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.

- Key responsibilities

- Author/review the Module 3.2 dossier sections to support Customer filings for Biologics early phase projects (e.g. IND/IMPD), commercial projects (e.g. BLA/MAA) and life cycle variations submission for DS, DP and Appendices, for newly developed products and/or site tech-transfers.
- Lead and co-ordinate submission related activities ensuring deliverables according to agreed timelines and in accordance to Lonza procedures and good practices.
- Act as point of contact for assigned projects and provide regulatory support to internal project teams.
- Track and negotiate within the project teams source documents availability required for clinical (e.g. IND/IMPD), and commercial (e.g. BLA/MAA) submissions.
- Preparation and review of responses to Health Authority submission review questions (RtQs).
- Preparation and review briefing documents for scientific advice meetings with Health Authorities.
- Attend Customer meetings and provide regulatory advice for assigned projects.
- Communicate and escalate risks and issues to management and project teams as applicable.
- Perform Regulatory assessments for deviations, change controls and VCNs to ensure compliance with internal procedures and regulations.
- Internal regulatory support for operation and control e.g.:
- Understanding of EU, US and other global regulatory requirements to support compliance in all phases of contract manufacturing of Biologics products.
- Support site-specific regulatory documentation and activities.
- Maintenance of Lonza sites facility registrations filings with regulatory agencies and plant-level documentation (e.g. Site Master File and Japan FMA).

- Key requirements:

- Master degree in Biology, Chemistry, Biochemistry, Pharmacy or equivalent. Higher education (PhD, PharmD) or Regulatory Affairs Certification (RAC) preferred.
- Experience (at least 5 years) in preparing and authoring M.3.2 CMC dossier sections for DS, DP and Appendices through the product life-cycle.
- Ability to work autonomously and in team.
- Previous experience in CMO/CDMO environment is a clear advantage
- Exceptional communication and interpersonal skills: Ability to interact with internal and external Customers regularly working in a global environment across time zones.
- Experience in leading project teams to successful filings and approvals.
- Demonstrated skills managing project timelines and priorities.
- Good understanding of regulatory requirements for Biologics.
- Good understanding of Biologics manufacturing processes (e.g. Mammalian, Microbial, ADCs, Vaccines).
- Previous experience in the Pharma industry (e.g. QA, MSAT, Operations and Analytical).
- Fluency in English required, German is a plus.
- Hybrid work conditions

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.