or inspections
- Training and Mentoring
- Due Diligence and Integration Planning
- Valuation service (company or device)
- Royalty arrangements
- KOL status and payment rate sheet development
- Co-branding fair market value