



COMPANY DESCRIPTION

Somru Bioscience Inc. is an emerging biotechnology company dedicated to developing breakthrough antibody technology for research, diagnostic and therapeutic applications. The company utilizes a unique and proprietary Somru™ technology which produces antibodies with superior binding affinity and bioactivity in a wide variety of biological assays in a short period of time. We also offer a wide range of quality reagents for research and diagnostics applications as well as for biosimilar research and development.

Job Title:

R&D Biosimilar Manufacturing Manager

Job Duties:

Responsibilities include but are not limited to:

- Responsible for leading the research and development of bioprocesses for biosimilar production
 - Provide functional leadership and subject matter expertise to establish phase-appropriate cell culture-based recombinant protein/antibody production processes
 - Plan and execute experiments to evaluate downstream processing strategies and process conditions to produce high titer and product quality with high recovery rate in support of the expanding biosimilar pipeline
 - Design and implement rigorous product development strategies utilizing Design of Experiment (DoE) and other process-design elements aligned with a Quality by Design (QbD) approach
 - Facilitate process transfer, scale-up, validation and product/process comparability activities
 - Proactively identify issues, provide general guidance to resolve CMC project issues, and develop solutions to meet productivity and quality milestones
 - Deliver development reports and sections of regulatory submissions including comparability, similarity, and QbD risk assessments
 - Work closely with the assay development team to guide efforts toward specification and method of analysis development.
- Provide hands-on and strategic leadership to a team of scientists and engineers to support company goals and activities
- Establish and achieve budget and timeline targets

- Support the technical team to validate and maintain equipment
- Develop and maintain productive relationships with internal and external collaborators and partners
- Responsible for multiple projects via cross-functional (matrix) management
- Work in collaboration with Operations group to execute protocols, experimental plans, critical production batches, and tech transfers.

Requirements

- MS/PhD Biology, Biotechnology, Chemical Engineering or equivalent field.
- PhD with 5+ years of experience or a MS with 8+ years in of experience.
- Strong background in biosimilar development in both CHO cells and *E.coli*, molecular cloning, cell line development, process development (both upstream and downstream processing), assay development and non-clinical trial.
- Knowledge of current GMPs, and FDA and / or European validation practices for biopharmaceutical processes
- Outstanding organizational and communication skills (especially technical writing, verbal and presentation), and excellent supervisory skills
- Demonstrated experience with process improvements, knowledge of manufacturing, and understanding of site operations, R&D, and production systems
- Demonstrated success with regulatory filings including BLA submissions and product launch is preferred
- Knowledge of SIMCA, DoE and other supportive soft wares a plus
- Willingness to work a flexible schedule including some nights and weekends
- Able to travel frequently

If you are interested in being considered for this position, please submit a resume to:

E-MAIL: hr@somrubioscience.com

Somru BioScience Inc.
19 Innovation Way
BioCommons Research Park
Charlottetown, PE, C1E 0B7 Canada
TEL: 902-367-4322 | Fax: 902-367-4323
E-MAIL: hr@somrubioscience.com
Web: <http://somrubioscience.com>