GLYCOERA

Job Profile: **Principal Scientist Upstream Process Development** (MSAT)

Overview

The Principal Scientist Upstream Process Development, will play a pivotal hands-on role in developing, transferring, implementing and scaling our processes and novel expression system at CDMOs. This position is ideal for a highly experienced, hands-on laboratory-focused upstream expert who combines deep engineering intuition with strong scientific understanding. The role requires someone who thrives on solving complex bioprocess challenges, has gained experience as MSAT expert through multiple tech transfers, brings creativity and out-of-the-box thinking, and is comfortable working independently in a fast-moving biotech environment.

The successful candidate will contribute directly to technology transfer, implementation, scale-up activities to external manufacturing partners and closely monitor execution. In our laboratories you will participate in process development and improvement of our novel expression technology. Extensive experience with multiple expression systems and industrial-scale bioreactors (1000 L and above) is essential.

Key Responsibilities

Upstream Process Development

- Own end-to-end technology transfer, implementation, and scale-up of our novel expression system at CDMOs.
- Perform hands-on fermentation activities at bench and pilot scale, including setup, operation, troubleshooting, and data analysis, to support development, comparability, and scale-up readiness.
- Critically assess CDMO facility, equipment, and operational fit-for-purpose, asking probing, technically grounded questions to identify gaps, risks, and constraints.
- Define and align the transfer strategy in close collaboration with CDMO technical teams, ensuring full understanding and correct execution of process intent, critical parameters, and control strategies.
- Translate development processes into robust, executable manufacturing processes, adapting as needed to site-specific equipment, control systems, and operational realities without compromising process performance or product quality.
- Lead scale-up activities from laboratory to pilot and industrial scale (≥1000 L), applying sound bioprocess and engineering principles to ensure robustness, scalability, and reproducibility.
- Prepare comprehensive MSAT deliverables, including process descriptions, risk assessments, scale-up rationales, and technology transfer packages to support successful implementation at CDMOs.

- Closely monitor process execution during implementation, engineering runs, and GMP batch manufacturing, maintaining active oversight of process performance, deviations, and trends.
- Provide person-in-plant support (on-site or remote) during CDMO runs, proactively identifying issues, driving root-cause analysis, and implementing corrective and preventive actions.
- Act as the technical owner of the upstream process at the CDMO, ensuring continuity of knowledge, rapid decision-making, and alignment between development intent and manufacturing execution.

Innovation & Problem Solving

- Apply creative, engineering-driven thinking to improve and adapt a novel expression system.
- Identify process bottlenecks and propose innovative solutions based on scientific and technical insight.
- Evaluate new technologies, tools, and approaches that could enhance upstream performance.

Cross-Functional Collaboration

- Work closely with internal process development, analytical development, and protein sciences teams.
- Contribute to project planning, timelines, and risk assessments.
- Communicate results clearly and effectively to internal stakeholders.

Qualifications & Experience

- MSc/PhD in Biotechnology, Biochemical Engineering, Microbiology, or related field.
- 8+ years of extensive industry experience in MSAT / upstream process development, technology transfer and implementation for biologics, ideally across multiple expression systems.
- Strong hands-on expertise with bioreactors, fermentation control systems, and scale-up principles.
- Experience designing and reviewing contamination-control strategies for long upstream processes, operational risks, equipment risks, cleaning strategies, and monitoring plans.
- Demonstrated success transferring processes to CMOs and supporting external manufacturing campaigns.
- Strong familiarity with how CDMOs operate, including facility constraints, equipment variability, scheduling realities, and cross-functional communication pathways
- Ability to critically evaluate whether a CDMO's facility, utilities, and equipment can support the process as designed, and to identify required adaptations without compromising product quality.

- Solid understanding of bioprocess engineering fundamentals, metabolic principles, and cell physiology.
- Broad hands-on experience with mammalian cell culture platforms, including fed-batch and perfusion, across small-scale, pilot, and commercial environments.
- Experience with diverse mircobial expression system is a plus
- Ability to work independently, prioritize effectively, and drive progress with minimal supervision.
- Willingness to work on the bench
- Strong data analysis skills and familiarity with common bioprocess software tools.
- Creative, resourceful, and energized by technical challenges.
- Strong engineering mindset paired with scientific depth.
- Highly independent and proactive in identifying and solving problems.
- Comfortable working in a dynamic, time-bound project environment.
- Clear communicator with a collaborative spirit.