REGULATORY AFFAIRS

Bannick LLC
a primary device group

BannickPrimary.com

Bannick provides clinical, regulatory, quality, auditing, and medical writing consulting services to the medical device industry to help you get your product through regulatory approvals and to market.

Regulatory Affairs Consulting Services We Offer:

- Development & execution of regulatory strategies
- Support "napkin" sketch to post market activities
- MDD/MDR Gap Assessments & Remediation
- IVDR support
- Submission preparation for US, EU & global markets: Tech Docs, PMAs, 510(k)s, DeNovo, IDEs
- Predicate device and claims evaluation
- Regulatory Intelligence
- FDA Meeting planning and support
- Technical file & notified body response

Increasingly complex regulatory requirements and rapidly evolving technology can create headaches for medical device developers, and we can help you navigate this complexity. Through our strategic guidance and input into the product development process, the Bannick team will lead you through the changing regulatory environments.

Our integrated approach helps our global clients overcome regulatory hurdles, assisting from one regulatory milestone to the next, reducing risk and facilitating compliance on the way towards a successful submission.

We want to help you improve patient lives by putting devices on the market that are shown to be safe and effective. As an industry leader who has worked in the medical device clinical area, our high-performing, adaptive team is ready for any task.