



Centre for Diagnostics Development (CDD) – Clinical Development Lead (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.

LifeArc is pioneering new ways to turn great science into greater patient impact. It brings together a network of partners to tackle specific diseases and directly funds academic and early stage research.

At our Centre for Diagnostics Development (CDD) in Edinburgh, we help develop early stage diagnostic opportunities to a point where they can be partnered for commercialisation and deliver real patient benefit. The opportunity has arisen to develop the Clinical Development team within CDD who will work alongside our Assay Development teams and our Industrial Partners to gather the clinical evidence needed for regulatory approval of our diagnostic products.

This role is integral to CDD's ability to deliver clinical performance evaluation data to our industrial collaborator or regulatory body. The Clinical Development Lead will work in line with CDD's **Clinical Development Strategy** in collaboration with the Assay Development Teams and from this design, implement, and monitor the requisite clinical studies of new and modified *in vitro* diagnostic products; they will also lead in the preparation of **regulatory submissions and international registration packages, as required.**

The Clinical Development Lead collaborates in the development of the scientific validity dossier and supports the Assay Development Teams with feasibility studies including preparation of the clinical evidence dossier of the IVD product(s) in development.

You will already have established a high degree of competence in clinical research and have experience in all aspects of a clinical research program and regulatory submissions.

This position requires a detailed understanding of the clinical laboratory and how it functions; experience or thorough understanding of assay and instrument principles involved in *in vitro* diagnostic product design and usage and in the scientific, statistical, regulatory and compliance requirements of clinical research is essential.

You will be a strong communicator able to communicate with both internal teams, external collaborators as well as individuals and groups at clinical sites. You will demonstrate a high degree of accuracy in your writing and good attention to detail for preparation of documents such as clinical protocols and regulatory submissions

You will ideally have a background and degree in Biomedical Sciences, Biology or other pertinent Life Science, have experience in GCP, be a holder of either a PhD or MD and have industrial experience in a relevant field.

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: recruitment@lifearc.org

Closing date: 13th December 2019.