

Reaching the market in time

A global approach for medical devices Quality Management System



Medical Device Quality Assurance Compliance Consultants

Services

- Development of Quality Management System
- ISO 13485 and US FDA QSR Consulting and Certification for Medical Device Manufacturers
- Implementation of Pre-production Quality Management System
- Medical Device Audits for ISO 13485, US FDA QSR and more
- Pre-Production QMS Implementation for Startup Medical Device Companies
- Quality System internal audits
- Supplier ISO 13485, US FDA QSR and GMP audits
- Vigilance & Post-Market Surveillance
- Training

Gemar is an independent Medical Device Consulting firm, operating worldwide with extensive Regulatory Compliance Experience.

Global Medical Device Registration and Medical Device Approval

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