



National Surgical Adjuvant
Breast and Bowel Project

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 and colorectal 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, Ireland, 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 Regulatory Affairs 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 the submission of protocols and protocol-related correspondence to federal agencies;
- Preparing correspondence to instruct NSABP members about safety updates and protocol-related issues associated with NSABP trials;
- Answering questions from NSABP members and their Institutional Review Boards (IRBs) about regulatory matters both verbally and in writing;
- Providing explanations of regulatory requirements to NSABP staff and members;
- Reviewing consent forms for regulatory compliance;
- Coordinating consent form translation efforts;
- Coordinating the preparation of investigational new drug applications and annual reports;
- Being the primary liaison with the CTSU and Canadian 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