

Level -9 Senior Scientific Manager

Role/Job Description:

- The individual will be leading and managing a mid sized team of scientists and engineers involved in downstream process development and technology transfer of recombinant Bio-therapeutic
- Candidate will be solely accountable for team deliverables of Downstream Biosimilar process development, meeting all the regulatory agency expectation and tech transfer from Lab to Pilot and Manufacturing
- The candidate will be responsible for technology transfer (of the developed process steps) from R&D to pilot plant and manufacturing ensuring that relevant scale up parameters were studied in small scale
- The candidate will be expected to write and review the technical reports
- The candidate will be expected to actively participate and add values in cross functional discussions within RND and with other cross functional teams (MSAT, Mfg, QA, QC, Regulatory and Program management)
- The candidate is required to actively display multifunctional skills, manage teamwork and ensure good lab practices from the team

Technical / Functional Skills

- Hand on experiences in unit operation of downstream process steps of biological products like-
- Candidate should have though understanding of parameters to be important for appropriate scale up of each unit operations and type of experiments to be designed in lab (scale down) for ensuring successful scale up
- Candidate should be experienced with Process characterization and DOE studies along with required statistical knowledge
- Experienced in technology transfer with appropriate scale up and scale down understanding
- Experiences in regulatory document writing for dossier submission and facing technical audits
- Complete understanding of requirements of CMC section Biosimilar product BLA submission requirements and expectation from FDA/EMA agency
- Person should be capable of managing a group of technical team and experience the cross functional interactions
- Good communication, writing and technical negotiation skills.