Job Description

Downstream Process

The Company:

Yapan Bio is a Biotechnology Company established to serve the rapidly expanding Custom Development and Manufacturing (CDMO) market for Vaccines and Biologics/Bio-therapeutics. Yapan Bio has established state-of-the-art facilities for process development and GMP manufacturing for human clinical studies, including both Drug Substance (DS) and Drug Product (DP - Liquid Vials), at Genome Valley in Hyderabad. The facility is built as per the quality and regulatory expectation of the global regulatory authorities. The current facility includes two manufacturing suites, including one Bio Safety Level 2+ (BSL-2+) suite to develop and manufacture high containment product classes.

As we expand our team, we are looking for talented and experienced individuals, with can- do attitude, who are self-starters with excellent communications & leadership skills, who enjoy working on the details without losing site of the larger organizational goals, and are adaptable to a dynamic "startup" environment, to join our team.

At Yapan Bio, you will get a supportive, collaborative, and empowering work environment to make a significant impact along with ownership as we drive the growth of the company together. This is an excellent opportunity to be a part of the team to establish a new biotechnology company in India, with global impact.

The Role:

The incumbent will be responsible for establishing and managing the downstream processes for vaccines and/or biologics products, starting from early stage process development to executing GMP batches for human clinical trials. Depending on the experience and expertise, the incumbent will either be a part of the team or lead the downstream team to deliver as per the project goals, budget, and timelines.

Duties and Responsibilities:

This individual will be responsible for downstream process development and scale up to pilot/large scale. The individual is also expected to execute process under cGMP. A person in this role is expected to lead, troubleshoot, incorporate latest systems and processes, and interact frequently with quality and senior management.

This position requires excellent interpersonal and presentation skills with demonstrated ability to present effectively in various interactions, meetings and reports. The candidate should be self- sufficient in planning and executing daily activities along with applying innovative thinking to improve effectiveness and efficiency of the function.

- Downstream process development for various Biologics and Vaccines
- Scale up from flask scale to bioreactors
- Conduct process under cGMP and complying to Quality systems of organization and expectations of global regulatory organizations
- The key functions involve
    - Planning and execution of the experiments related to Downstream process.
    - Protein/product profiling work by proteomic analysis
    - Sample preparation for purification.
    - Packing of the columns, its CIP and maintaining them with proper storage solution.
    - In-process analysis of samples by SDS-PAGE, Western blot and IEF.
    - Downstream equipment and facility purification system Maintenance.
    - Technology transfer
    - Document preparation: SOP preparation, process validation
    - Designing experiments for process Optimization for vaccine and biologics development
    - Stability study sample analysis and report preparation of on-going projects.
    - Data compilation and report preparation for conducted experiments.
- Literature review related to the purification process.
- Oversee hiring of staff as well as external consultants
- Recruit, train and mentor staff
- Perform other duties as required

- Prepare and manage department operating plans and budgets

Education and Experience Required:

- Post graduate or PhD degree in Science required; advanced degree is preferred.
- **5-10 or more years** of experience in vaccines/biologics industry
- Experience in compiling data for IND approval is essential; i.e., transition from product development to commercial quality systems and operations
- Experience establishing and/or enhancing development and commercial process and systems compliant with Indian and international requirements.
- Extensive knowledge of GMP, and GLP including 21 CFR Part 11 is preferred
- Strategic thinker, able to integrate complex business considerations in formulating a quality approach
- Strong management and interpersonal/communication skills. Prior success in working effectively with senior scientific, medical, commercial and operations staff
- Proficiency in Microsoft Word, PowerPoint, Excel and Project

Skills:

- Ability to work in a fast paced environment
- Excellent organization and planning skills
- Capable of working within a team or independently with minimal direction
- Must have strong communication skills and interpersonal skills.
- Excellent stakeholder management skills and ability to develop strong relationships with senior leaders and other key stakeholders
- Strong strategic thinking and problem solving skills
- Strong communication and interpersonal skills including ability to deliver effective presentations and provide information to influence major decisions
- Must have a positive attitude and be adaptable to a dynamic "startup" environment without losing focus on business goals.
- Extensive understanding and experience of global cGMP regulations and requirements for vaccines and biologics.
- Ability to work with computer controlled systems and proficient with Microsoft Word, Excel, and PowerPoint required

The Next Steps:

If the above role fits your experience and expertise and you would like to build and grow your career with a dynamic start-up, working on the next generation products and technologies, please share your CV at hr@yapanbio.com.