



*Visionary science for
life changing cures.*

Medical Writer

Applied Genetic Technologies Corporation (AGTC) is a clinical stage biotechnology company dedicated to developing novel gene therapies for ophthalmic diseases. AGTC is aggressively expanding and seeks a full-time Medical Writer

Reporting Relationship:

- The Medical Writer will report directly to the Vice President, Clinical Research & Development (VP, Clinical R&D).

Responsibilities:

Job responsibilities will include, but are not limited to, the following.

- Oversee document preparation activities.
- Build and maintain knowledge base to improve the overall medical content of documents.
- Write and/or review reports and regulatory submission documents, protocols, amendments, review statistical analysis plans and ensure appropriate incorporation into reports.
- Write and/or review submissions to peer-reviewed journals, scientific meetings and presentations
- Drive the clinical study report writing process by conducting or ensuring the following activities have been accomplished:
 - Identify report contributors and their responsibilities.
 - Develop and maintain timelines.
 - Ensure that all possible report activities are completed prior to database lock.
 - Review primary statistical output and participate in results review meetings.
 - Lead discussions on report finalization.
- Ensure Quality Control review of protocols, protocol amendments, Clinical Trial Reports, Investigator Brochures and regulatory submission documents.
- Work effectively with other staff in Clinical Operations (e.g. Clinical Trial Management, Clinical Research Management, Biostatistics, Data Management, and Clinical Monitoring) in team situations.

Requirements:

The successful candidate will meet the following requirements.

- Master's degree in science or writing discipline with three to five years medical writing experience with thorough understanding of FDA and ICH guidelines.
- Demonstrated strong writing skills as evidenced by good quality writing in publications in peer-reviewed journals.
- Knowledge of statistics and their application to the interpretation and presentation of clinical data.

AGTC offers competitive compensation commensurate with education and experience. AGTC is an EOE and maintains a drug-free workplace. Please send CV or resume to:

Human Resources
Applied Genetic Technologies Corporation
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Alachua, FL 32615
jobs@agtc.com

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