YOUR PARTNER IN QUALITY SYSTEM DEVELOPMENT

Consistency, quality and repeatability are key to a successful medical product company. A robust quality system helps to confirm that your organization is designing and producing safe medical products, whether you are a newly emerging company or an existing multinational corporation.

BBA's philosophy for developing and implementing Quality Systems is to execute a staged approach to meet your needs based upon your current phase of product development. Our team will ensure that the systems we develop meet regulatory requirements while not burdening you with cumbersome systems.

OUR QUALITY SYSTEMS INCLUDE:

- Full-service data management
- US QS Regulation contained in the Code of Federal Regulations
- Requirements of ISO 13485 and/or ISO 9001, CMDCAS (Canada), and TGA (Australia)
- Management and organization responsibility
- Quality manual preparation
- Document control
- Personnel training
- Design control
- Risk management
- Purchasing and vendor controls
- Identification and traceability
- Inspection and calibration
- Production and process controls
- Nonconforming materials
- Packaging and labeling control
- Corrective and Preventive Actions (CAPA) process
- Handling, storage, distribution, and installation
- Process validation
- Sterilization
- Product release
- Complaint handling and product returns
- Field corrective actions
- Management review

QUALITY SYSTEM IMPLEMENTATION

- Full-service data management
- SOP implementation and employee training
- Corrective and Preventive Actions (CAPA)
- Process Quality system audits
- Quality system maintenance
- Notified body selection
- ISO 13485/9001 certification
- Quality management

QUALITY SYSTEM IMPLEMENTATION

As a medical company, you are required to have a documented process and a valid and reliable information about your product throughout its lifecycle. BBA can conduct a gap analyses to assess your company's internal Quality System and analyze your clinical sites' ability to accurately collect and document information pertinent to your clinical trial. We also help you prepare for audits (FDA, Notified Body, or other Regulatory bodies) and conduct various types of internal and external auditing including:

AUDIT SERVICES

- ISO 13485/9001
- Quality System Regulation (QSR)/ Current
- Good Manufacturing Practices (cGMP)
- Vendor and supplier audits
- Institutional review boards
- GCP (Good Clinical Practice)
- GLP (Good Laboratory Practice)
- GTP (Good Tissue Practice)
- QSR (Quality System Regulations)
- EU medical device directive
- Medical Device Reporting (MDR)/ vigilance reporting systems

REGULATORY INSPECTION PREPAREDNESS

- Conduct FDA and MHRA mock regulatory inspections
- Provide training to prepare investigator sites for regulatory inspections
- Assist preparing responses to inspection findings

SYSTEM VALIDATION SERVICES

- Electronic computer systems
- Databases

VALIDATION AND AUDIT OF STUDY RELATED DOCUMENTS

- Protocols
- CRFs
- Clinical study reports
- Study files
- Tables & Listings

CONNECT WITH BBA AT: info@bbacro.com or follow us on LinkedIn and twitter today. For more information about BBA and other clinical trial and regulatory strategies we offer visit www.bbacro.com