CSL Behring – the global biotherapeutics provider driven by its promise to save lives. Our more than 1,400 employees in Bern are committed to developing and delivering live-saving therapies to help people with primary immune deficiencies to live full lives.

We are looking for a

Global Regulatory Affairs CMC Lead Albumins, Senior Manager

The GRA CMC Lead Albumins is responsible for overseeing all relevant regulatory CMC aspects of multisite projects related to CSL Behring's Albumin products globally and will have his/her office in Bern.

Main Responsibilities and Accountabilities:

- The GRA CMC Lead provides tactical and strategic regulatory leadership and global oversight for all CMC regulatory aspects related to Albumins.
- The GRA CMC Lead is the subject matter expert for Albumins and the primary regulatory interface to relevant global technical expert functions. He/she oversees and interprets relevant existing or new regulatory requirements, evaluates draft guidelines, writes impact assessments, leads gap analysis and proposes solutions and strategies to remediate risks.
- The position holder acts as Global Regulatory Project Lead for CMC projects related to Albumins affecting multiple manufacturing sites across CSL Behring's global manufacturing network and collaborates in a GRA project team with CMC colleagues of affected site as well as regional, labeling and publishing representatives.
- Additionally, the GRA CMC Lead might be a permanent member of Global Regulatory Affairs Strategy Teams related to Albumins, and in this role will chair the respective CMC Regulatory Sub-Teams as applicable.

Qualifications & Experience:

- Advanced scientific degree / PhD; preferably degree in Regulatory Affairs
- Minimum 5 years' experience in Regulatory Affairs demonstrating significant knowledge and technical expertise in CMC matters.
- Extensive regulatory technical expertise across a range of project types and products with demonstrated capability to develop global regulatory strategies in a matrix team environment
- Significant regulatory planning and submission experience across multiple Health Authorities/Regions
- Excellent communication, project management, planning, problem solving and presentation skills are required to be successful in this role

We are looking forward to receiving your online application. 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.