

**Quality & Regulatory Affairs  
Manager**



Phone :  
Web :

**Job Summary**

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Vacancy :  
Deadline : Sep 01, 2024  
Published : Aug 01, 2024  
Employment Status : On-site  
Experience : Any  
Salary :  
Gender : Any  
Career Level : Any  
Qualification :

## Job Description

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At Cobionix, we are pioneering the future of healthcare with our state-of-the-art autonomous robotic platform designed specifically for medical procedures. Our cutting-edge technology integrates advanced robotics to transform medical interventions, making them safer, more precise, and efficient.

**Mandatory Requirement:** In office (Mississauga or Ottawa)

### Overview:

We are currently looking for a Quality Affairs & Regulatory Affairs Manager, keen on joining the emerging medical robotics space. The QA/RA Manager will work closely with every department, having top management support, to ensure quality and regulatory standards are adhered to.

### Responsibilities:

- Work with quality consultants, auditors, and vendors to assess and implement a quality management system for the purpose of ISO 13485 certification.
- Accountable for leading ISO 13485 re-certification and interim audits to ensure that quality requirements are being met.
- Ensure compliance with MDSAP (Medical Device Single Audit Program) requirements, including preparation and management of audits.
- Qualify suppliers that meet quality management requirements and audit supplier processes as necessary.
- Translate design history documents into the QMS system.
- Implement, review, and approve design documents, such as Design Verification/Validation Plans/Protocols, Risk Management, Design Inputs, and Design Reviews.
- Implement, review, and approve process design documents, such as process validation and process control; participate in manufacturing reviews and design output documents.
- Implement, review, and approve outputs from manufacturing records and inspections.
- Implement, review, and approve manufacturing documents such as instructions, protocols, test methods, process changes, and deviations.
- Independently analyze and draw conclusions on investigations/work.
- Provide training within the scope of objectives of the assigned work as necessary.
- Ensure compliance with UKCA (UK Conformity Assessed) marking requirements, including relevant documentation and certification processes.
- Participate in projects as assigned.
- Other duties as required.

### Required Experience

- Bachelor's Degree in a related field (Engineering, Biomedical, Biology, etc.)
- 5+ years of industry experience
- Experience with the overall design and development process.
- Excellent knowledge of ISO 13485 and regulatory requirements for medical devices.
- Experience with obtaining FDA, Health Canada, UKCA, and CE Approval
- Familiarity with MDSAP and UKCA frameworks.
- Excellent analytical and communication skills (written and oral).
- Excellent organization and time management skills.

### Nice to Have

- Medical Robotics Experience
- Six Sigma Certification
- A keen interest in accelerating the adoption of robotics in healthcare

*Cobionix Corporation is an equal opportunity employer. We are committed to providing a diverse and inclusive work environment while providing ongoing education for all employees. Qualified applicants will be considered without regard to race, colour, religion, gender, gender identity or expression, sexual orientation, national origin, genetics, disability, age, or veteran status. We firmly believe that our differences make us stronger.*

*Please inform us if you require any accommodations during the recruitment process. While we thank all applicants, only those being considered for an interview will be contacted.*

Job Type: Full-time

Pay: \$80,000.00-\$120,000.00 per year

Benefits:

- Casual dress
- Company events
- Dental care
- Disability insurance
- Employee stock purchase plan
- Extended health care
- Flexible schedule
- Life insurance
- On-site parking
- Paid time off
- Stock options
- Vision care

Job Types: Full-time, Permanent

Pay: \$80,000.00-\$120,000.00 per year

Benefits:

- Casual dress
- Dental care
- Employee stock purchase plan
- Extended health care
- Life insurance
- Stock options
- Vision care

Flexible Language Requirement:

- French not required

Schedule:

- Monday to Friday

Ability to commute/relocate:

- Mississauga, ON: reliably commute or plan to relocate before starting work (required)

Education:

- Bachelor's Degree (required)

Work Location: In person

**Education & Experience**

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**Must Have**

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**Educational Requirements**

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**Compensation & Other Benefits**

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