Company Overview

WuXi Biologics (stock code: 2269.HK), a Hong Kong-listed company, is a leading global open-access biologics technology platform offering end-to-end solutions to empower organizations to discover, develop and manufacture biologics from concept to commercial manufacturing. Our company history and achievements demonstrate our commitment to providing a truly ONE-stop service offering and strong value proposition to our global clients. As of December 31, 2018, there were a total of 205 integrated projects, including 97 projects in pre-clinical development stage, 94 projects in early-phase (phase I and II) clinical development, 13 projects in late-phase (phase III) development and 1 project in commercial manufacturing. With total estimated capacity of biopharmaceutical production planned in China, Ireland, Singapore and US reaching 280,000 liters by 2022, we will provide our biomanufacturing partners with a robust and premier-quality global supply chain network.

Job openings

Senior Director Process Development

Responsibilities
- Support senior leadership to build up global DS technical capability;
- Support senior leadership to align global DS technical capability across the Company;
- Lead and provide overall coordination to execute late stage process development, process characterization, technology transfer, PPQ readiness;
- Lead and provide oversight for DS commercial launch – facility start up, PPQ, BLA, pre-license manufacturing site inspection;
- Serve as technical point-of-contact to Client on CMC issues;
- Provide guidance and mentorship to DS technical staff;
- Lead DS related assignments as directed by management – development, transfer, commercialization.

Qualifications
- PhD in engineering, biology, chemistry, or related field.
- 15+ years relevant work experience.
- Late stage biologic product/process development and commercialization expertise.
- SME of global standards in DS CMC, GMP, GDP, regulatory applications (IND to BLA).
- Effective management of projects and staff, cross-departmental collaborations are expected.
- Outstanding communication and language skills.

Senior Director Quality Assurance

Responsibilities
- Support senior quality leadership to build up and maintain a global quality and compliance program;
- Support senior quality leadership to align the global quality system across the Company;
• Lead and conduct internal audits across the Company as well as vendor audits for the Company as needed;
• Host and facilitate external audits by clients and/or regulatory agencies and follow-up CAPAs;
• Provide readiness support for inspections by international regulatory authorities at designated Company sites;
• Act as a QA representative on CMC projects and communicate with clients about quality issues and provide routine updates;
• Provide general and advanced GMP trainings to quality and technical staff;
• Recruit QA talent to build up a strong quality team and quality management system at designated Company sites;
• Lead quality related assignments as directed by management.

Qualifications
• Advanced degree in engineering, biology, chemistry, or related field.
• 10+ years relevant work experience.
• SME of global standards in GMP, compliance, regulatory applications (IND to BLA).
• Late stage biologic product development and commercialization expertise are highly desirable.
• Effective management of projects and staff, cross-departmental collaborations are expected.
• Outstanding communication and language skills.

Senior Scientist Upstream Process Development
Job Locations US-PA-King of Prussia  Job ID: 2019-5658

Responsibilities
• Work independently on defined biopharmaceutical projects for development and/or characterization of vaccine upstream manufacturing processes.
• Manage project workflow to ensure on time delivery: from initial planning, experiment execution, to data evaluation.
• Design and execute lab-scale experiment in supporting upstream process development, verification, characterization, and tech transfer. Perform independent data analysis and interpretation and develop strategies for optimization and troubleshooting.
• Represent Vaccine Upstream Process Development Group in internal cross-functional teams and external communication with client.
• Manage technical transfer of processes into the non-GMP pilot plant or GMP production facility.
• Document development work in concise reports and provide project updates in written and oral presentations.
• Support maintenance tasks and new technology evaluations for laboratory instrumentation; interact with outside clients/vendors/suppliers

Qualifications
• The candidate should have background in one of the following fields: chemical engineering, biochemical or biological engineering, cell/molecular biology, biochemistry, or microbiology.
• Hands-on experience in mammalian cell culture or vaccine manufacturing using bioreactors is preferred.
• PhD degree and 0-2 years industry experience, or with MS degree and at least 3 years industry experience.
• Strong written and verbal communication skills are required, as well as ability to take on multiple tasks simultaneously.
• Excellent communication and good interpersonal skills, work well with diverse team members

**Senior Scientist Downstream Process Development**

**Responsibilities**
- Work independently on defined biopharmaceutical projects for development and/or characterization of vaccine downstream manufacturing processes.
- Manage project workflow to ensure on time delivery: from initial planning, experiment execution, to data evaluation.
- Design and execute lab-scale experiment in supporting downstream process development, verification, characterization, and tech transfer. Perform independent data analysis and interpretation and develop strategies for optimization and troubleshooting.
- Represent Vaccine Downstream Process Development Group in internal cross-functional teams and external communication with client.
- Manage technical transfer of processes into the non-GMP pilot plant or GMP production facility.
- Document development work in concise reports and provide project updates in written and oral presentations.
- Support maintenance tasks and new technology evaluations for laboratory instrumentation; interact with outside clients/vendors/suppliers

**Qualifications**
- The candidate should have background in one of the following fields: chemical engineering, biochemical or biological engineering, cell/molecular biology, biochemistry, or microbiology.
- Hands-on experience in downstream process unit operations and lab scale experimental execution.
- PhD degree and 0-2 years industry experience, or with MS degree and at least 3 years industry experience.
- Strong written and verbal communication skills are required, as well as ability to take on multiple tasks simultaneously.
- Excellent communication and good interpersonal skills, work well with diverse team members

**Senior Scientist Analytical Sciences**

**Responsibilities**
- Work independently on defined biopharmaceutical projects for development, qualification/validation of assays for vaccine development.
- Manage project workflow to ensure on time delivery: from initial planning, experiment execution, to data evaluation.
• Design and execute lab-scale experiment in supporting assay development, transfer, qualification, and validation. Perform independent data analysis and interpretation and develop strategies for optimization and troubleshooting.
• Represent Vaccine Analytical Science Group in internal cross-functional teams and external communication with client.
• Manage method transfer into the non-GMP analytical science group located at the other sites or GMP QC labs.
• Document development work in concise reports and provide project updates in written and oral presentations.
• Support maintenance tasks and new technology evaluations for laboratory instrumentation; interact with outside clients/vendors/suppliers

**Qualifications**

• The candidate should have background in one of the following fields: biochemical or biological engineering, analytical chemistry or biochemistry.
• Hands-on experience in vaccine assay development and lab scale experimental execution.
• PhD degree and 0-2 years industry experience, or with MS degree and at least 3 years industry experience.
• Strong written and verbal communication skills are required, as well as ability to take on multiple tasks simultaneously.
• Excellent communication and good interpersonal skills, work well with diverse team members

Please feel free to contact me at le.zhang@wuxiapptec.com or +1 609-703-3769 if you have any questions. Thanks.