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 Regulatory Affairs & Quality Assurance

The position is based in Allschwil and will report to the CMDO (Chief Medical and Development Officer) with a direct dotted line to the CEO of Polyphor to ensure independence of the role while keeping a close contact to the services and processes supported by QA.

Responsibilities in Regulatory:

- Act as the regulatory key representative, developing and implementing the regulatory strategy according to the drug development
- Establish and manage regulatory timelines, leading the planning and preparation of global regulatory submissions
- Management of regulatory service providers by gathering all data and documents required to prepare and file Regulatory submissions with local authorities
- Strong knowledge of regulatory with regards to Oncology and Anti-infectives as well as the pharmaceutical pathways (FDA, EMA, etc)
- Ensure the company remains permanently in compliance with regulatory legislation
- Act as the key player with regulatory bodies and prepare meeting request and briefing documents for regulatory agencies. Coordinate and prepare responses in regards to Regulatory Agency requests
- Develop and maintain regulatory knowledge of global regulations
- Responsible for budgetary needs related to the regulatory activities of the company

Responsibilities in Quality:

- Ensure requirements to operate and perform clinical trials according to GCP and ICH guidelines/ EU CTD and other applicable laws and regulations are met
- Develop, maintain and get senior management endorsement of the Quality Management project and strategic audit program
- Implement and manage clinical QA documents' system, protocol deviation, investigations and change control management systems / tools. Author, review and approve GCP documentation from QA perspective
- Identify, revise/develop and implement SOP's and the Quality Management System that can be global in scope. Ensure regular review of SOPs
- Interact with Regulatory agencies directly during inspections as well as providing input into documents that are part of regulatory filings (
- Participate in GxP vendors' qualification program, plan and perform audits of clinical vendors and investigators, follow-up the CAPAs, report the associated quality metrics
- Plan and perform company-internal audits in form of essential clinical trial document audits and drug development process audits

- Ensure clinical staff is properly trained on Polyphor SOPs and applicable industry guidelines and regulations. Develop clinical QA training programs and materials and facilitate training drug development entity
- Take responsibility for the Inspection Readiness program, and preparation, coordination and management of regulatory sponsor inspections, and clinical site inspections. Facilitate the elaboration of inspection CAPAs and ensure tracking and reporting

Qualifications:

- A minimum of 8 years' experience in a biotech or pharmaceutical environment in a regulatory affairs management role
- Graduate degree in Pharmacy, Biology or Life Sciences
- Practical experience of GCP and related EU & FDA regulatory requirements and ICH guidelines and in conducting clinical audits of vendors, sponsor, prepare sponsor and investigational sites for EU and FDA Regulatory inspections is preferred.
- Experienced in Quality Assurance and all relevant practices (experience in audit methodology and at least 3 years in Clinical Quality Assurance)
- Experiences in other quality standards would be a plus, e.g. GLP, GMP
- Excellent interpersonal skills with ability to lead project on his/her own
- Strong verbal and written communication skills.
- Fluent in English, any other language would be a plus.
- Willingness to travel within the EU and international
- Require a highly motivated, resourceful individual who can set goals, work independently and collaborate effectively with various scientific and business representatives.
- Results orientated with a hands-on, can-do attitude.
- Positivity, Flexibility and adaptability with agile thinking.
- Entrepreneurial mindset (creative thinking and innovation) required

Ideal start would be Q2/2019. 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.