AMAREX JOB DESCRIPTION

Position Title: Regulatory and Scientific Analyst (RSA)	**Department: Regulatory**
Reporting Requirements: Reports to the Regulatory Department Head or other supervisor as assigned	**Travel Requirements: < 10%**

POSITION SUMMARY

The Regulatory and Scientific Analyst (RSA) performs all activities related to development, preparation, writing, reviewing and editing of integrated reviews of literature and related materials that summarize data from published papers and clinical studies for submission to clients, the FDA and other regulatory agencies.

Key Duties and Responsibilities:

- Write technical reports summarizing scientific papers and clinical/non-clinical study reports.
- Coordinate document preparation for submission to regulatory agencies, including IND, NDA, IDE and PMA items.
- Assist in reviewing, developing, writing, and/or editing Investigator Brochures, annual reports and clinical protocols.
- Prepare and integrate tables, graphs, and graphics for all documents.
- Responsible for creating and editing all sections of IND and NDA documents/submissions.
- Prepare and submit regulatory filing (DMF, IND, BLA, PMA, 510k) and supports program for electronic formatting of regulatory submissions.
- Review reports, tables and listings for completeness and accuracy.
- Interact with various departments to collect information and synthesize it into documents.
- Develop procedures for new projects and provide guidance to other personnel or consultants.
- Keep updated guidelines and requirements of the FDA and other international regulatory agencies for reference in the development of required documents, including ICH Guidelines.
- Act as a member of study teams, clinical project teams and interdepartmental project teams.
- Work with outside and internal database managers and statisticians to obtain data listings and analyses needed to support the preparation of Clinical Study Report/ publications.

REQUIRED EDUCATION AND EXPERIENCE

- Minimum of Master's degree, PhD preferred
- Extensive writing experience. Publishing scientific papers in peer-reviewed journals is strongly preferred.
- Ability to work effectively both independently and in a team environment, contributing to a collaborative work atmosphere.
- Strong verbal and written communication skills.
- Experience in writing, reviewing, and preparing clinical study reports and regulatory submissions is preferred.
- Strong presentation skills.
- Strong analytical skills.
- Strong Microsoft Office skills particularly in MS Word and Excel.