



Full Service Medical and Technical Documentation

Mains Associates' team of experienced science and medical writers is able to communicate with your researchers, scientists, and managers to create a broad range of content, helping you achieve your business objectives. Whether using your templates or helping you create a template structure, we deliver accurate documentation on time, even under tight deadlines. If your product line is broad, working with Mains Associates provides you multiple topic experts for a lower cost than a single employee!

Documentation Services

FDA Documentation

- CTD/eCTD
- BLA
- IND
- NDA
- PMA

Other Documentation

- Clinical Development Plans
- Product Development Plans
- Review Articles/Manuscripts
- Sales Sheets
- Abstracts
- Posters and Presentations
- RFP/RFI
- ISO Documentation

Clinical Documentation

- Template Standardization
- Protocols
- Informed Consent
- Clinical Trials Reports
- Investigator Brochures
- Quality and Training Manuals
- GxP Audits and Reports
- SAE/AE Narratives
- Toxicology Reports
- Statistical Analyses
- PK Reports
- ISS/ISE
- CMC Reports
- SOP and Work Instructions
- MSDS

Complete Content Solution

Our grant writers, who have won more than \$1Billion in federal grants for clients, can help you create a winning grant proposal. Once you've won the grant, we can support you with our clinical and FDA documentation services, and complete the cycle with business content development to help you find the right partner, pitch a VC, or market your product or service to customers. After more than 25 years supporting research organizations varying from startups to world leaders, you can count on Mains Associates to deliver on-time and on-budget.

To discuss your particular Documentation needs, please contact us at info@mainsgate.com or call us at 510.548.1262

