ISO 13485

Ensuring the Success of Your Medical Device Quality Management System (MDQMS)

ISO 13485 is an ISO standard, published in 2003, that represents the requirements for a comprehensive management system for the design and manufacture of medical devices. This standard supersedes earlier documents such as EN 46001 and EN 46002 (both 1997), the ISO 13485 published in 1996 and ISO 13488 (also 1996).

The certification of a quality management system, specifically for medical devices, to ISO 13485 proves advantageous, and in many cases essential, for medical companies which export their products to the global market.

ISO 13485: 2003 has been harmonized against the three Directives (Medical Devices, In-vitro Diagnostic Devices and Active Implantable Devices) so certification to this standard by an accredited certification body which are reputed worldwide automatically demonstrates compliance with specific clauses in the regulations.

Why choose i3 Consulting?

- ✓ B-Pharm, RAC, Msc (Microbiology), BE (Electronics) Certified and experienced technical team for consulting services.
- ✓ Experience of successfully providing ISO 13485 Consultancy for 120 organizations across India, Malaysia, UAE, Srilanka etc...
- ✓ Turn key services offer includes Consultancy, Training, Documentation and Certification.
- ✓ Improved legal and regulatory or contractual requirements compliance.
- ✓ Risk identification and management.
- ✓ Complete transfer of technology by the end of project
- ✓ Improved ability to respond to Customer Requirements.
- ✓ Phase wise payment option.

Why Consultant is required for ISO 13485 Certification.

- ✓ Learn about the ISO 13485 Standard
- ✓ Lean about trends in medical device industry
- ✓ Good manufacturing practice (GMP)
- ✓ To perform an ISO 13485 Gap Analysis
- ✓ Plan your ISO 13485 Implementation project
- ✓ Training on ISO 13485 and Regulatory aspects
- ✓ Document your Quality Management System
- ✓ Risk analysis - FMEA / HACCP
- ✓ Implement your MD-QMS and conduct business
- ✓ Audit your QMS using Process Auditing
- ✓ Selection of Accreditation Body / Certification Body
- ✓ Registration Audit

Let us help you become ISO 13485 certified!

Call us (24x7) + 91 80 5064 8432

Or

Write to *info@i3consulting.in*

i3 Consulting

WE QUALIFY YOU

www.i3consulting.in