QUALITY AND REGULATORY CONSULTING SERVICES

Regulatory strategy and quality management system (QMS) implementation are often two of the most challenging aspects of launching a medical device. The process can seem complex and overwhelming for new device developers and, unfortunately, there is no one-size-fits-all guide that defines the exact regulatory path for a specific device. Further, the use of an inflexible, standardized QMS is typically outside of the monetary and operational constraints of many smaller companies.

Unlike other consulting firms, iFyber can help simplify the process to create and implement a manageable and cost-effective plan that makes sense for your specific product and business objectives. We work with you to define individualized strategies and act as an extension of your team to provide regulatory support during all phases of medical device development. Through assessments of your current and future operational goals we aim to provide a tailored regulatory strategy and QMS that fits your organizational needs.

SERVICES	iFyber	Other Consultants
Regulatory Strategy	Individualized to product and organizational goals	Standardized approaches
QMS Development	Documents and procedures optimized to fit workflows	Boilerplate documents and templates
Risk Management	Appropriately manages business and regulatory risks to meet objectives	Seeks to eliminate all risk at the expense of other opportunities and benefits
Project Timelines	Quick turnaround times	Longer timeframes
Deliverables	Actionable project plans	Generalized suggestions
Communication Style	Collaborative and transparent	Transactional
FDA Approach	Cooperative and communicative	Avoidance and reticence

We understand the challenges of medical device development–what works for one size company will not work for another. Through early and often conversations with regulatory agencies and critical examination of the required regulations, standards, and guidances we help our clients efficiently navigate the regulatory landscape with confidence.

To legally market a medical device in the US, manufacturers must design, develop, test, and manufacture products according to Current Good Manufacturing Practices (cGMPs) and other applicable standards and guidances. In support of these efforts, iFyber offers individualized regulatory and quality consulting services, including strategy development, regulatory submission support, and Quality Management System development.

REGULATORY STRATEGY AND CONSULTING

- Submission strategy development
- Predicate identification for premarket notifications
- 513(g) Requests for Information, device classification
- Intended use and claims
- Identifying applicable regulations and standards
- Informational meetings with FDA

REGULATORY SUBMISSIONS AND POST-MARKET ACTIVITIES

- Pre-submission applications
- Investigational Device Exceptions (IDE)
- 510(k) Premarket Notifications
- De Novo Petitions/De Novo 510(k)
- Emergency Use Authorizations (EUA)
- Additional Information requests
- Post-market evaluation of device changes
- Collateral materials and labeling

QUALITY MANAGEMENT SYSTEM (QMS) DEVELOPMENT AND SUPPORT

- Quality System Gap Analyses and Audits
- Establishing QSR (21 CFR Part 820)/ISO 13485 compliant quality systems
  - o Modifying quality system to include FDA/ISO requirements
  - o Drafting manuals, policies, and procedures
  - o NCR/CAPA procedures
  - o Developing work instructions and process flows
  - o Ensuring appropriate design, change, and document control
  - o Internal Auditing
- Design and Development Planning
- Design History Files
- Manufacturing documentation and design transfer activities
- Validation master plans, SOPs, and protocols
- Quality Assurance Support and Quality System Training

iFyber is a preclinical research organization offering customized services to companies that operate at the interface of chemistry, microbiology, and materials science. iFyber is unique. We pride ourselves on providing access to top scientists and creatively solving problems with quick turnaround times.

THINK OF IFYBER AS:

- Consultants with a laboratory to back up ideas with data
- An academic lab, solving R&D problems on corporate or start-up timelines
- A testing lab that develops new methods tailored to clients' products and services
- An extension of your quality, regulatory, and R&D teams