

“Assisting the clinical development of medical advances...”

Bio-economy Career Profile

Position: Director, Quality Management

Name: Meta Mitchell

Company: ASKA Research

Salary Range: \$60,000 to \$80,000 per year
(salary range for Quality Managers)



What I do:

I work for ASKA Research (ASKA) in Vancouver as the Director of Quality Management. ASKA is a clinical services provider offering clinical trial development, management and monitoring services to pharmaceutical and biotechnology companies. ASKA ensures that the client's regulatory requirements are met, such as those for clinical management and monitoring, while ensuring patient safety is not compromised.

My role is quality management. I work to ensure that documentation systems, such as Standard Operating Procedures (SOPs) and controlled processes are in place for activities carried out by ASKA with respect to clinical trials. I also control quality activities within ASKA's internal systems and produce nonconformance reports, providing suggestions for corrective or protective actions, where regulatory systems are not followed.

I assist in developing budgets for comprehensive quality management, including clinical trials, system audits, quality assurance, and controlled documentation; and contingency plans to keep the project in compliance with regulatory requirements.

What education and skills do candidates need for this position?

I hold a Ph.D. in Organic Chemistry. Most people in positions similar to mine have, at least, an undergraduate degree in science. Experience in quality assurance and

quality control is definitely an asset in this position. You also require a breadth of expertise in a number of subjects, such as project planning, auditing, regulatory requirements (Health Canada) and Good Clinical Practice. I feel that my background in sciences, math, and advanced writing skills have been particularly beneficial to my work.

Someone working in quality management requires a keen eye for detail. You need detective skills to discover errors in documentation or systems and the cause of these errors, and to be flexible and dynamic to provide creative ideas for mitigating problems and preventing re-occurrence.

To work in quality management, you need to be very organized and fastidious in your approach. It is also important that you possess good people-management skills and can work with a team. The human factor in quality management cannot be discounted; when human error does occur it's the role of the quality manager to identify where this has been caused by inadequate training or documentation, or by poor systems and practices.

What are the best parts of your job?

I believe strongly in what I do and how medical advances may benefit the lives of so many people. The ability to assist the industry in delivering essential medical help to people who require it is very rewarding.