

Medical Devices

*Seasoned professionals
guiding winning practices*



SMART 
CONSULTING GROUP

Smart Consulting Group – Medical Devices

The new environment

In recent years there has been an explosion in the number of new devices reaching the market place and many of these are also being linked with various pharmaceuticals to provide their therapeutic benefit.

To service this sector appropriately, clients need a seasoned team that understands all sides of the technology as well as the new rules and regulations relating to quality and regulatory expectations. Nowhere is this more the case than in relation to device drug combination products which now has a special branch of the FDA specifically charged with regulating this sector.

Why Smart Consulting Group?

■ Experience

We have an experienced team of professionals that can address, answer and resolve your concerns due to our integrated holistic team approach to problem solving.

■ Program management

We drive our approach using a customer-driven project management philosophy which underpins everything we do structurally.

■ Use of process excellence tools

Through the use of process excellence tools we ensure that our approaches to problem resolution are always efficient, cost effective and organizationally robust.



Services

The following is a list of services we can provide for medical device companies:

Quality

- Quality systems support
- GMP inspections
- Audits: GXP, vendor and internal regulatory
- Stability management/strategy
- Validation
- Master plans
- GXP training
- Compliance remediation

Manufacturing

- Strategy
- Sterilization support
- Technical writing

Regulatory

- Submissions
- Post market surveillance systems
- FDA mediation

Call us at 610-344-9218 to find out more.



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