Has an agency ever posed questions arising from avoidable errors?

Precision Research, Inc.

Document quality control is often neglected or overlooked.

As lengthy, complex, and multiple documents are developed, mistakes are often made because of:

- Inadequate or lack of knowledgeable staff on the project
- Inaccurate or incomplete information
- Inconsistent or conflicting data within or between documents
- High-pressure timelines
- Misinterpretation of data

At PRI, we view quality control as essential and complementary to medical writing. Document quality control is necessary to avoid problems that may cause delays in submission or agency review. PRI:

- Works on **all clinical documents** relevant to NDAs and BLAs
- Engenders the same kind of **collaborative approach** as with medical writing
- Partners with clients and adds value by becoming part of the **review process**
- **Detects errors** in the database that can be corrected prior to regulatory submission
- Provides **clinical input** that enhances document development
- Ensures **consistency** where needed—within and between documents

PRI routinely provides quality control for:

- Clinical Investigator Brochures and their annual updates
- Protocol and Protocol Amendments
- Clinical data (including summary tables and listings)
- Patient narratives
- Interim and Final Clinical Study Reports
- All NDA/BLA submission documents
- Periodic and Post Approval Safety Updates
- Responses to agency inquiries

Our document Quality Control is distinct from your Quality Assurance (QA) review. We focus on the document and its data.

You can also turn to PRI for medical writing and quality control for documents that are not part of a submission package.