SANARIA
MALARIA ERADICATION THROUGH VACCINATION

**Job Announcement**

**Clinical Quality Manager**

Sanaria Inc., an award-winning biotechnology company based in Rockville, Maryland, USA, offers a unique and challenging opportunity to join a world-class team developing and commercializing a live sporozoite-based malaria vaccine for use in international travelers and in residents of malaria-endemic countries, where malaria causes half a million deaths each year, mostly in children. Sanaria is conducting clinical trials at multiple sites in Africa, Europe, and the United States aiming for licensure in the next few years. Sanaria is seeking a **Clinical Clinical Quality Manager** experienced with clinical quality systems including internal activities (standard operating procedures, documentation, internal audits) and external activities (quality review of clinical sites and vendors) as they relate to Sanaria-sponsored Phase 1 to Phase 3 clinical trials adhering to the US CFR and ICH-GCP guidelines. The CQS position will reside in the Clinical Department and report to Sanaria's Chief Medical Officer (CMO) but will work functionally with heads of Quality, Pharmaceutical Operations, Clinical Immunology and Regulatory to ensure compliance with GCP and with Sanaria's internal procedures including its Quality Management System.

**Responsibilities:**

The CQS will (1) review and update Clinical Department Standard Operating Procedures (SOPs) in accordance with Sanaria Quality Systems; (2) conduct internal clinical quality audits, including internal adherence to SOPs, computer system validation, and trial master file compliance with applicable US CFR, ICH-GCP and EU Directive quality standards; (3) identify potential systemic gaps and non-compliance, and coordinate the response with stakeholders to ensure timely remediation; (4) provide quality assurance review of clinical documents such as clinical protocols, consent forms, clinical study reports and pharmaceutical operations and clinical immunology data; (5) conduct external audits of vendors or clinical sites, including the drafting of audit plans, confirmation letters, agendas and audit reports; (6) review the responses and actions performed by vendors or

clinical sites in response to audits such as corrective action and preventative action (CAPA) plans and provide appropriate metrics for tracking and trending; (7) ensure adequate and up-to-date training and oversight of the Clinical Department members relating to GCP and SOP adherence. The CQS will also assist with quality issues at clinical sites, including the collection of high-quality data and deviation reporting compliance.

**Qualifications:**

Qualified Candidates will have a bachelor's or master's degree in a science- or public health-related field, 3 to 5 years of experience as a clinical research associate including at least 1 year experience working with clinical quality systems such as quality audits, SOP authoring/compliance and/or use of a risk-based quality management approaches; and will have demonstrated knowledge of GCPs. The successful candidate will be mission-driven, exhibit high professional standards, and communicate effectively as a member of a collaborative team. Also required is willingness and availability to travel.

We offer a competitive salary and benefits package. Please send cover letter, resumé and salary history to: **careers@sanaria.com**, subject line Clinical Quality Specialist. For more information, please visit **www.sanaria.com**. Sanaria Inc. is an equal opportunity employer.

Job Type: Full-time.

Location: Remote working can be considered.