Regulatory Affairs Senior Specialist

Job Description Summary

Today Lonza is a global leader in life sciences. We are more than 15,000 employees in more than 100 locations around the world. While we work in science, there is 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.

For our site in Visp we are looking for a Regulatory Affairs Senior Specialist.

Key responsibilities

- Provide Regulatory Affairs (RA) expertise for Small Molecule (Chem) Active Pharmaceutical Ingredient (API) and/or intermediate Projects including:
    - Review and evaluate the regulatory impact of the change requests for the API manufacturing process incl. technology transfer
    - Review and write chemistry, manufacturing and controls (CMC) documentation appropriate for clinical and commercial applications incl. Drug Master Files (DMF)
    - Submit country-specific health authority supporting documents such as Site Master Files (SMF), Master Batch Records (MBR) and/or executed Batch records on behalf of customers
    - Coordination and drafting of briefing books for scientific meetings
    - Respond to health authority questions and deficiencies
    - Provide regulatory & strategic guidance (Regulatory Plans) to internal and external customers (site Visp) as well as internal Lonza maintaining regulatory databases.
    - Participate and presents in customer project meetings
    - Interact with the microbial & mammalian cell culture fermentation regulatory affairs groups for Antibody Drug Conjugates
- Proactively ensure functional leads are informed of project developments and maintain transparency throughout projects
- Utilize prior analytical (Quality Control) and/or manufacturing process (Operation) experience to question and propose alternative solutions to challenges by internal and external customers.
- A solution and service minded proactive approach should be applied even with challenging customers.

Key requirements

- Master or Bachelor degree in Life Sciences (e.g. Chemistry, Chemical Engineering, Pharmacy, Pharmaceutical Science or Technology) or above
- Practical experience in preparing and authoring CMC (Chemistry, Manufacturing and Control) sections for regulatory documents appropriate for clinical and commercial applications
- Ability to concisely convey regulatory requirements and propose alternative solutions to both subject matter experts in other scientific fields as well as customers with limited regulatory experience
- Demonstrated priority management according to project timelines
- Ability to work in a complex matrix environment across multiple projects and with attention to details
- Fluency in English required; German (manufacturing procedures) is an advantage; French a plus (not required)
- Empowered and transparent workstyle sharing information and experiences

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.