ITalent SA are search and recruitment experts for Executives, Managers and Technical Specialists positions.

We are recruiting on behalf of our client, a pharmaceutical company, an experienced and qualified:

Product Development Director (M/F)

Responsible for directing all technical aspects of the API process development and manufacturing activities: contract manufacturers including scale-up, validation, launch, on-going manufactuing support and process improvements. Working with development, the Product Development Director is responsible for the pharmaceutical (drug substance) process development, the chemistry, manufacturing and control (CMC) sections of regulatory documents.

Requirements

- Provides onsite oversight and direction for all aspects (scale-up, validation, launch and on-going commercial support) of the manufacture of the company's commercial API (drug substance) requirements at CROs and/or CMOs around the world to ensure integrity of the company's supply chain
- Participates as the CMC representative on internal and external project teams to review and help establish corporate-wide supply needs and systems
- Interfaces with and provides onsite direction and management of the company's CROs and CMOs to ensure bulk API operations are maintained in compliance with cGMP requirements at all times.
- Reviews and provides oversight of all documentation related to the production of the company's API commercial production including but not limited to: development, scale-up and validation protocols/reports batch records, deviations, process excursions, etc. In conjunction with the CMO and other groups with Tech Ops adjudicate deviations, excursions, etc.
- Develops and/or provides critical review of commercial manufacturing documents (batch records, formulation/process data, SOPs, analytical methods, protocols, reports). Contributes to and support the creation and maintenance of quality systems, especially in relation to manufacture of commercial pharmaceutical products

Profile

- MS/PhD in Chemistry, Chemical Engineering, Biochemistry or related field with 10+ years' experience in the pharmaceutical industry working in development/commercial manufacturing operations for pharmaceutical APIs (drug substances).

- Superior communication skills (both written and oral) are essential. Experience working in a multi-cultural, multi-lingual environment is necessary with a demonstrated ability to contribute successfully in a multi-disciplinary team environment.
- Must have demonstrated experience in managing diverse project activities with third party manufacturing facilities at different geographical locations Strong project management experience with cross-functional team leadership and participation skills.
- Demonstrated scientific knowledge and abilities relevant to development and manufacture of APIs (drug substances) as well as the drug development process considered essential.
- Demonstrated ability to successfully work with and influence contract manufacturing partners while maintaining a positive working relationship.
- Demonstrated strong working knowledge of supply chain management is considered essential for the position. Competence in material management and forecast planning is required. Requires expert understandings of: formulation/drug product process development and scale-up; packaging, technology transfer; cGMPs, FDA, EU, ICH guidelines; as well as CMC content of regulatory submissions.
- Demonstrated experience in the implementation of quality systems in development and/or commercial operations.
- Strong understanding and working knowledge of cGMPs for pharmaceutical development and commercial operations.
- Office environment with extensive international travel required (20 – 50 %)

Please apply on our website: recrutement@i-talent.com and attach a copy of your resume and a motivation letter. We thank you in advance for your interest in this opportunity.

Please note that only applications via this e-mail address will be considered for this position. If you don’t receive a reply to your application within 2 weeks, please consider that your file has not been shortlisted.