

Medical Affairs Associate (10-011/012)

Azur Pharma, Inc., a dynamic, growing, privately-held specialty pharmaceutical company with commercial franchises in psychiatry, women's health and orphan drugs, is currently seeking experienced candidates to fill two Medical Affairs Associate positions, which will assist in managing both Pharmacovigilance and Medical Affairs.

Pharmacovigilance responsibilities include the timely collection, processing, follow-up, analysis, and regulatory reporting of adverse events (AEs) and serious adverse events (SAEs) for all marketed products and investigational compounds when applicable:

- Ensure timely submission of reports regulatory agencies in accordance with applicable regulations and that all inquiries from the FDA are responded to in a timely manner;
- Respond to inquiries from health care professionals, consumers, and company personnel regarding safety issues with marketed products;
- Prepare periodic comprehensive written reviews of all assigned AEs;
- extract AE data from various clinical trial cases and spontaneous sources;
- Manage case-related information including interpretation of medical conditions, lab results, and procedures as well as compile complete narrative summaries;
- Ensure proper coding (MedDRA) into the safety files; and maintain source documents and files;
- Interact with various contractors and partners to fulfill these responsibilities.

Medical Affairs responsibilities include assistance in managing the medical information aspects of the Medical Affairs Department and provide scientific support for other departments within Azur Women's Health and CNS.

- Triage external and internal drug information queries or MIRs (medical information requests);
- Assist in drafting responses to MIRs, filing MIRs, and creating standard response letters for FAQs for all marketed products;
- Research and provide responses to medical and drug information inquiries received by Azur Drug Information through various avenues (phone center, fax, and e-mail);
- Serve as information resource for internal scientific inquiries from marketing, sales, and other Azur departments;
- Provide medical review of promotional material as part of Medical/Legal/Regulatory review process;
- Provide logistical support for review of grants and IITs (investigator initiated trials);
- Provide support for other medical affairs activities as assigned such as: draft abstracts, posters, manuscripts, training materials/presentations, congresses/symposium, and advisory meetings, speakers training programs;
- Draft abstracts, posters, and manuscripts as assigned.

To be considered for this position, you must have a Bachelor's degree in a related field (preferably in biology or chemistry) and at least 3 years of experience in drug information and/or medical communication or medical affairs within pharmaceutical/hospital industry is required. Candidates with a Pharm D, BS Pharmacy, or Master of Science are preferred. Experience must include an advanced level of medical literature research and analysis experience (to include the demonstrated ability to interpret medical literature and prepare written summaries) as well as familiarity with all phases of clinical research, drug approval process, FDA/internal regulations and requirements for AE reporting and for product promotion, Good Clinical Practice (GCP), and familiarity with other applicable FDA. The successful candidate will have excellent presentation, verbal and written communication skills, and the ability to communicate effectively at all levels of the Azur organization

To be considered for this position, the well qualified candidate should send a resumes and salary requirements to:

Azur Pharma, Inc. / Human Resources
1818 Market Street, Suite 2350
Philadelphia, PA 19103
e-mail: jobs@azurpharma.com, Fax: 443 487-9252

Azur Pharma is an Equal Opportunity Employer.

EOE M/F/D/V