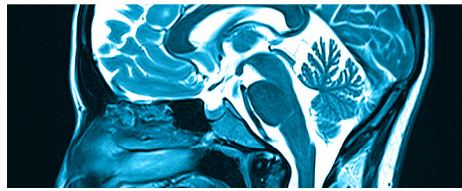


# IMRIS careers

**Functional Area**

Operations – Quality Assurance and Regulatory Compliance

**Position Title**

Director, Quality Assurance and Regulatory Compliance

**Job Time**

Full-Time

**Job Description**

Working within a small team of professionals to achieve quality and regulatory compliance goals, your responsibilities will be to implement, maintain and improve a quality management system in accordance with ISO 13485, Canadian Medical Device Regulations, European Medical Device Directives, and FDA Quality System Regulations. You will be responsible for coaching of project team members and process owners, distributing quality metrics throughout the product lifecycle, contributing to business and technical risk management, as well as preparing for external audits and inspections from regulatory bodies. With a Bachelor's Degree in Engineering and practical experience with ISO 13485 and FDA Quality System Regulations in addition to proven experience in worldwide quality management of medical device products you have a thorough understanding of product development and configuration management principles and product lifecycle phases. Solid schedule and project management skills as well as excellent verbal and written skills are required. You are a self-motivated, team oriented and proactive leader.

**Essential Duties and Responsibilities**

As leader of the Quality and Regulatory Team, you will define and execute IMRIS' Quality and Regulatory Strategy and lead the development of IMRIS corporate quality policies. This would include:

- Management and optimization of the company's Quality Systems.
- Management of our Regulatory submissions and strategy
- Continuous assessment of industry and regulatory trends to assure that our system and strategy reflect current requirements.
- Support development of a corporate culture that is based on excellence, continuous improvement methodologies and the expectation of high standards from all employees.
- Communicate the Quality and Regulatory strategy and key programs to the organization; promote these programs with employees, suppliers and customers.
- Acts as a mentor for Quality and regulatory personnel, supporting process improvement initiatives and development of innovative and efficient quality systems for the company
- Assure that the Quality System is compliant, in control and 'audit ready' as measured by the successful results of both internal and external quality and customer audits.
- Acts as a quality consultant to site personnel on complex GMP issues that require a unique interpretation of GMP, MDD, FDA, and Canadian Medical Device Regulations.
- Develop and implement employee communication and training initiatives in connection with the company's quality objectives
- Manage the Quality Department
- Makes go/no go decisions regarding product release when exceptional issues arise. Review results of multidisciplinary team investigations held to resolve complex product issues or GMP manufacturing system failures and ensure QS group and/or customers implement the necessary system improvements.
- Leads all Quality audits and interactions with appropriate regulatory bodies

To apply for this position please send your resume in confidence to [hr@imris.com](mailto:hr@imris.com).

Only those candidates selected for interviews will be contacted.

**Knowledge, skills and abilities requirements**

- Bachelor's degree in engineering, physics, or other related discipline preferred with a minimum total of 10 years medical device industry experience.
- Must have a minimum 5 years experience as a QA or QC manager.
- Direct experience with FDA inspections and ISO 13485 audits is required.
- Experience with Canadian Medical Device Regulations, and European Medical Device Directives.
- Demonstrated experience and knowledge to contribute to and lead the development of compliance policy.
- Trained in Process Excellence and Six Sigma and Lean methodologies preferred.