Quality Assurance Manager (m/f/d)

VPM is a development consulting firm for the biopharmaceutical industry. Unique about us is that VPM began as a project management organisation, successfully developing and out-licensing three out of five proprietary products sourced from academic laboratories. VPM now offers consulting and services for the entire product development value chain.

We live product development - transforming ground-breaking ideas into life-saving medication.

We belong to Serum Institute of India Pvt. Ltd., the world's largest vaccine manufacturer. Together, we bring lifesaving medication to the market. Two out of three children worldwide are vaccinated at least once with a vaccine from Serum Institute.

To support our Quality Assurance Team we are looking for a

QUALITY ASSURANCE MANAGER

to join our team at the earliest opportunity (full time employment).

Job Profile:

- Conduct QA review of clinical trial specific documents as requested (e.g. study protocols, ICFs, CSRs)
- Provide help, advice and guidance to operational departments on matters of quality/GCP
- Coordinate, conduct and track GCP training of new and existing staff
- Create, maintain and revise departmental Quality Documents (SOPs, Templates etc.)
- Management of Quality Documents according to the respective written procedures
- Plan, prepare and conduct audits (vendors, processes, systems, documents etc.);
- Write audit reports and communicate findings and recommendations and evaluate the adequacy and completeness of corrective and preventive action plans
- Provide support/participate in authority inspections
- Ensure the timely and effective follow up of all identified or assigned quality issues
- Maintain required knowledge of applicable regulations, guidelines, company standards, procedures
- Be part of national and international team work

Requirements:

- PhD in life sciences or master's degree as medical documentarist/medical information manager or comparable qualification
- Demonstrated Quality Management System experience (GCP specific experience preferred)
- Profound knowledge of current GxP regulations and best practices
- Experience with global late-stage clinical trials leading to market authorization
- Demonstrated Issue Management and CAPA experience in a clinical environment
- Experience with Inspections of clinical trial sites, sponsors or CROs
- Excellent written/oral communication skills in English and German and interpersonal skills
- Attention to detail with an ability to detect and correct errors in various types of documents
- Self-starter and team-player
- Knowledge in Microsoft Office applications, Adobe
- Experienced in working with EDC, IRT, eTMF, document management systems
- Willingness to travel (national and international)

What we offer:

- *Contribute* to our mission to provide life-saving and affordable medication for the entire globe
- *Manage* cutting-edge and challenging national and international projects in pharmaceutical development of vaccines, biologicals and other medicinal products
- *Participate* in a diverse, international, experienced and highly motivated team that values common goals and supportive working environment
- *Benefit* from our extensive on-boarding process with targeted training and support by personal mentoring
- *Develop* yourself and your career within the company with external and internal trainings
- *Enjoy* a competitive salary and non-monetary incentives that value sustainability within the company and the environment.

Contact details

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