

Job Title: Associate Director/Director
Field: Process Development
Company: Salubris Biotherapeutics, Inc.
Location: Gaithersburg, MD

Salubris Biotherapeutics, Inc. (or SalubrisBio) is a science-driven biotechnology company dedicated to the discovery and development of novel antibody therapeutics for the treatment of cancer, cardiovascular and metabolic diseases. We strive to develop novel therapeutic molecules which shall provide clinically meaningful improvements in disease burden and quality of life to patients with significant medical needs.

SalubrisBio is seeking a highly motivated individual with exceptional expertise in process development for the antibody drug product manufacturing. The candidates shall have strong leadership and are expected to work in a fast paced, dynamic and changing start-up environment.

The company offers competitive benefits including medical, dental, vision and life insurance, as well as 401(k) match and stock incentive. SalubrisBio is an equal opportunity employer. To apply for this job, please contact HR specialist Liping Yuan at liping.yuan@salubrisbio.com

Job Responsibilities:

- Lead the process development team to develop and optimize robust and scalable process for antibody product manufacturing;
- Supervise/coach scientists and associate scientists and manage routine team operation;
- Define and manage timelines and deliverables of manufacturing process;
- Design and lead assessment of critical process parameters and process characterization;
- Write, review, approve technical reports;
- Lead and manage technology transfer to clinical manufacturing sites;
- Closely work with other functional teams (research, analytical, formulation) to move projects forward;
- Plan and manage department budget;
- Support regulatory filing.

Qualifications:

- PhD in Biochemical/Chemical Engineering, or related scientific discipline;
- Minimal 7 years of industry experience in process development for therapeutic antibody manufacturing;
- Able to apply scientific and engineering approaches to problem solving and process development;
- Able to introduce new technologies to improve and accelerate manufacturing process;
- Deep experience in process optimization, risk assessment, process characterization, validation, and SOP authoring;
- Experience in DoE is plus;
- Experience in biologics IND and/or BLA filing; familiar biologic CMC development regulation;
- Strong verbal and written communication skills, ability to manage multiple projects simultaneously and attention to details, highly organized and self-motivated;
- Management level experience in R&D environment required.