

AUDITING



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.

Auditing Services We Offer:

- Technical File Audits
- Clinical Trial Audits
- Internal Audits
- Supplier Audits
- Process Audits
- Gap Assessments
- Audit Responses
- CAPA

Our auditors help you achieve and maintain compliance with standards and regulations in the US and around the world. We can identify compliance gaps and find opportunities for improvement.

We can help ensure your suppliers meet your quality expectations and do not negatively impact your QMS. Bannick will help make sure your processes are meeting your requirements through process audits.

We specialize in audits for quality management systems for ISO 13485:2016, 21 CFR 820 and ISO 9001:2015.