I-Talent SA are search and recruitment experts for Executives, Managers and Technical Specialists positions.

We are recruiting on behalf of our client, a major international group, an experienced and qualified:

DIRECTOR, DRUG PRODUCT TECHNICAL SERVICES (M/F)

The Director of Drug Product Technical Services is responsible for all technical activities associated with commercial manufacture of products from contract manufacturing partners globally. This role will lead and manage commercial readiness activities, deviation, change control and CAPA championing, as well as post-approval regulatory submissions.

In working with U.S. Pharmaceutical Operations, this position is responsible for providing strong scientific leadership and support for all aspects of commercial product manufacturing, change management, and process troubleshooting of drug product manufacturing activities. Position will work in partnership with local Quality Assurance partner to ensure successful manufacturing of all products. Incumbent will foster effective cross-functional working relationships with internal and external groups, lead interactions with Pharmaceutical Operations, Quality Assurance, Supply Chain, Packaging Technology and Quality Control for commercial products and provide support for post-approval Regulatory submissions related to products manufactured the site. The Director, Drug Product-Technical Services reports to the head of Business Operations, in Basel, CH.

Accountabilities

- Provide guidance/direction on suitability of technologies, scalability and manufacturability to Pharmaceutical Operations during process development activities.
- Serve as lead for all technical activities associated with the commercial manufacture of drug product at Axovant's global contract manufacturing partner sites:
- Partner with CMO to ensure successful manufacture of drug product required for commercial supply.
- Provide guidance to process validation activities at the contract manufacturing facilities. Provide technical l input to Pharmaceutical Operations for defining the critical process parameters of new processes.

- Collaborate with local Quality partner and US teams to develop processes and systems that enable compliant, successful technology transfers, operation and lifecycle management of cGMP commercial manufacturing processes.
- Provide significant technical depth to support troubleshooting efforts and lead high-level deviation investigations at manufacturing facilities.
- Manage technical relationships with contract manufacturers including, but not limited to providing commercial manufacturing support, deviation, change control and CAPA management. Drive timely decisions, and facilitate active communication and information flow between contract manufacturer and Axovant team members.
- Direct change management activities for commercial drug products including:
    - Support NDA, MAA, and other technical documents for regulatory agency submission in support of manufacturing processes and serve as process subject matter expert in health authority interactions.
    - Identify and drive process optimization initiatives and address innovation opportunities for efficiency improvements in all areas of commercial manufacturing.
- Program management of commercial technical projects. Develop project plans and corresponding project managements tools to support the execution of:
    - Drug product process technology initiatives.
    - Manage cross functional teams (including 3rd party resources).
    - Monitor and report project management progress and corresponding risks and issues.

Education

- B.S. /M.S. in Engineering, Pharmacy or Life Sciences. Certifications in lean six sigma and project management are preferred.

Experience & Skills

- 10 years pharmaceutical industry experience in drug product development and commercial manufacturing technical service related activities.
- Proven strong working knowledge 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 are considered essential for the position.
- Comprehensive understanding of cGMP requirements for commercial pharmaceutical manufacturing.
- Demonstrated experience supporting technology transfers and cGMP manufacturing operations at third party manufacturers required.
- Experience supporting global Contract Manufacturing Organizations highly desirable.
- Successful track record in working with and influence contract manufacturing partners while maintaining a positive working relationship.
- Must have hands on experience in managing diverse project activities with pharmaceutical drug product manufacturing facilities at different geographical locations as well as with cross-functional team leadership and participation skills.

- Ability to work/lead in a dynamic group that takes a multi-disciplined team approach to executing and achieving departmental and corporate goals.
- Superior communication skills (both written and oral) and interpersonal skills are essential. Experience working in a multi-cultural & lingual environment is necessary with a demonstrated ability to interact with all disciplines in & outside Business Operations to ensure company needs are met.
- Speak and write English fluently. Additional languages are preferred.
- Extensive international travel required (20 to 50%).

Please apply on our website: www.i-talent.com
together with your CV and motivation letter. Thank you.

Only applications via this e-mail will be considered for this recruitment. If you don't receive a reply to your application within 2 weeks, please consider that your file has not been shortlisted.