Job Description

1 Position in the Organization	
Job Title:	Associate Director CMC Regulatory Affairs
Department:	Chemistry, Manufacturing & Controls
Manager Job Title:	Senior Vice President Chemistry, Manufacturing & Controls (CMC) and Intellectual Property (IP)
GxP Functions:	☐None ☐All GxP ☐GLP ☐GCLP ☒GCP ☐GPvP ☒GMP ☒GDP
Location:	Dublin, Ireland

2 Description

The Associate Director CMC Regulatory Affairs is responsible for creating and writing Module 2 and 3 CTD documents for regulatory submissions as well as CMC component writing and review of clinical documents (e.g. protocols, reports).

This role is responsible for overseeing the regulatory submission processes and representing CMC in internal or external meetings (external CMOs, health authority).

3 Duties and Responsibilities

- Creating, organizing, and overseeing Module 2 and 3 eCTD regulatory submissions of small molecules together with CMC experts
  - NDA and MAA
  - INDs and IMPDs
  - Briefing documents and meeting requests
  - Information requests
  - Marketing applications with Nabriva partners in territories outside the EU and US
- CMC component writing and review of clinical protocols and reports
- Develop CMC post approval filing strategies
- Representing CMC regulatory internal and to external organizations including contract manufacturers, regulatory agencies, Nabriva's commercial partners
- Evaluate, assess and improve existing CMC regulatory risk strategy and make recommendations to management
- Keep up to date with global CMC regulations – make recommendations for any development changes

4 Qualifications and Skills

- University degree (PhD) in Chemistry, Pharmacy or a related field
- Minimum of 5 years in a CMC Regulatory Affairs function with experience in NDA and MAA submissions and post approval filings
- Proven track record in Module 2 and 3 CTD regulatory submissions, i.e. CMC regulatory lead in at least one successful NDA/MAA submission
- Substantial experience with eCTD submissions, related submission tools, and document management systems

Job Description

- CMC background in drug development and management of CMOs
- Ability to quickly step into a new drug area and take over responsibility
- Passion for organizational and coordinative tasks including prioritization to support company goals and objectives
- Distinctive project management knowledge and profound problem-solving skills
- Good appreciation of multidisciplinary complexities and interdependencies
- Strong team player with excellent interpersonal skills for necessary collaboration between CMC, Regulatory and Quality
- Very good organizational as well as negotiation and communication skills
- Self-motivated and mature personality
- Highly reliable and responsible person
- Fluency in English is required
- Demonstrated ability to work independently and communicate efficiently from a remote location

5 Competencies

- **Customer-centric & entrepreneurial mindset**. Ability to address issues, communicate, and develop programs, and take on other tasks as assigned with a customer focus based on a foundation of ethics, integrity, and quality.
- **Results-driven individual** with strong levels of perseverance, resilience, and resourcefulness; works toward both individual and team goals. Demonstrates high degree of emotional intelligence, personal initiative/self-leadership, self-motivation and the ability to be involved at various levels and willingness to “roll up sleeves” to drive results and outcomes. Ability to adapt quickly and act with urgency, welcoming change, while producing high quality work with minimal direction.
- **Continuous learner** showing a desire and ability to solve complex business problems and provides innovative, value added solutions.
- **Superior organizational/project management skills**. Demonstrated ability to manage multiple assignments/projects, strict timelines, and to identify project interdependencies, resource needs, potential risks/pitfalls and mitigation plans. Recognized as an integrator and solution provider.
- **Highly collaborative workstyle**; with an ability to see the “big picture’ and influence others across businesses, functions, geographies and levels, motivated by collective success.
- **Communicate with clarity both verbally and non-verbally**; be clear, concise, detailed and actionable. Seeks and provides meaningful feedback. Trusted advisor.