PE PharmEng Technology

THE LEADER IN GLOBAL ENGINEERING AND CONSULTING SERVICES FOR THE LIFE SCIENCES INDUSTRIES

CONTACT US

📞 **416-385-3922** (CANADA)
919-474-8309 (UNITED STATES)

✉️ techservices.pti@pharmeng.com

Technical Writing

At its core, technical writing involves the translation of highly complex information into accessible formats, including everything from drug development reports & clinical trial documentation to product manuals & regulatory submissions. Our technical writers ensure that each document adheres to guidelines & regulations set forth by regulatory bodies.

When precision & clarity are paramount, technical writing plays a pivotal role. From R&D to regulatory affairs, effective communication is essential to ensure compliance, safety, & successful product launches. Technical writing bridges the gap between complex scientific concepts & clear, understandable documentation.

Our skilled technical writers possess a unique blend of scientific knowledge, writing proficiency, & regulatory expertise. They are adept at distilling complex data into concise summaries & creating comprehensive documentation that maintains compliance with Good Manufacturing Practices (GMP) & Good Clinical Practices (GCP).

Examples of content types in pharmaceutical technical writing are as follows:

Standard Operation Procedures (SOPs):

Written guides that articulate a conceptual description of a process from start to finish.

Investigational New Drug (IND) Applications:

IND Applications are technical documents submitted to regulatory bodies to request authorization for the conduct of clinical studies for novel pharmaceutical products.

New Drug Applications (NDAs):

NDAs are technical documents submitted to regulatory organizations to get permission to market a new pharmaceutical product.

Safety Data Sheets (SDSs):

SDSs are documents that detail risks & secure handling of hazardous materials used in production of products.

Clinical Dossiers:

Clinical dossiers are technical documents that summarize clinical evidence, such as safety & efficacy, of a new product & are used for marketing & educational purposes.

Validation Protocols and Reports:

Validation protocols & reports are the benchmark tools that ensure compliance in a pharma process or product over time.