



**Quality Assurance / Regulatory Affairs Manager – (Part time 3/4 days pw)
Edinburgh**

LifeArc is a medical research charity with a 25-year legacy of helping scientists and organisations turn their research into treatments and diagnostics for patients. We are pioneering new ways to turn great science into greater patient impact at LifeArc.

Our Centre for Diagnostics Development (CDD) in Edinburgh operates at the interface between academic research and industry. We transform novel ideas in diagnostics, and with patient benefit as our driver, we identify unmet need, and commit our own staff, funds, expertise, and ISO 13485:2016 certified laboratories to drive and translate those ideas into real-world products.

The role:

This part-time (0.6-0.8FTE) role has arisen as a result of expansion and progression of the pipeline of IVD projects.

A key member of the CDD Management Team, you will be responsible for the management of our Quality Management System in accordance with ISO 13485:2016, the requirements of our partners, and with best practice of ISO14791, and FDA QSR requirements in mind. You will also lead on all quality and regulatory aspects around product development of in vitro diagnostics, helping to identify key regulatory and quality inputs early in development. You will actively contribute to Design History Files and Risk Management documentation, and you will help ensure best practice from concept to launch.

Other key responsibilities include the training of new staff on quality expectations, updating product specifications and documentation for potential certification whilst always promoting a culture of audit-readiness throughout the extended team.

Who you are:

Educated to degree level and capable of leading and coaching by example. You will have strong influencing skills and the ability to engage both internal and external stakeholders in understanding the importance of quality compliance whilst displaying a willingness to use the principles of regulations and standards to create a QMS that meets requirements and is balanced.

Essential Requirements:

- Educated to a degree level, ideally a postgraduate education in a life science
- Demonstrable experience of leading key quality processes, including management review, internal audits, quality agreements and management of a QMS in accordance with international standards (ISO 13485:2016 / FDA QSR)
- Experience of compilation and update of product specifications and documentation for certification.
- Demonstrable working knowledge of medical device EU CE marking process and the IVDR
- Excellent understanding of Quality and Regulatory requirements as they apply to R&D and NPD
- Communicative and service oriented, supporting a wide variety of stakeholder needs, and levels of compliance experience.
- Strong background of working within the IVD space (ideally a background in, or good understanding of molecular diagnostics)
- Strong understanding of the regulatory landscape as it pertains to IVD in UK, EU and US



Salary

Your salary will be determined by qualifications and experience. In addition, LifeArc offers a defined contribution pension scheme, private health insurance, a flexible benefits scheme and 31 days paid holiday per year.

LifeArc is committed to the principles and practices of equal opportunities and to encouraging the establishment of a diverse workforce. It is our policy to employ individuals on the basis of their suitability for the work to be performed and their potential for development, regardless of age, sex, race, colour, nationality, ethnic or national origin, disability, marital status, pregnancy or maternity, sexual orientation, gender reassignment, religion or belief. This includes creating a culture that fully reflects our commitment to equal opportunities for all.

To apply please email your CV and covering letter explaining why you want to work for LifeArc to: adam.rudman@lifearc.org or by post to Recruitment, LifeArc, Accelerator Building, Open Innovation Campus, Stevenage, SG1 2FX (electronic applications preferred).

Closing date:

Friday 24th April 2020