Our high-performing, adaptive team at Bannick Primary are subject matter experts, ready to tackle any aspect of medical technology product development and clearance.

We can provide strategic direction and technical execution to ensure projects are completed compliantly, on time, and on budget.

Along with our years of industry experience, the team at Bannick LLC are active members of professional societies such as Regulatory Affairs Professional Society (RAPS), American Society for Quality (ASQ) and American Medical Writers Association (AMWA). This ensures that we are always up to date with current trends and best practices.

Whether you have a small task or a full system redesign, Bannick LLC is ready to be your partner

**Bannick LLC**
**Medical Device Consulting since 1998**

**CORE VALUES**

- We promote a healthy and balanced life for our team, our clients, and patients worldwide.
- We act for the greater good of the organization, not our self-interest.
- We exemplify integrity and loyalty.
- We are knowledgeable and discerning; collaborative and adaptable.
- We are mindful of confidentiality.
- We deliver high quality, efficient solutions.

**info@bannickprimary.com**
**BannickPrimary.com**

**KEY BUSINESS PRACTICES**

- We listen to understand, translating your needs into targeted solutions.
- We begin with the end in mind. We re-assess and adapt should challenges arise.
- We work strategically, then transactionally.
- We practice lean billing practices.

Medical Device Consulting Since 1998

Bannick LLC
a primary device group

**We are your experienced partner, providing strategic solutions to bring medical technologies to global markets**

Offices in MN and FL
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a primary device group

*We are your experienced partner, providing strategic solutions to bring medical technologies to global markets*

**Whatever your goals are, Bannick Primary is here to partner with you to achieve them.**

**Our integrated approach helps our global clients overcome regulatory hurdles, reduce risk, and facilitate compliance on the way towards a successful submission and product lifecycle.**

**We want to help you put devices on the market that are safe and effective for patients by accelerating the global device-to-market process. We know that the most efficient way to get your product to market matters, and we will work with you to determine what solution is best suited to your needs.**

**When you need guidance working with regulatory agencies to negotiate submission strategy, to prepare or maintain your quality management system, or to design a clinical strategy and complete required documents, including looking ahead to reimbursement, we truly have "been there, done that."**

## Regulatory Affairs

**Our regulatory experts can accelerate the complex device-to-market process.**

- Submission preparation for US, EU and global markets
  - Tech Docs, PMA, 510(k), DeNovo
  - Investigational Device Exemption (IDE)
- FDA /Notified Body Meeting support
- Gap Assessments and Remediation
  - MDD to MDR / IVD to IVDR

## Medical Writing

**Our team's extensive background coupled with excellent writing skills results in your document success.**

- Design and execution of Clinical evaluation process / CEP and CER
- Summary of Safety and Clinical Performance (SSCP) and Clinical Development Plans (CDP)
- Literature searches and statistical analysis
- State-of-the-Art (SOTA) analysis
- Review of existing documents

## Quality System

**Our Quality services are tailored to help you achieve your goals.**

- QMS development and redesign
- Risk-based and right sized
- Audit, complaint and CAPA responses
- Root cause analysis and process mapping
- Procedures, training and system integration
- MDD to MDR transition

## Audits

**Our experienced team can support you through the entire audit process.**

- Technical File Audits
- Clinical Trial / BIMO Audits
- Audit responses / warning letters
- Back-room support
- Internal / Process / Process Audits

## Clinical Affairs

**Our expertise can optimize your path to regulatory approval.**

- Clinical study design/execution
- Protocol and CRF development
- Statistical analysis
- Usability and claims evaluation
- Post Market Clinical Follow Up (PMCF) plans and reports