Job Title: Project Lead, CMC

The Project Lead, CMC, is responsible for supporting the Analytical CMC functions at NoNO Inc., including CMC clinical supply, commercial development, marketing registration, launch and lifecycle efforts. Within the CMC group, this position reports directly to the Sr Director, CMC, and will work closely with Regulatory, Quality and Drug Supply Management to ensure smooth information flow between departments. The Project Lead, CMC is responsible for technical oversight of external analytical and testing functions to ensure an uninterrupted global drug supply and is responsible for building and supporting related sections of dossiers for marketing approval by regulatory authorities. This includes project management and interfacing directly with the drug substance and drug product CMOs as well as the CMOs/CROs for product testing for release and stability. The successful candidate will work effectively across entire internal and external organizations to build and sustain (i) the development of multi-year project plans to supply drug for clinical studies and support regulatory marketing approval and commercial supply for drugs in multiple countries, (ii) sound project management and tracking capabilities for ensuring progress, and (iii) development of risk mitigation strategies for manufacturing and business risks.

Responsibilities

- Oversee CMOs/CROs for the implementation, coordination and execution of Quality Control Strategy including definition of specifications (Drug Substance and Drug Product), analytical method transfer program, definition and execution of analytical method validation strategy, routine GMP testing (in-process, lot release), definition and management of stability programs.
- Ensure GMP testing is conducted in accordance with applicable SOPs, compendia, approved methods, and in accordance with company's and regulatory agencies' policies and procedures.
- Coordinate the review and assessment of analytical data to define and support expiry setting, identify data trends, evaluate method performance and resolve OOS/OOT investigations at CMOs/CROs.
- Anticipate potential areas/gaps for regulatory questioning and analyze product license commitments; develop and execute problem resolution strategies/corrective actions.
- Facilitate and manage internal and external project teams, monitor critical path and team activities, document meetings, decisions, risks and actions. Ensure cross-functional communication and tracking of technical deliverables.
- Write relevant analytical CMC sections including Stability to support Regulatory Submissions
- Support the Sr Director, CMC on project timelines and work with the CMC function SMEs to drive progress across the product life cycle and to ensure CMC team analytical deliverables and activities are aligned with all teams and departments. Support the Sr Director, CMC in developing timelines to support CMC submissions (e.g., INDs, NDAs, NDSs) and provide structure and leadership to ensure all CMC analytical sections of regulatory submissions are of high quality and completed on-time.
- Support the development and management of integrated CMC timelines across all research, development and commercialization projects. This includes timelines for activities to Analytical development, Process Transfer (to CMOs/CROs) and Quality Control (Drug Substance, Drug Product).
- Contribute to the definition, implementation and monitoring of Key Performance Indicators.
- Coordinate and track product license commitment status and completion of activities related to product license commitments/regulatory responses (prepare/review progress update reports for submission to regulatory agencies), including the preparation of statistical reports or supportive studies for product license activities.
- Ensure compliance of documentation packages with regulatory requirements and quality standards, for both product approvals and Establishment licenses.

Qualifications

- Bachelor of Science degree, in appropriate discipline such as chemistry, chemical engineering, biochemistry or analytical chemistry. Master's Degree or PhD preferred.
- 5+ years of direct experience in GMP Quality Control Activities thereof specifically for clinical research or commercial supply required. Experience with Sterile Products strongly preferred.
- Demonstrated project management experience managing Analytical CMC activities.
- 3+ years of experience in project management of external CMOs, an asset

- Extensive knowledge in the area of expertise, specific techniques include chromatography (HPLC and RP-HPLC, GC, LC-MS-MS), FT-IR and other compendia methods including KF.
- Strong knowledge of cGMP quality control activities, and FDA, EMA, GMP and ICH requirements specifically relating Quality Control Activities
- Experience with US, Canadian and European drug manufacturing and testing regulations
- Experience with generation of regulatory filings as a lead or supportive role (INDs, NDAs, NDSs, etc)

Skills:

- Contributes to an environment of teamwork & excellence, through effective communication & cooperation
- Excellent technical writing skills to support technical documentation
- Excellent project management capabilities with advanced Excel skills
- Strong analytical, problem solving and troubleshooting skills
- Ability to communicate complex financial issues in simple, understandable terms
- Ability to work independently and fulfill responsibilities with limited supervision
- Ability to take a teamwork approach to the job by cooperating with others

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