MEDICAL WRITING

Bannick LLC
a primary device group

BannickPrimary.com

At Bannick, we partner with you to get your product through regulatory approvals and to market. We provide clinical, regulatory, quality, auditing, and medical writing consulting services to meet your needs.

Medical Writing Consulting Services We Offer:

- Clinical evaluation strategy development
- Claims analysis
- Creation of MDR documentation such as:
  - Clinical Evaluation Plans & Reports (CEP, CER)
  - Summary of Safety & Clinical Performance (SSCP)
  - Post Market Clinical Follow-up Plans & Reports (PMCF P, PMCF R)
- Prepare manuscripts & clinical study reports
- Evaluation of PMS data
- Conduct scientific literature searches
- State-of-the-Art summary (SOTA)
- Validation reports

Today's medical device industry is a complex and evolving regulatory environment. Bannick's expertise in regulatory and medical writing can help you navigate this complexity.

Bannick's experienced staff have authored over 150 clinical evaluation reports and plans. Our knowledge of working with notified bodies has allowed us to write 15 MDR submissions with no major nonconformities. In addition, we have prepared over 75 PMCF plans and reports and are well-versed in MDR requirements for PMCF.

We've supported products in several medical areas including, but not limited to, cardiology, urology, brain stimulation, neurostimulation, infusion pumps, peripheral vascular, wound care, and urinary incontinence.

Our focus on quality, flexibility, and collaboration leads to high-quality deliverables and ensures efficient and accurate documentation.