



About CSL Behring

CSL Behring is a global biotherapeutics leader driven by its promise to save lives. Focused on serving patients' needs by using the latest technologies, we develop and deliver innovative therapies that are used to treat people with life-threatening medical conditions and to help them live full lives. The parent company, CSL Limited, is headquartered in Melbourne, Australia.

In May 2014, CSL selected Lengnau in the Canton of Bern in Switzerland as the location of a new manufacturing facility to support the commercial production of our promising novel therapies. In May 2020, CSL announced the strategic partnership with Thermo Fisher Scientific, the world leader in serving science. Thermo Fisher will lease and operate the Lengnau state-of-the-art biotech manufacturing facility once construction is completed in 2021. It is anticipated that employees at the site who are engaged for the operation of the site and the commercial production of our therapies in Lengnau will automatically transfer to Thermo Fisher Scientific once construction is complete. Today, more than 200 employees work in Lengnau.

You can find more information on the strategic partnership with Thermo Fisher [here](#) and some more information about the prospects of a future career with Thermo Fisher [here](#). We are currently recruiting for a

Regulatory Affairs Manager (m/w/d)

RESPONSIBILITIES

- Develops and executes international regulatory strategies in close collaboration with the site Quality and Manufacturing Departments and with regional regulatory experts to license product changes.
- Develops and executes international regulatory strategies to obtain new marketing authorizations of established product in agreement with the commercial organization.
- Represents the international Regulatory Affairs function in cross-functional project teams.
- Responsible for the maintenance of the content of regulatory submissions of the licensed products from the site of manufacture, meeting appropriate standards and content requirements.
- Responsible for the compilation of relevant high quality documentation for CMC submissions according to agreed schedules while taking into account regional specific requirements.

QUALIFICATIONS & COMPETENCIES

- PhD in Natural Science (Preferably a degree in Regulatory Affairs)
- First experience in the pharmaceutical industry and Regulatory Affairs desirable
- Strong background in natural sciences with a focus on biological medicinal products, ideally plasma-derived and recombinant products
- Ability to work with minimal supervision, with sound technical judgment and analytical skills
- Flexibility to work in a international regulatory cross-cultural work environment and can work independently as well as in a team
- Fluent in English, German is a plus

If you are interested in this exciting opportunity, we are looking forward to meeting you at our career event.

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