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| **JOB DESCRIPTION****Closing Date for applications: 23rd March 2022****Start Date: As soon as possible****Please send CV & covering letter to** **recruit@hcsafrica.com** |
| **Job title & Department:**  |
| Associate Director, R&D (Product Development & Clinical Studies) |
| **Location:**  |
| GALVmed Nairobi office (would consider GALVmed Edinburgh office with significant travel required) |
| **Salary Range:**  |
| KES 7,600,000 – KES 9,000,000 p.a. |
| **Reporting Line & Key Interfaces:**  |
| Reports to: Director, Research and Development (VITAL)Direct Reports: Associate Manager, Clinical ResearchKey Interfaces: Executive Director, R&D; Director, R&D (TAHSSL); TAHSSL management team and partners (ILRI, Clinglobal); Portfolio Managers; Project Leaders; Contracts management; GALVmed consultants; External clinical trial partners, Scientific Community.  |
| **Main Purpose and Scope of the Job**  |
| To serve as Manager contributing to product development projects under the VITAL and future GALVmed R&D programmes.The jobholder will also be responsible for initiating and managing implementation of regulatory and non-regulatory clinical and non-clinical trials as per GALVmed’s required standards. |
| **Key Activities** |
| * Manage and contribute to achievement of objectives of VITAL, and future R&D projects as agreed with funders and in support of GALVmed 2030 Strategy.
* Manage assigned R&D project budgets through proactive intervention to achieve alignment with budget forecasts
* Create product development plans to fit specific assigned and future R&D project objectives.
* Together with the Portfolio Manager, oversee the product development planning of assigned projects via MS Project to ensure transparent planning and communication of tasks and timelines.
* Lead assigned R & D projects to product development and registration and achieve the objectives of the funded projects within timelines.
* Ensure that all product development work under assigned projects is conducted in accordance with written and approved procedures/protocols, and in accordance with good scientific practices.
* Map out and maintain awareness of relevant scientific literature to aid success of assigned product development projects.
* Maintain accurate records on assigned projects and issue reports as per project milestones
* Design internal studies in consultation with Director R&D (VITAL) and in collaboration with R&D partners
* Manage GALVmed clinical operational staff.
	+ Co-ordinate all study activities, including protocol writing, conduct, site monitoring and close out.
	+ Prepare study protocols, data capture forms, test article documentation and study reports
	+ Maintain study files in accordance with SOPs and regulatory requirements
	+ Coordinate/Oversee data management processes including data entry, review, tracking, verification, and validation
	+ Coordinate animal related study activities (i.e., clinical sampling, test article administration, and clinical observations).
	+ Monitor all studies appropriately including training of investigators and other study personnel.
* Serve as the clinical communication link between GALVmed, the sponsor and study site.
* Act as a team leader of assigned projects as required, and to interact with external commercial and academic partners and funders to achieve efficient project progression and assessment.
* Manage functions of GALVmed study monitor, archivist, SOP coordinator and study number allocator for the R & D Group
* Contribute to the selection and management of consultants and partners as may be required from time-to-time for effective implementation of assigned GALVmed R&D projects.
* Represent GALVmed within the research and scientific community in Africa and South Asia through regular contact, and attendance and presentation at scientific meetings
* Contribute to scientific manuscript writing and/or review.
* Improve GALVmed’s performance by continuous review and improvement of R&D procedures to achieve the most efficient methods and procedures for product development.
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| **Qualifications / experience required** (in order to successfully carry out the job role) |
| **Essential*** Minimum: PhD in Biological Sciences or equivalent
* At least 5 years’ experience of product (essentially vaccine) development within a commercial environment
* Familiarity with design & management of clinical trials in animals
* Experience in conducting registration trials
* Project Leadership and Management experience with demonstrated ability
* Solutions driven, and creative
* Attention to detail & ability to prioritise work
* Excellent team-player and ability to work across functions
* Willingness to travel as needed, sometimes to challenging locations
* Knowledge & experience with Veterinary Good Clinical Practices & Good Laboratory Practices
* Experience of working in low & middle income countries
* Knowledge and experience on poultry diseases ((IB, IBD (Gumboro), FP, ND, Coccidiosis)
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