Regulatory Affairs Manager

At Lonza, we invest in great people. We encourage our employees to challenge themselves and we offer an environment that fosters creativity and success. Headquartered in Basel, Switzerland, we operate production, R&D, and business sites around the world, including Europe, North America, and Asia.

Our vision:
We strive to be the leading supplier using science and technology to improve the quality of life.

Our mission:
We work with passion, using advanced technologies, to transform life science into new possibilities for our customers.

Do you want to help us as we shape the future of this great organization?

Job Description Summary

Provides Regulatory Affairs Support to the site (Visp, Braine) and customers.

Job Description

Prepare and support DMFs and NDA/MAA/BLA for customers (for small molecules, peptides, ADCs and/or microbial biotech products)

- Support site specific regulatory documents
- Provide regulatory support and advice for internal and external customers in line with defined
- Regulatory plans and in response to ad-hoc questions
- Maintain documented regulatory project plans in line with best practice recommendations
- Update functional leads and maintain transparency of information across regulatory function.
- Facilitate and support the development and documentation of revised regulatory processes in line with global processes within the LPB RA team. (Reporting to Head of RA LPB Basel)

Responsibilities

Prepare and support DMFs and product licence applications for customers

Provide strategic and operational regulatory direction for projects under responsibility

Lead and implement all submission activities (planning, review, coordination, submission) for new document creation and document updates

Support country-specific regulatory documents

Support assessment of change requests

Oversee preparation of answers to Health Authority Questions or customer requests on regulatory documents

Provide regulatory support and advice for internal and external customers in line with defined Regulatory plans and in response to ad-hoc questions

Establish and maintain sound working relationships with internal and external customers

Maintain documented regulatory project plans in line with best practice recommendations

Update functional leads and maintain transparency of information across regulatory function.

Support site specific regulatory documents Interact with internal departments to improve facility processes and systems and provide regulatory impact of proposed improvements.

Evaluate process and system improvements for potential regulatory impact

Provide regulatory advice to functional areas on site :

Regulatory developments & new guidelines

Interpretation of Health Authority regulatory requirements

Facilitate and support the development and documentation of revised regulatory processes in line with global processes within the LCM-C RA team.

Support the implementation of change control activities within the Global Regulatory LCM-C team, as appropriate Projects under responsibility include development and marketed drug substances (synthetic or semi-synthetic small molecules, biologics or antibody-drug conjugates) for human or veterinary use.

Education

Master: Biochemie, Master: Biologie, Master: Chemie

Work Experience

Quality, Regulatory

Experience Level

Intermediate

Skills

At least 2-4 years of related pharmaceutical experience in regulatory affairs, At least 2-4 years of related pharmaceutical industry experience in regulatory affairs, CMC Regulatory Affairs, Competent in Microsoft Office Software (Word, Demonstrated ability to manage priorities and work under tight timelines, Experience of preparing and authoring module 3 CTD, e.g. for IND/IMPD and NDA/MAA/BLA, Superb organisational skills and attention to detail

Language(s)

Deutsch, Englisch, Französisch