**Job Profile: Quality Assurance Manager**

**Company Description**

**DKT International** is a global non-profit organization headquartered in Washington DC and one of the largest providers of family planning, HIV/AIDS prevention & safe abortion products and services globally, with offices in 24 countries that cover over 65 markets. DKT combines private-sector marketing techniques, cutting-edge technologies, and creative advertising to ensure women and men have the products, knowledge, and services when needed.

**DKT WomanCare Global** is a wholly owned subsidiary of DKT International that works closely with leading manufacturers to expand access, availability, and affordability of family planning and safe abortion products globally to advance DKT International’s mission of providing couples with affordable and safe options for family planning, safe abortion, and HIV/AIDS prevention through dynamic social marketing. DKT WomanCare Global operates in several capacities: as manufacturer of record for the Ipas Manual Vacuum Aspirator, as a global distributor, and as a marketing and distribution partner for other manufacturers. DKT WomanCare is **recruiting a Quality Assurance Manager** responsible for ensuring **effective implementation of DKT WomanCare’s Quality Management Systems and maintenance of its MDR, ISO 9001 and 14001 company certifications as well as the ISO 13485 certification for the Ipas Manual Vacuum Aspiration medical device technology**, of which DKT WomanCare Global is the manufacturer on record.

The position will report to the Managing Director and be based in our Paris, France offices or potentially a remote location within a similar time zone.

**Position Summary**

The Quality Assurance Manager is responsible for defining, planning, and overseeing the Quality System strategic initiatives in support of immediate and long-term business needs of the organization. Through effective implementation of the company’s Quality Management Systems, the position ensures management, employees, vendors, and products are in compliance with applicable rules and regulations of the pertinent regulatory authorities to effectively maintain relevant certifications and processes.

**Job Responsibilities**

**Quality Management System:**

* Ensures effective implementation of the company Quality Management Systems including quality policy and quality manual.
* Develops, maintains, distributes, and documents controlled documents and records for the Quality Management System
* Measures and monitors performance for compliance and reports performance to management and key stakeholders.
* Ensures compliance to internal and external ISO 9001 / ISO14001 / ISO 13485 / MDR policies and requirements; acts as Management Representative for controlling authorities
* Ensures conformity with Medical Device Regulation 2017/745: technical documentation, including EU declaration of conformity are maintained appropriately and reporting obligations are fulfilled, including acting as PRRP (Person Responsible for Compliance) as per MDR 2017/745.
* Maintains audit schedule and performs internal audits as needed; ensures effective preparation and management of external audit activities, including responsibility for CAPA system.
* Manages and contributes to safety data exchange agreements/QA agreements.
* Manages and ensures effective system for handling customer complaints and adverse event reporting.
* Drives improvement and efficiency efforts for the entire quality system; ensures quality system is efficiently implemented across the organization, including support to sales and marketing teams to ensure quality considerations are integrated in documentation and contracts.
* Demonstrated creativity, foresight and mature judgment in anticipating and solving problems, determining program objectives and requirements, organizing programs and projects, and developing standards and guides for quality
* Recruit and manage QA staff when necessary

**Management of Contracted Manufacturing Site and Technical Product Files (Manual Vacuum Aspirator Range):**

* Leads oversight of Quality Control and contracted manufacturing, including annual audit of contract manufacturer
* Ensures the management of suppliers and manufacturing sub-contractor adheres to quality standards and certifications.
* Develops and maintains the quality agreement.
* Oversees the risk management process, including product release and distribution.
* Develops and maintains the technical construction files
* Ensures conformance with US, EU, and international regulation
* Supports Regulatory Department to respond to questions related to products where we are manufacturer on record.

**DKT WomanCare Expectations**

The successful candidate will have:

* Minimum bachelor’s degree in engineering or applicable life science discipline; master’s degree preferred.
* At least 5-7+ years of demonstrated progressive experience in establishing, implementing, and administering electronic-based Quality Management Systems (e-QMS)
* Demonstrated expertise in ISO 13485, ISO 9001, and ISO 14001 requirements
* Experience working with and managing external auditing bodies and representing the Company at these audits
* Experience with sterile invasive medical devices
* Professional fluency in English as organizational working language (written and spoken); professional fluency in a 2nd language a bonus (Chinese preferred)
* Willingness and ability to travel internationally approximately 15% (2-3 trips per year on average for on-site audits or other QA requirements)
* Excellent written and verbal communication skills and superb computer skills, including the Microsoft Office Suite (Outlook, Word, PowerPoint, and Excel). Experience with ERP systems, preferably Dynamics 365.
* Highly goal-oriented, "hands-on" professional who can interact effectively with personnel at all levels; and possess a proven track record of active involvement in a Company’s daily operations
* Ability to perform well under time pressure to meet deadlines.
* Strong analytical and decision-making skills; ability to synthesize information and data from multiple sources.
* Enjoy a multi-cultural working environment.
* A ‘can do’ attitude and self-starter with an eagerness for growth.
* A passion for improving people’s lives by contributing to increased access to contraception and safe abortion products and technologies

**How to Apply**

Come join a multi-cultural global team and company that is working daily to improve people’s lives. We are looking for exceptional talent to join our team and contribute to our rapid growth trajectory.

All qualified candidates will be considered without regard to race, color, religion, gender, gender identity or expression, sexual orientation, national origin, genetics, disability, or age.

Please send your resume/CV, your application letter, and at least 3 professional references by July 18, 2024 to HR@dktwomancare.org.