Lonza

Head of Regulatory Affairs Small Molecules (f/m/d)

Job Description Summary

Today, Lonza is a global leader in life sciences operating across three continents. While we work in science, there's no magic formula to how we do it. Our greatest scientific solution is talented people working together, devising ideas that help businesses to help people. In exchange, we let our people own their careers. Their ideas, big and small, genuinely improve the world. And that's the kind of work we want to be part of.

The Head of Regulatory Affairs, Small Molecules role is a leadership position for a technical expert and strategist with expertise in small molecule pharmaceutical products. The role will report to the Global Head of Regulatory Affairs and will support Lonza's Small Molecule Division (https://www.lonza.com/small-molecules) to support Lonza's customers and manufacturing sites. This role will be responsible for closely monitoring all legal and regulatory issues at the global, national and/or regional level and assessing impact to Lonza's business. The incumbent will lead direct reports.

Key responsibilities:

- Responsible for the Small Molecules internal and customer related regulatory affairs and CMC project activities globally
- Provide strategic and technical regulatory leadership, expertise and advice to the Small Molecules division and related internal and external customers / stakeholders
- Ensures presence in external and internal regulatory expert networks, to anticipate and identify applicable regulatory evolutions in the domain of excipient, pharmaceutical, ingredient and food manufacturing
- Managing a team of professional RA staff covering Small Molecules across the Lonza network
- Develop and maintain high level contacts with external RA stakeholders including customers, regulatory authorities, academic institutions, scientific experts in regulatory and toxicology – as well as Lonza worldwide RA functions
- Provides RA input into Division Strategy
- Anticipation, evaluation and Influencing (both internal and external) of global regulatory trends and legislation
- Provide regulatory support and advice for internal and external customers in line with defined Regulatory plans and in response to ad-hoc questions

Key requirements:

- Successfully absolved Bachelor or Master studies in biological sciences, chemistry, biochemistry or equivalent
- Substantial experience within a GMP related environment, including several years of experience in regulatory affairs in preparation, approval and authoring of complex regulatory submissions of EU and US API and drug products
- Knowledge of US and EU regulatory requirements for API and drug products
- Proven leadership experience and ability to foster opportunities for talent development
- Expertise in the interpretation and communication of CMC regulatory requirements for site product and process issues
- Fluency in English, additional languages are advantageous
- Willingness to travel internationally

Every day, Lonza's products and services have a positive impact on millions of people. For us, this is not only a great privilege, but also a great responsibility. How we achieve our business results is just as important as the achievements themselves. At Lonza, we respect and protect our people and our environment. Any success we achieve is no success at all if not achieved ethically.

People come to Lonza for the challenge and creativity of solving complex problems and developing new ideas in life sciences. In return, we offer the satisfaction that comes with improving lives all around the world. The satisfaction that comes with making a meaningful difference.