Position: Scientist (Sr. Scientist) for process optimization and scale up

Job Description:

MST department oversees and manages the production process encompassing technology transfer to GMP manufacturing governed by QbD (Quality by Design), ensuring successful progress at every stage, and ultimately deliver target products with expected quality. During the process, MST will provide scientific and technical advice and support for upstream technology transfer, optimize manufacturing process and troubleshoot problems incurred during manufacturing by necessary scale-up or scale-down processes. Therefore, MST will work with internal or external entities, and carry out above described functions. Align with the functions of the MST department, the incumbent will be responsible for the effective technical transfer of from lab scale process to pilot and manufacture scale by using scale down models and to solve the problem encountered in manufacture with effective way

Requirements:

1) Master's degree or above in bioengineering, biotechnology, biochemistry or related fields, relevant working experience is preferred
2) In depth understanding of the upstream and downstream process of biological drug development, interest in process optimization and process validation
3) A minimum of 5 years GMP experience, and 5-10 years of using 2L to 50L microbial fermenters and bioreactors in PD capacity, protein production experience is preferred
4) Team player with innovative thinking, fast learning and strong organization and time management skills
5) Have hands on experience and good track record of upstream process development (bioreactor for mammalian cell/microbial fermentation) or downstream process development (purification process). The experiences of using DOE and scale down models are preferred
6) Basic understanding and/or hands-on experience of molecular biology in gene expression, vaccine development, etc.
7) Project management experience with knowledge of QbD, Lean Six Sigma and 4DXs

Responsibilities

1) Oversee technology transfer between following work units
    a) Internal or external R&D/PD to downstream pilot or large scale manufacturing plants
    b) Production process from pilot plant to manufacturing facility
    c) Scale down from manufacturing to pilot runs for process optimization
    d) Scale down from pilot to R&D or small scale runs to improve process
    e) If necessary, manage technology transfer from pilot or manufacturing scale to external contractor(s)
2) Manage product development to manufacturing project through coordinating with PC

management team following QbD criteria.

3) Provide technology evaluation of MR (manufacturability review) check point, to ensure successful delivery of final products.
4) Lead and/or conduct scale up trial runs to provide optimized process for the manufacturing department.
5) Draft and finalize PFD (Process Flow Diagram) and CMC documents with great understanding of the characteristics of the product and process and quality requirements
6) Other relevant tasks assigned by upper management