POWERS REGULATORY CONSULTING

REGULATORY CONSULTING
MEDICAL DEVICES

Powers Regulatory Consulting is a medical device regulatory consulting firm that can be an extension of your organization to help with any regulatory needs.

Consulting with regulatory early will help make a more efficient and predictable product development process. Grace Powers can provide valuable expertise and insight into the regulatory process.

REGULATORY STRATEGY

A regulatory strategy early in the development process is critical to efficiently move a medical device through product development.

- When should we talk to the FDA?
- Do you need an FDA submission? An EU submission?
- Do you need a clinical study?
- What is the classification of my device in the US and Europe?

REGULATORY STRATEGY SERVICES

Device Classification Document that includes :

- Strategy planning
- Regulatory submission pathway
- Predicate devices (if applicable),
- Next Steps with FDA
- Applicable Guidance Documents
- Overview of product testing requirements

Grace Powers, MS, MBA, RAC (US, EU, Global, Device)

Grace Powers is an independent regulatory affairs consultant. She founded Powers Regulatory Consulting in 2015 to help clients with regulatory strategies and submissions. Her clients have included universities, investors, start-ups, and mid-size medical device companies. She has twenty years of industry experience in medical devices including research and development.

Atlanta, GA

PRE-MARKET SUBMISSIONS

- 510(k)- Traditional, Abbreviated or Special
- 513(g)- Request for designation
- Pre-Submissions (Pre-IDE, Pre-510(k), Submission Issue, Significant Risk study, etc)
- Investigational Device Exemption (IDE), supplements and annual reports
- Pre-Market Approval (PMA), Supplements, Real Time Reviews, 30 day noctices and annual reports
- European Technical Documentation
- QC/QA of regulatory submissions

REGULATORY SERVICES

- eCopy production
- Instructions for Use Writing
- Labeling Review
- Promotional and advertising materials review
- Establishment registration and device listings
- Regulatory due diligence and integration
- Regulatory project management
- Regulatory training
- Expert witness for legal cases

POST-MARKET ACTIVITIES

Even after there is a device clearance or approval, there are many post-market requirements.

- Regulatory Change Assessments including Letters to File
- Annual Reports
- Change management for USA and EU Class I, II and III devices
- Change notification to notified body
- Technical Documentation audits
- Dossier lifecycle management

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