Polyphor is a clinical stage biopharmaceutical company based in Allschwil, Switzerland, and is focused on the discovery and development of antibiotics and other specialty pharma products for severe or life-threatening diseases.

We are currently looking for a:

Head Medical Safety & Pharmacovigilance

The key roles of the Head Medical Safety and Pharmacovigilance are:

Pharmacovigilance**:**

- Responsible for the writing of clinical documents in collaboration with stakeholders, ensure feedback is adequately integrated into protocol;
- To assume responsibility for Company's Pharmacovigilance (PV) system and oversight of all PV-related vendors and activities including;
- Ensuring that Company's PV system complies with Company's obligations as sponsor of clinical trials globally
- To assume responsibility for and to ensure Company's obligations in relation to Pharmacovigilance are fulfilled
- To work with QA to identify any gaps in the SOP system are identified and filled both for PV vendor management
- To ensure that information of any adverse events and suspected adverse reactions reported to Company personnel or to vendors working on behalf of Company, is collected, collated consistently and analysed and is readily accessible
- To ensure that Individual Case Safety Reports (ICSRs) from clinical trials, post-marketing use, registries, patient's named programs and literature are readily and accurately processed, evaluated and reported to the competent health authorities, ethics committee and investigators as appropriate and within the due timelines
- To oversee the functioning of the PV providers and management of the company safety database.

Medical Safety:

- To understand the safety profile of the company's products and develop a safety profiling plan that actively manages the product safety profile through recommendations for AE management in development protocols through writing the Risk management plan at time of submission.
- To oversee the operation of Company's independent DSMBs associated with the Clinical Trials.
- To ensure that Development and Periodic Safety Update Reports (DSURs/PSURs), Annual Safety Reports and all other documents providing a comprehensive evaluation of aggregate safety data are prepared, reviewed and submitted to the competent health authorities according to the regulations
- Provide adequate guidance to the planning and execution of clinical development programs with regard to drug safety-related matters including
- Proving input into IBs, IMPDs and protocols and development and maintenance of Company's core safety data sheets and information
- Ensuring regular and continuous monitoring of safety profile is performed seamlessly, from the early stages of clinical development to the end of the drug's life cycle. This should allow the rapid identification of potential safety signals, and the management / communication of safety risks

- Appropriate drug safety quality control and quality assurance procedures are in place, including standard operating procedures, database operations manuals, contractual arrangements, compliance data (e.g. in relation to the quality, completeness and timeliness for expedited reporting and submission of periodic safety reports), audit reports and training of personnel in relation to pharmacovigilance
- Provide input into the preparation of regulatory action in response to emerging safety concerns (including amendments, variations, urgent safety restrictions, and communication to investigators, patients and healthcare professionals, scientific advice meetings etc.)
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Qualifications:

- Medical Degree. Experience in pharmacovigilance or medical safety strongly preferred.
- At least 10 years of experience in all aspects of drug development including Pharmacovigilance and/ or Medical Safety
- Understanding of GVP and knowledge of global PV regulations and standards
- Previous experience in setting up and/or overseeing the PV system for an ethical pharmaceutical company would be highly preferred
- Fluent in both written and spoken English; German or French is a distinct plus
- Adhere to Company values
- Leadership and communication skills well developed
- Can-do attitude and entrepreneurial spirit
- Problem solver, individually and in working teams
- Proactive and detail oriented

Please send your full application documents to the following address: hr@polyphor.com. Direct applications are preferred. For further information about the offered position, please contact: Franziska Müller (+41 61 567 16 00).