TLI Development

A Pharmaceutical Support Service Company

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Regulatory Affairs:

- IND/ NDA/ ANDA/ BLA/ PLA/ ELA/ DMF/ CTX/ MAA Preparation & Review
- Analytical Methods & Validation Report Review
- Specifications Development & Review
- Product Development Reports
- Stability Testing Protocols & Stability Summaries
- Prescribing Information/ Labelling Preparation & Review/ Advertising

Medical Writing:

- Preclinical Reports - Compilation & Review
- Clinical Protocols
- Informed Consents
- Study Reports
- External Publications
- Investigator Brochures

Quality Assurance:

- cGMP Audits
- Mock Pre-Approval Inspections (PAI)
- SOP Reviews/ SOP Writing
- Product/ Process Reviews
- DEA/ Controlled Substances Audits & Compliance

Medical/ Technical Writing Support - Overview

The importance of documenting a development program has grown significantly over the last 15 years with high level summaries now required in market applications. However, some firms may not have enough resources to dedicate to this activity or don't view this as a priority. As time goes on, records may be lost. Compound that with employee turnover and the loss of corporate history on a project, it becomes even more imperative to document the findings in a timely manner.

TLI Development can help. We have provided cost-effective medical and technical writing support for countless programs. A listing of the major types of projects is provided below.

· technology transfer protocols and reports

· manufacturing process development reports

· formulation development reports

· batch analyses & justification of specifications

· impurity profiles & justification of starting dose in man up to highest proposed dose

· SOPs for regulatory filings (IND, NDA, BLA, etc.)

· SOPs for quality related activities (OOS investigations, CAPA programs, AE reporting, labeling of CTM, etc.)

· SOPs for clinical related activities (AE reporting, clinical trial site qualification, CTM accountability, etc.)

· SOPs for controlled substances compliance and audits

· informed consents & informed assents

· prescribing information/ annotated labeling

· analytical methods, method transfer reports, validation protocols, and validation reports

· stability protocols and stability summaries

· clinical protocols and clinical study reports

· external publications

· investigator brochures

· editing a pharmacology textbook