

QUALITY MANAGEMENT



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.

Quality Consulting Services We Offer:

- Implementation of Quality Management Systems (QMS)
- Remediation of existing QMS
- Risk Management/FMEA
- Audit response & CAPA
- Complaint management & reportability
- Create quality manuals & procedures
- Change management support
- QMS training
- Specialize in ISO 13485:2016, 21 CFR 820, and ISO 9001:2015

Establishing a Quality Management System is a global requirement for the medical device industry. Product development and patient safety begins and ends with quality management. Having an efficient Quality Management System is a business differentiator and shows your commitment to continuous improvement.

Bannick partners with clients to evaluate and implement effective Quality Management Systems. Whether starting from scratch or helping you improve your existing system, we use a right-sized, risk-based approach to meet your individual business needs.