Medical Expertise

Optimal Productivity for Healthy Profitability
Medical device manufacturers operate in one of the world’s most competitive and highly regulated industries where success can hinge on time-to-market and traceability. That’s why Class 1, 2, and 3 device manufacturers turn to EnterpriseIQ from IQMS for advanced capabilities that help sustain their competitive advantage.

Manage Compliance and Quality
IQMS understands that medical manufacturing requires higher standards. EnterpriseIQ’s medical quality suite provides the tools and capabilities necessary to cost-effectively manage compliance with quality issues while facilitating internal communication and collaboration. These industry-specific modules address:

- ISO 13485 and ISO 9001 standards
- FDA and CFR requirements
- Up-front risk assessment
- Electronic signature and document control capabilities
- Complete audit trail of manufacturing processes
- Comprehensive Corrective Action/Preventative Action (CAPA) functionality
- Non-conforming product review and tracking

Complete Communication
The single database structure of EnterpriseIQ increases communication across all your departments. Eliminating the need for duplicate data entry translates to features such as customer service being notified about quality issues with parts before an order is entered.

Meeting Medical Device Manufacturers’ Needs
IQMS offers a powerful solution tailored to comprehensively meet the unique challenges of the medical manufacturing industry. When FDA compliance, medical device quality and enterprise-wide traceability are critical factors of success, IQMS customers turn to our customized modules (such as our suite of medical quality tools including DHR) to address their ever-evolving and complex needs.

Seamless Tracking
The Device History Record (DHR) module allows medical device manufacturers to cost-effectively:

- Eliminate time-consuming, paper based tracking systems
- Streamline product development
- Better ensure quality standards compliance
- Gain total visibility and control over the manufacturing process

Powerful Tools for Success
EnterpriseIQ from IQMS offers a comprehensive, enterprise-wide solution that provides a host of critical capabilities needed for success, such as:

- Lot and serial tracking
- Warranty and service tracking
- Complaint tracking
- CAD library management