

Medical Director - Clinical Development – Gastrointestinal Rockaway, NJ

Provide medical leadership for new product development and support for established brands throughout life cycle including development for the purpose of registration and post approval development for purpose of maximizing the brand market potential.

About Warner Chilcott

Warner Chilcott is a leading specialty pharmaceutical company currently focused on the women's healthcare, gastroenterology, dermatology and urology segments of the U.S. and Western European pharmaceuticals market. It is a fully integrated company with internal resources dedicated to the development, manufacturing and promotion of its products. We have established strong franchises in women's healthcare and dermatology through our marketing techniques and specialty sales forces. We believe that our proven product development capabilities, coupled with our ability to execute acquisitions and inlicensing transactions and develop partnerships will enable us to sustain and grow our business.

The individual will be responsible for the following activities:

- Develop the appropriate medical/clinical development plan for each product leading to approval of an NDA:
- Participate in a leadership capacity on multidisciplinary project teams.
- Contribute to creation of overall product development plan.
- Plan and manage the clinical component of product development including:
 - Produce Investigator Brochures for each product.
 - Design and write protocols to support registration for products.
 - Oversee the conduct of clinical trials.
 - Coordinate analysis and writing of clinical study reports.
 - Contribute to NDA.
 - Identify and interact with key external personnel including advisers, consultants, and investigators.
- Plan and contribute to company's scientific advisory board meetings.
- Solicit and integrate expert opinion into ongoing development activities.
 - Work with the Commercial Team to assess medical market needs for development of new products or expansion of current products.
 - Continue to monitor the safety of brands through development and marketing to meet company and regulatory requirements.

- Support Commercial Team in developing launch plans and initial marketing activities:
- Formulation/negotiation of product label.
- Contribute to development of abstracts and publications of clinical data.
- Support speaker's bureaus/professional education programs.
- Develop the appropriate post-approval clinical plan for each product:
- Design clinical studies to bridge any gaps in target product label.
- Support ongoing marketing messages.
- Explore new indications to prolong product life cycle.
- Knowledge of clinical trial design.
 - Knowledge of regulatory requirements for development, registration, tracking and marketing of pharmaceuticals.
- Understanding of marketing needs in terms of medical support for success of brand.
- Possess strong organizational and communication skills.
- Ability to interact credibly with opinion leaders, investigators and prescribers.

Qualifications

- MD Degree with minimum of 5 years experience in the pharmaceutical drug development field.
- Experience in the gastrointestinal area

Please visit www.wcrx.com for more information about our exciting product portfolio.

Candidates must be authorized to be employed in the United States. Candidates must be willing and able to travel as necessary. Candidates must also successfully pass a drug test and background check.

Warner Chilcott realizes that our success as an organization is dependant upon our people. We seek aggressive, success oriented and adaptable associates. Please apply at jobs@wcrx.com and reference "MedDirGI" in the subject.