



06/01/2021

## DEPUTY GENERAL COUNSEL, QUADRANT BIOSCIENCES

### COMPANY

This is a fantastic opportunity to join a rapidly growing biotech company. Quadrant Biosciences works with top academic institutions, medical researchers and engineers to translate breakthrough findings into thoughtfully developed, scientifically sound commercial products. We develop and commercialize diagnostic health assessments which utilize our proprietary ability to identify, analyze and interpret epigenetic biomarkers for neurological conditions such as concussion, autism spectrum disorder, and Parkinson's disease. Quadrant Biosciences was recently highlighted on CNN, NPR, Bloomberg, and Huffington Post for its groundbreaking work.

### JOB SCOPE

The deputy general counsel is a member of the Company management team and provides legal services and consultation on matters that arise in the course of Company operations, primarily in the areas of regulatory compliance and commercial transactions. Experience with patent filings and prosecution would also be helpful. The deputy general counsel must be business oriented and adept at risk assessment and risk management.

The regulatory compliance aspect of the role emphasizes: 1) thorough analysis of the Company's business plan and situations that arise from operations to identify Company activities that are subject to regulation, and 2) the ability to design compliance solutions that are effective to achieve compliance as well as efficient with respect to deployment of Company resources. The principle areas of regulatory compliance that affect the Company's operations include:

- Medical device regulation by the FDA domestically, and by analogous regulatory agencies in international jurisdictions. Responsibilities in this area include:
  - Assist in preparation of regulatory submissions
  - Participate in product development projects to ensure design and development of products that satisfy regulatory requirements, such as design controls, verification and validation testing, and the design of any necessary clinical studies
  - Review marketing materials to ensure compliance with medical device regulatory requirements
- Privacy and security regulations, such as the Health Insurance Portability and Accountability Act (HIPAA)
- Healthcare fraud and abuse regulations, such as the anti-kickback regulations and the Stark regulations
- Regulations of clinical laboratories, including federal CLIA (Clinical Laboratory Improvement Amendments) and state regulations

The deputy general counsel will have responsibility for developing and maintaining Company policies and procedures that are necessary to achieve regulatory compliance as well as training materials to facilitate training of Company personnel who perform activities that are subject to regulatory compliance.

The focus of the work relating to commercial transactions is to prepare contracts that are as simple and straightforward as possible to facilitate understanding and administration by Company stakeholders, while ensuring that the contract mitigates relevant legal risks to the Company to the maximum extent possible. The principal types of contracts for which drafting and negotiation support will be required include:

- Agreements for services obtained by the Company from third party contractors
- Distribution and sales representative agreements that govern the marketing and sale of the Company's products and services to customers
- Agreements for purchase of goods used by the Company both in production of its products and services and for use by Company personnel in performing work for the Company
- License agreements for intellectual property embodied in the Company's technology, products and services and also for software used by the Company
- Contracts for sale of Company products and services to the Company's customers

The deputy general counsel's role in management of the Company's intellectual property includes the following responsibilities:

- Participate in product development projects and work with R&D personnel to identify inventions that should be protected as intellectual property and ensure that such inventions are documented with appropriate written materials
- Determine the inventions that will be protected as trade secrets and the inventions for which patent protection will be pursued. Ensure that trade secrets are protected with adequate security measures and assist in writing invention disclosures that will be incorporated into patent applications
- Manage outside patent counsel with respect to preparation and filing of patent applications as well as prosecution of patent applications
- Advise management regarding nationalization of the patent portfolio as well as periodic culling of the patent portfolio to identify patents to be sold, licensed, or abandoned

## **QUALIFICATIONS**

The deputy general counsel must have a JD, and at least five years (preferably at least 7 years) of experience in advising corporate clients, or as a corporate counsel, with an emphasis on as many of the three legal areas described above as possible (ie regulatory compliance, commercial transactions, and intellectual property).