CSL Behring – the global biotherapies provider driven by its promise to save lives and to improve the quality of life for people with rare and serious medical conditions.

For our location in Bern or in Marburg, we are looking for a

CTA Operations Team Leader, Global Regulatory Affairs

Main Responsibilities and Accountabilities:

- Lead a dedicated CTA Operations team to ensure timely clinical trial approvals globally in accordance with the Company strategy, appropriate international regulatory standards, and within the agreed timeframe and budget.
- Maintain and improve processes, procedures and systems which support the global management of CTAs
- Ensure management and oversight of the CROs performing CTAs to ensure quality, timely approvals, and compliance.
- Be a Subject Matter Expert for CTA related topics and ensure continuous process improvement.
- Responsible for the generation, maintenance and provision of metrics on workload as well as KPIs for key CTA activities and analyze consolidated data.
- Support budget development and forecast management related to CTA activities.
- Maximize the use of human and fiscal resources through effective planning. Calculate manpower and cost projections.
- Assess the activity/performance of team members and/or subordinates by establishing objectives, and conducting performance appraisals for team members.
- Will act as a Global Regulatory Study Lead (Lead CTA activities for all Clinical Trials during the entire study lifecycle; Perform CTA submissions in selected countries; Disseminate the CTA project status like CTA submission, CTA approval, CA questions to the concerned stakeholders, etc.).
- Establish and maintain excellent communication and working relationships with Clinical Development Operations to ensure timely clinical trial approvals globally and with GCSP for the management of regular safety reporting to Health Authorities, during the clinical development phase of CSL Behring products.

Qualifications & Experience:

- BSc/MSc degree or equivalent in life science, pharmacy, medical laboratory technology, or other health/medical related area. (Other degrees and certifications considered if commensurate with related quality management, regulatory or clinical research experience.)
- As a guide, a minimum of 8+ years' experience in managing Clinical Trial Authorizations.
- Experience in leading and managing a global team of professional staff.

- Excellent written and oral communication skills in English – German is a plus.
- Demonstrated project management skills including simultaneous management of multiple projects. Possesses excellent planning, time management & coordination skills.
- Demonstrated ability to problem solving and use clear judgment in relation to regulatory requirements, interactions with external parties, timelines, and complex clinical studies.

We are looking forward to receiving your online application on our website:

https://csl.wd1.myworkdayjobs.com/CSL_External/job/EMEA-DE-Marburg-CSL-Behring/Global-Regulatory-CTA-Operations-Lead_R-054621-1

Applications must include a motivation letter and CV, as well as letters of references and copies of relevant transcripts and/or diplomas in the original language. **Please include all these in one document together with the CV.**

CSL Behring is committed to provide equal employment opportunity for all.