

# “Diligent Commitment...”

## Bio-economy Career Profile

**Position:** Senior Manager, Clinical Trial Operations

**Name:** Laura Brodowski

**Company:** ASKA Research

**Salary Range:** \$50,000 to \$70,000 per year



## What I do:

I work for ASKA Research in Vancouver as the Senior Manager of Clinical Trial Operations. ASKA Research is a Contract Research Organization (CRO) that provides clinical research outsourcing services to the investigational product development industry, specifically pharmaceutical, medical device and biotechnology companies. We “fill in the gaps” for companies that may be in any number of phases in the development of drugs and devices. ASKA’s specialty is monitoring and managing clinical trials, ensuring the data provided to the client is accurate and complete. ASKA Research also is contracted to provide educational workshops and assist with the development of training manuals, which provide industry-standard training modules.

My role as a project manager is predominantly to manage resources. I am the conduit between the company and the Clinical Research Associates (CRAs) in the field who are providing services at the clinical trial sites. I report the project progress and updates to our client, I review CRA monitoring reports, and I assist in the collection and management of regulatory documentation from physicians involved in the clinical trials. A significant part of my job is to manage many moving targets, timelines and priorities without losing sight and perspective of the “big picture.” One particularly “regulatory” aspect of my role is to manage Trial Master Files that are essentially the auditable paper trail and may be examined by Health Canada or the FDA. My other duties include assisting with managing the training requirements for ASKA employees, and sourcing and contracting resources for the company as needed.

## What education and skills do candidates need for this position?

At minimum you need a Bachelors of Science. It is not necessarily having a specialty that ASKA Research looks for, but the relevance of completing a degree illustrates skills and abilities such as diligence; organization; focus; and ability to establish priorities and work under, sometimes, extreme pressure.

It is recommended that you have project management training or experience. Formal training isn’t necessary, but a comprehensive understanding of the basic processes and communication requirements is essential. You must be forward thinking, able to project or foresee consequences and mitigate them. Having an understanding and skills related to risk management is also important. Soft people skills are key to working in teams; this requires an understanding of the difference between leadership and management, and when each applies.

Some of the traits that can assist you in this job include patience, especially since you work with so many diverse personalities. You need to understand your role in managing differences of opinion and perceptions. You also need to have attention to detail, but most importantly...you must be able to work efficiently under pressure and be willing to do what needs to be done regardless of your title and list of accountabilities. This industry is a remarkable example of teamwork and collaboration, and extended family.

## What are the best parts of your job?

The most satisfying part of my job is the diversity of each day and project. I am not afraid of change, so I’m in the right environment! Also, I have experienced the result of a successful drug approval; knowing the rigorous effort that everyone made makes me proud to have contributed even a small portion.