

## Quality and Regulatory Affairs Manager – Medical Devices (F/M)

### POSITION DETAILS

Imagine Eyes, an SME renowned for its cutting-edge innovations in medical imaging, is seeking a Quality and Regulatory Affairs Manager. The role entails organizing, coordinating, and monitoring quality and regulatory affairs. Your work will be crucial for the international rollout of our products in the field of ophthalmology. Your responsibilities will include:

Quality management:

- Implement quality policy and objectives,
- Maintain ISO 13485: 2016 certification,
- Manage, evaluate and improve the QMS,
- Prepare and lead management reviews,
- Manage non-conformities and CAPAs,
- Control changes,
- Organize internal and external audits,
- Maintain and improve document management,
- Educate and support teams on quality, risk management and regulatory requirements.

Regulatory affairs:

- Obtain / maintain medical device certifications and regulatory approvals,
- Establish and maintain regulatory compliance files,
- Organize and document post-market follow-up,
- Organize risk management and keep it up to date,
- Ensure regulatory compliance (PRRC),
- Maintain vigilance and regulatory watch.

### REQUIRED SKILLS AND EXPERIENCE

We are looking for someone with a solid knowledge of:

- ISO 13485 and ISO 14971 standards,
- European Regulation 2017/745 (MDR),
- FDA regulation 21 CFR part 820 and 510(k),
- Quality management tools,
- Problem-solving techniques,
- Change management methods,
- Meeting conduct.

Proficiency in English is required.

Ideally, the candidate should possess a Master's degree from a university or college with a specialization in quality/regulatory affairs. Additionally, the candidate should have at least 5 years of experience in a QRA management position in the medical device field.

### PRACTICAL INFORMATION

- Type of contract: permanent
- Place of work: Orsay, France (Paris area)
- Salary: from €45k+, depending on profile and experience
- Advantages: bonus, profit-sharing, savings plan, transportation allowance, lunch vouchers
- Hours: 9:30 a.m. to 6:30 p.m. i.e. 39 hours/week
- Accessibility: 5-mn walk from RER-B station "Le Guichet"

### ENGAGEMENTS AND IMPACTS

- Our team is passionate about our public health mission: to preserve and improve the sight of millions of patients.
- Our devices are cutting-edge medical imaging technology, made in France, and exported to over 20 countries.
- We are actively engaged in national and European collaborative innovation programs.
- Our products contribute to the advancement of medical research with over 250 scientific publications.

### RECRUITMENT PROCESS

Send your resume with a cover letter or email to: [jobs@imagine-eyes.com](mailto:jobs@imagine-eyes.com)

[Discover us in 2 minutes 30 on Youtube](#)

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