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Regulatory Affairs and Quality Assurance Assistant – Medical Devices

Hiring organization
Newton Colmore Consulting Ltd

Employment Type
Full-time

Duration of employment
Permanent

Industry
Medical Devices

Job Location
Cambridge, Cambridgeshire

Date posted
15th July 2026

Valid through
31.10.2026

Apply below or email directly: andrew.welsh@newtoncolmore.com

Description

Due to the growth of a medical devices company based in Cambridge, there is need for a new Regulatory Affairs and Quality Assurance Assistant to work with and support the company's Quality Assurance and Regulatory Affairs Manager. The team provide quality assurance and regulatory affairs advise on the creation of new products and the improvement of existing technologies.

It would be highly advantageous if you have knowledge of design processes, but it's not essential. This team does not just fill out quality assurance and regulatory documents; this is a team where they will be very involved with the R&D team, providing vital advice on the creation of medical devices, and ensuring the team operates within the FDA 510k, ISO 13485, and FDA 21 CFR Part 820 standards.

It would be ideal if you have both quality assurance and regulatory affairs knowledge. However, people have moved into this role from either regulatory affairs or quality assurance background, but with a general knowledge in the other side.

It is essential that you have medical devices knowledge, especially ISO 13485 and FDA 510k knowledge. Although writing submissions will not be a major part of your role, you will relay information to the teams responsible for this, so ideally you will have done this in the past or at least assisted.

Ideally, you will have QMS experience. If you do have this knowledge, I would advise making it clear on your CV as this is highly desirable in this role.

The products this company has been developing are industry-changing and will improve the lives of people around the world.

It is expected that you would hold a 1st or 2:1 degree within an engineering or sciences discipline along with some experience within regulatory affairs or quality assurance. Although experience working within a medical devices R&D or design team is more important than education.

This is a growing company; due to this, they offer career progression, excellent salary, benefits package, the chance to work on life-improving devices, and share options.

If you have regulatory affairs knowledge in the medical devices sector and are looking for a challenging role, then apply now.

I expect a lot of interest in this role, and the company are looking to recruit quickly. So, if you are interested in this role, I suggest applying immediately or risk missing out.

For more information, please feel free to call Andrew Welsh, Director of Medical Devices recruitment, Science recruitment and Biotech recruitment specialists Newton Colmore Consulting, on +44 121 268 2240 or make an application, and one

of our team at Newton Colmore Consulting will contact you.