US-PA-Pittsburgh – Regulatory Specialist, Regulatory Affairs, NSABP Operations Center

The National Surgical Adjuvant Breast and Bowel Project (NSABP) is a clinical trials cooperative group supported by the National Cancer Institute (NCI) with a 40+ year history of designing and conducting clinical trials that have changed the way breast cancer is treated, and, more recently, prevented. The NSABP headquarters is located in Pittsburgh, Pennsylvania. We work with more than 200 research sites at major medical centers, university hospitals, large oncology practice groups, and health maintenance organizations in the United States, Canada, Puerto Rico, and Australia. For more information about the NSABP, please visit our Web site at http://www.nsabp.pitt.edu.

The NSABP is seeking to fill a full-time position for a Regulatory Specialist who will assist the Director of the Regulatory Affairs Section with preparing and submitting protocol-related documents to the National Cancer Institute, the U.S. Food and Drug Administration, the Canadian Health Products and Food Branch, Institutional Review Boards, and NSABP sites.

Specific duties include:
- Facilitating communication among physicians, nurses, statisticians, and other NSABP personnel who collaboratively develop protocols;
- Preparing correspondence to instruct NSABP members about administration and study protocol-related issues associated with NSABP trials;
- Writing informed consent documents and reviewing modified consent forms to ensure compliance with government guidelines;
- Coordinating the preparation of investigational new drug applications and annual reports;
- Answering questions from NSABP members about regulatory matters;
- Providing explanations of regulatory requirements to NSABP staff and members;
- Independently researching regulatory issues through the Internet and other resources;
- Preparing standard operating procedures and policies.

The successful candidate must be detail-oriented; possess excellent oral and written communication skills; be able to meet deadlines; and have computer skills, including working knowledge of word processing (MS Word), e-mail (MS Outlook), and Internet-based search engines. Work hours are 8:30 a.m. to 5:00 p.m., Monday through Friday. This position also involves travel to NSABP conferences and regulatory meetings several times a year.

A minimum of 3 years’ experience with clinical trials and/or regulatory processes is required. A Master’s degree is preferred, but not required. Knowledge of tissue repository procedures is a plus.

The NSABP provides a comprehensive benefits package that includes:
- medical, dental, and vision coverage;
- 401K and profit-sharing plans,
- long- and short-term disability; and
- life insurance and long-term care policies.

Interested candidates should submit a CV or résumé to:

NSABP Human Resources
NSABP Operations Center
Four Allegheny Center, 5th Floor
East Commons Professional Building
Pittsburgh, PA 15212

or by fax at (412) 330-4661
or by e-mail to betty.trocchio@nsabp.org

EOE M/F/D/V