DCVMN Recruiting Talent in India/ South Africa

The Developing Countries Vaccine Manufacturers Network (DCVMN) is a voluntary public health-driven alliance of 43 vaccine manufacturers from developing countries, firmly engaged in research, development, manufacturing, and supply of high-quality vaccines that are accessible to protect people against known and emerging infectious diseases globally.

DCVMN works to strengthen vaccine manufacturers through the provision of knowledge sharing programs and professional training on technical capabilities, research in vaccine production, encouraging technology transfer initiatives, and educating the public about the availability of safe and effective vaccines, from developing world manufacturers and several other related programs.

DCVMN Secretariat is responsible for the effective coordination and organization of the Network's operational excellence and drives the alliance's strategic initiatives.

DCVMN, as a part of its global expansion program, is looking for a talented and self-driven individual for the position of **Senior Manager, Medico-Regulatory Affairs** based in **India** (Gurgaon) **/South Africa** (Cape Town) to support its global training activities on a full-time basis (100% FTE).

Job Purpose: The basic purpose of this job, being an important & integral part of the DCVMN Secretariat, would be to support the organisation deliver its agreed objectives by harnessing talent and professional development of the technical workforce of its member companies in coordination with global agency/ies and effectively utilising and monitoring funds received through grants from the multilateral funding agencies for building member companies' capacity and capability to accomplish overarching goal of global vaccine equity!

Reporting: The position reports directly to CEO-DCVMN.

Duration & Package:
Position initially will be for a period of 2 years from Jan 1st, 2023 until December 31st, 2024 during which the incumbent will be paid a fixed salary commensurate to qualification, experience and expertise as per standards prevailing in not for profit organisations.

Key Responsibilities:

- Support designing and implementing clinical development of vaccines, including clinical trials.
- To oversee and monitor all aspects of clinical trials including clinical trial design, ethical issues, safety data collection, operational implementation aspects, statistical analysis, clinical study reports and publication of results in peer reviewed journals
- Strategizing the new product filings, regulatory approval process, post approval variations, life cycle management of products from lab scale to commercial production and supply.
- Dealing with WHO (essential), EMA, FDA and Other SRAs as appropriate
- Participation in international clinical meetings

- Participation in the preparation of summary of product characteristic (SmPC), Package Insert, Periodic Safety Update Report (PSUR), Site Master file, Drug Master File (DMF) in collaboration with preclinical, clinical, manufacturing and legal.
- Response to queries from National and International Regulatory Agencies
- Interactions with Member companies, Academia, Research Institutions and Industry partners
- Generating quality reports, preparing effective grant applications and presentations
- Chasing & achieving time bound goals and challenging objectives

Skills and Qualifications:

- Strong knowledge of the clinical regulatory aspects of clinical development to obtain MA/WHO PQ
- Experience with US FDA/EMA/WHO & other SRAs as appropriate
- Full understanding of preparation and filing of dossiers for submission to various regulatory agencies all over the world (including eCTD, CTD format & ACTD Format) where appropriate.
- Ability to present clinical trial results to subject matter expert group before and after MA is obtained
- 10-12 years experience in related field/s in multinational setting
- Experience of working with global/international agencies
- Good experience in CRO management
- Energetic and go-getter
- Ability to learn quickly, take initiatives, and work both independently and within a team setting
- Excellent written & verbal communication skills
- Strong knowledge of all Microsoft Office Applications

Requirements:

- Very high communication skills, **both written and verbal English**
- Team Member
- An out of box thinker & Solution Finder
- Goal oriented behaviour with OTIF (On Time In Full)
- Advanced qualifications (Masters' degree from a reputed University/Institution) in Medicine
- Publications in peer reviewed journals like Lancet, Vaccines, Human Vaccines & Immunotherapeutics, Journal of Infectious Disease etc
- 10-12 years experience preferably in MNCs/ global public health institutions like GAVI, CEPI, WHO.PATH or any other international organisation of repute.
- Previous experience in vaccine industry will be preferred.
- Must be prepared to travel with valid passport

Application: Please send your detailed CV and a cover letter in English to r.suri@dcvmn.net latest by January 10th 2023. Applicants who are considered for an interview will be contacted through mail.