Head of Clinical and Regulatory Affairs

100%, starting immediately
Location: Europe (Geneva or UK) or Africa (Cape Town or Nairobi)

Organization

FIND is an international non-profit organization based in Geneva, Switzerland, dedicated to R&D activities to expand and accelerate access to new diagnostic technologies, and to build global capacity for diagnostic testing for poverty-related diseases in low- and middle-income countries. FIND's vision is a world where diagnosis guides the way to health for all people. The FIND team is devoted to driving the development, clinical trialing, and early implementation of innovative diagnostic solutions that can have a high impact on patient care and disease control in low-resource settings.

Summary

The Head of Clinical and Regulatory Affairs at FIND will lead the organization's clinical programme. The position will support diagnostic clinical studies/trials across multiple disease programmes in the FIND portfolio and provide regulatory support and oversight to the organization. This role reports to the Chief Scientific Officer and supervises/manages the rest of the programme's functions, which include project management, stage-gating in clinical studies, trial design, risk-based monitoring, data management, statistical analysis and biobanking. The management system for the programme falls under the scope of FIND's ISO13485:2016 certification, and also follows ICH GCP. As such this role will be responsible for close alignment and interfacing with operations and quality management to ensure compliance and audit-readiness of the programme's system against the ISO 13485:2016 standard. Leading FIND's strategy and efforts in developing and assessing the impact of integrated sequencing solutions in resource limited settings.

Responsibilities

The specific responsibilities and activities will include but are not limited to:

1. Responsible for the oversight, management and coordination of FIND's clinical activities, while ensuring compliance with regulations
2. Protocol, SOP and template development for the different studies run by FIND
3. Guidance and assistance to disease teams and trial managers with all aspects of trial design, conduct and close-out
4. Ensuring that all clinical activities meet acceptable quality standards for diagnostic tests and that Human Subject Research is conducted in conformance to ICH GCP E6 R2 guidelines
5. Provide regulatory expertise and ensure that there is capacity within the programme to provide strategic regulatory support for products in FIND's portfolio.
6. Develop new strategic approaches for regional / country-specific submissions for regulatory clearance to achieve smoother and faster country adoption pathways.
7. Responsible for risk management and for reporting against key performance indicators for the programme

8. Host external GCP or regulatory audits ensure any findings are addressed in a timely manner, as well as those from internal audits that apply to the programme.
9. Ensure that the programme prepares for and accommodates internal audit schedules and is prepared for annual external ISO audits

Education, knowledge and skill requirements

1. Advanced degree in Health or Life Sciences, or equivalent
2. At least 8+ years of experience in a similar role in or supporting the in-vitro diagnostics (IVD) industry
3. Experience with electronic data capture and eTMF/eQMS systems
4. Experience overseeing and conducting clinical studies, preferably in low- and middle-income countries (LMICs) to include protocol design/development, site feasibility assessments, eCRF design, project management, reference testing, monitoring and report writing.
5. Knowledge of IVDR (or at least an up-to-date understanding of the new regulations), FDA, and other SRA regulatory pathways, LMIC regulatory knowledge is a plus
6. Experience in quality management in clinical studies, to include QA/QC, KPIs, staff competency assessments, SOP writing, GCP auditing, hosting external GCP audits of FIND-led studies, and regulatory inspections
7. Excellent communications and interpersonal skills, and ability to work in team environment
8. Ability to manage multiple projects and deliver results on time
9. Fluent in English; French/Spanish are a plus

To apply:

Please send a motivation letter, a CV (maximum 2 pages) and three references to **hr@finddx.org**.

Deadline to send your application: **30 September 2019**

Please note that only applicants meeting the profile requirements will be personally contacted. Applications sent by recruitment agencies will not be considered.