Lonza

Manager, Regulatory Affairs

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.

In this exciting role, you will support clinical trial and product license applications for various CMC (Chemistry, Manufacturing and Control) biological projects for customers. You will work collaboratively with company personnel to co-ordinate the regulatory activities for clinical development, product license applications as well as life cycle management. The role will also provide support for the site with respect to change control and deviation assessment and other activities such as evaluation of new projects.

Key responsibilities:

- Review and provide input from a CMC perspective on relevant documents required for (BLA/MAA) submission for Biologicals
- Author/review the Module 3 section for IND/IMPD for biologicals
- Facilitated and attended CMC meetings with key stakeholders and regulators when applicable (e.g. FDA/EMA) for biologicals
- Provide regulatory advice to customers for biological projects as well as regulatory support for projects and project teams
- Prepare briefing documents for agency meetings and attend customer meetings and project team meetings
- Devise and maintain regulatory project plans in line with the best practice recommendations
- Update functional leads and maintain transparency of information across regulatory function

Key requirements:

- Master or Bachelor degree in Life Sciences (e.g. Biology, Biochemistry, Pharmacy)
- Experience in preparing and authoring CMC (Chemistry, Manufacturing and Control) sections for regulatory documents through product life cycle
- Good understanding of regulatory requirements for biologicals and good practical experiences in Regulatory Affairs in a pharmaceutical environment
- Previous experience in CMO/CDMO environment is a clear advantage
- Fluent in English required; German is a plus
- Ability to work across a complex matrix environment

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.