

Regulatory Affairs

*Experienced resources
providing detailed results
on time and budget*



Smart Consulting Group – Regulatory Affairs

Imprecise regulatory work can prove costly to a company, so why wouldn't you use an experienced team?

At Smart Consulting Group we use our experienced team working closely with the FDA to generate measurable performance for our clients.

Let our resources make this difference for your company.

We offer the following services:

- Regulatory strategy
- Regulatory project management
- Advertising promotion and labelling
 - Strategy
 - Medical, legal and regulatory review
 - Package insert
 - Website and social media
- Labelling strategy
 - Initial
 - Expansion
 - 505(b)2 submissions
- Regulatory agency meeting preparation
 - Preparation for an advisory committee meetings
 - Preparation of milestone meeting documents
 - Operational briefing documents
- Regulatory submission support IND and NDA BLA 510 K
 - IND/CTA preparation
 - Conversion of IND to eCTD format
 - Annual reports CBE and PAS submissions
 - Assessment of safety surveillance systems
 - State licensing for storage and distribution
 - Due diligence

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



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