CMC LIFE CYCLE PROJECT MANAGER

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Erkenningsnummer
VG. 1690/BO B-AB10.018.

A We are seeking a highly skilled and experienced Project Manager to oversee and manage the change control system within our biopharmaceutical company. This role is critical in ensuring compliance with CMC regulatory requirements, maintaining product quality, and facilitating efficient project execution. The ideal candidate will have a strong background in regulatory affairs, project management, and a thorough understanding of CMC requirements in the biopharmaceutical industry.

ROLE AND RESPONSIBILITIES:

- Participate in the development, implementation and maintenance of an effective change control system for CMC-related changes;
- Coordinate and document CMC changes, ensuring compliance with regulatory and quality requirements;
- Support cross-functional team to plan, execute and close CMC-related lifecycle management projects, facilitate communication between different stakeholders to ensure smooth execution of change controls;
- Develop project plans, track progress, identify potential risks associated with regulatory changes and develop mitigation strategies;
- Facilitate project meetings, communicate project status and resolve issues promptly;
- Review and approve change control documentation, ensuring accuracy and completeness, maintain comprehensive records of CMC lifecycle management activities
- Prepare regular reports on change control status, metrics and project progress for stakeholders, incl management, internal project teams and external partners
- Identify opportunities for process improvements in change control and project management.
- Implement best practices and standard operating procedures (SOPs) to enhance efficiency and compliance.
- Train and mentor staff on change control processes and regulatory requirements.

QUALIFICATIONS:

- **Education:**
  - Bachelor or Master degree in Life Sciences, Pharmacy, Chemistry, or a related field. Advanced degree preferred.
- **Experience:**
  - Minimum of 5 years of experience in the biopharmaceutical industry, with at least 3 years in a regulatory affairs or CMC role.

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- Proven experience in managing change control systems and CMC regulatory submissions.
- Strong project management skills with a track record of leading successful projects.

- **Knowledge and Skills:**
  - In-depth knowledge of CMC regulatory requirements and guidelines (FDA, EMA, ICH).
  - Excellent organizational, analytical, and problem-solving skills.
  - Proficiency in project management tools and software.
  - Strong communication and interpersonal skills, with the ability to work effectively in a team environment.
  - Attention to detail and a commitment to maintaining high-quality standards.