OUR CLIENT

Headquartered in the United States, our client is a $2.5 billion leader in rapid diagnostics – it delivers reliable and actionable information through rapid diagnostic tests, resulting in better clinical and economic healthcare outcomes globally. The company is organized into three business units: cardiometabolic, toxicology and infectious disease.

Within cardiometabolic business unit, its products and services include tests to assist in the diagnosis and management of many cardiometabolic factors and conditions including cardiac markers, glucose and HbA1C, cholesterol levels, blood gases, and oral anticoagulation. Her critical care tests such as cardiac markers, blood gases are used in emergency departments and critical care units in hospitals. Our chronic care tests such as lipids, A1C, oral anticoagulants are used in GP offices, hospital clinics, pharmacy and other outpatient settings.

The company believes that when diagnosing and monitoring health conditions, it delivers on this vision by providing reliable and actionable information through rapid diagnostic tests, enhancing clinical and economic health outcomes globally.

BACKGROUND

Africa is a key strategic focus as the company builds on its already strong footprint on the continent. This role is central to the company achieving the next leap in its exciting story of growth, and will provide the successful candidate with the opportunity to shape history in the making.

ROLE PROFILE

Job Title	Quality & Regulatory Affairs Manager – North East Africa
Reports to	Head of Regulatory & Quality Affairs - Africa
Location	Cote D'Ivoire / Morocco / Algeria / Egypt

PURPOSE

The **Quality & Regulatory Affairs Manager** will be responsible for planning, coordination, and implementation of the company's quality management and quality improvement programs as required in the designated territory. The Quality & Regulatory Affairs Manager monitors and provides assistance with quality assurance and compliance functions. Coordinate regulatory processes, license renewals, and product registrations to ensure the compliance of regulations for IVDs and medical devices in the designated territory.

RESPONSIBILITIES

REGULATORY

Assists the Head of Regulatory and Quality Affairs - Africa with the following:

i. supporting business operations for product registrations within the defined territory

ii. development of registration plans in accordance with the company's Africa business plans

iii. facilitation of all registrations of the company's products in Affiliate and Distributor countries in the defined territory.

iv. providing visibility and reporting of ongoing product registrations and its status and to other stakeholders with the use of the product registration trackers where required

v. communication of expected product design changes received from Legal manufacturers onto distributors and authorities, collects such information from distributors and authorities on their impact and informs the Legal manufacturer and distributor on actions resulting from these changes

vi. communicating and clarifying when required, the registration requirements through to the Legal Manufacturers

vii. communicating and informing the company's legal manufacturers of relevant expected regulatory changes, and keeping abreast of such changes in the defined territory.

viii. providing updates into GRID for Africa (the company's Regulatory Database) through regulatory intelligence gathered via Commercial team, Distributors and authorities in the designated territory.

ix. promoting awareness of Quality and Regulatory Affairs throughout the organisation /and with distributors through organised training programmes as and when required.

x. work together with the Technical Service Team in collating of information on any Potential Reportable Events in the designated territory.

QUALITY

xi. Ensures that all global quality procedures applicable to the region are implemented and maintained in accordance to procedure, through periodic audits and in country visits;

xii. Assists in onboarding of new distributors for the territory and implement distributor compliance program in the designated territory;

xiii. Performs distributor audits as per program. Identify risks that impact quality on the company's products and services and work with distributors on improvements for risk aversion;

xiv. Assists the Head of Regulatory and Quality Affairs - Africa in the planning, implementation, monitoring and close out of field corrective actions (FCAs) in the affected designated territory;

xv. Provides periodic updates of FCA status to Head of Regulatory and Quality Affairs - Africa and other stakeholders in the designated territory;

xvi. Assists the Head of Regulatory and Quality Affairs - Africa in product modification reporting and adverse event reporting to regulatory authorities within the defined territory as required.

QUALIFICATION / EXPERIENCE REQUIREMENTS

Education:

i. Bachelors level degree in Sciences or a related discipline

Experience:

ii. Minimum of five years within the medical industry in Quality / Regulatory / Product Management functions;

iii. Strong effective communicator both oral and written and have a command of English and French language;

iv. Familiar with ISO Quality System standard concepts and procedures will be advantageous;

v. Insight of the Regulatory Requirements of the region;

vi. Must be willing to travel;

vii. Competent in Word and Excel Demonstrated ability to increase productivity and continuously improve methods, approaches, and departmental contribution while remaining cost-sensitive;

viii. Attention to detail;

ix. Demonstrates reliability to get the assigned work done in accordance within prescribed deadlines;

x. Communicates constructively to express thoughts and ideas clearly in a positive, confident, and respectful manner;

xi. Shares openly and willingly information, knowledge, and experience and takes the initiative to keep other team members informed;

xii. Work with others to accomplish tasks in achievement of organizational goals;

xiii. Deals with problems in a solutions-oriented manner and collaborate with others to find solutions and form action plans;

xiv. Exhibits flexibility and adaptability in dealing with changing situations, with consideration and compromise to different points of views on order to move forward to making of decisions;

xv. Shows commitment to the own responsibilities and as well as the overall teams goals and successes;

xvi. Treats others in a respectful and supportive manner consistently;

xvii. Able to assess quality related issues thoroughly and solves complex problems; and able to removes roadblocks that hinder business growth;

xviii. Able to refine and aligns tools, systems and processes to drive distributor / partners engagement for compliance;

COMPENSATION

You will be offered an attractive compensation package. Work sponsorship and relocation will also be considered for a successful candidate (if required).

EXPECTED START DATE

The successful candidate will be expected to start as soon as possible.

LOCATION

The position is based in Morocco / Algeria / Cairo or Cote D'Ivoire. By nature of the role, travel may be required of the incumbent from time to time.

APPLICATION PROCESS

To indicate your interest, please mail your **cover letter** specifying annual salary details and notice period and **updated resume** to **hello@talentstoneafrica.com**