



Solutions in Operations

*How do you design,
manage, and improve your
key products and work
processes?*

*How do you ensure effective
management of your
operations?*



ISO 13485 Implementation

The key to long-term competitiveness in today's global marketplace includes products of optimum quality, at competitive prices, delivered in record time. Today, the ability to meet rigid quality standards is an expectation rather than a competitive advantage. A company must have, to survive and prosper, an in-depth Quality Management System; one that will meet and exceed the demands of customers. ISO 13485:2016, the current Quality Management System standard for medical devices, is aligned with US FDA and EU medical device regulations.

WORKING WITH IMEC

To assist companies, IMEC works on-site to instruct and guide all implementation activities to ensure a full understanding of the requirements, and to maximize the benefits of the Quality Management System. Additionally, IMEC serves as a catalyst to lead its clients through a full QMS implementation.

Working with a company's staff, IMEC provides implementation training and assistance through:

- Management awareness/employee overview for the requirements of ISO 13485:2016 and GMP
- Quality Manual and Procedures review and development
- Distribution of document templates as needed
- Process identification and mapping
- Quality planning and quality policy/objectives
- Management review
- Development of job descriptions/training schedules/training effectiveness analysis
- Product realization - including determination of customer requirements, supplier evaluation, and development
- Measurement and analysis of process activity
- Customer satisfaction/analysis
- Management of nonconforming product
- Continual improvement, corrective & preventive action
- Internal auditor training
- Integration of FDA QSR (21 CFR Part 820) regulations
- Risk Management planning

IMEC can assist with the development of required documentation and provide guidance on implementing the documented policies and procedures. The completion of assignments, development and implementation of plans and procedures, as well as overall accountability for the completion and implementation of identified activities, resides with the company. It is important that the company dedicate at least one individual to focus on implementation of QMS activities.

For more information, contact IMEC at 888-806-4632 or info@imec.org.

POTENTIAL BENEFITS

IMEC's assistance in implementing a sound Quality Management System include:

- An understanding ISO 13485:2016 and FDA QSR requirements for management & employees
- The tools and knowledge to maintain and continuously improve their QMS
- Trained internal auditors to monitor/report on the effectiveness of their QMS
- Readiness for the initial Certification Audit
- The ability to respond to the registrar's certification audit findings
- Focus on product safety and customer feedback

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