CLINICAL QUALITY

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.

Clinical Quality Services We Offer:

- Clinical SOP gap assessments
- Clinical SOP development
- Study site SOP development
- Clinical document template development (sponsor, study site)
- Audit strategy
- Audit preparation and coaching
- Clinical quality training
- Clinical audits:
  - For-cause/ad hoc (e.g., do you have a questionable investigator?)
  - eTMF
  - Pre-BIMO (site and/or sponsor)
  - Mock BIMO (site and/or sponsor)
  - Vendor (core lab, CRO, etc.)
- Audit response and CAPA

Sponsors of clinical investigations involving human drugs, biologics, devices, and combination products are required to provide adequate oversight to ensure protection of human subjects and the validity of the data submitted to FDA. This is a key concept of Good Clinical Practice.

Dedication to clinical quality is a business differentiator and shows your commitment to continuous improvement.

Bannick partners with clients to evaluate and implement effective Clinical Quality Programs. 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.