

Manager of QC Physical & Chemical Lab

Based in Hangzhou

Responsibilities:

- Responsible for organizing daily physical and chemical analysis and ensuring the accuracy and timeliness; drafting and reviewing SOP related to the physical and chemical methods and instrument operation as well as maintenance in various programs; sample testing, records review and deviation investigation and settlement; if necessary, drafting and reviewing the protocol for pharmacopoeia methods validation, and writing and verifying the 3Q protocol of relevant equipment;
- Responsible for ensuring that the current testing methods in GMP factory conform to CHP, EP and USP from the latest compendia standards (for method testing and product release); organizing and participating in the annual verification of public systems in the GMP facility, such as the water system for Pharmaceutical use ;
- Establish quality specifications for raw material and package materials used in the GMP facility; ensure the sampling method and approach are science based and reasonable, ensure testing and release of raw materials and package material based on business schedule;
- Daily compliance management and EHS management of the physical and chemical analysis group;
- Talent management in physical and chemical analysis group.

Qualifications:

- Education background in related field including pharmaceutical engineering, pharmaceutical analysis and biotechnology with a master's degree and 7 years of experience, or a bachelor degree and 10 years of experience in QC;
- Possess knowledge in physical and chemical analysis and familiar with pharmaceutical water system and quality control of raw and auxiliary materials;
- Familiar with physical and chemical testing and analysis technology; familiar with or mastered in purity and concentration analysis technologies such as gas chromatography, titrator, TOC, infrared and ultraviolet spectrophotometer, and capable of processing, integrating and interpreting analysis results;
- Familiar with cGMP/GLP and ICH regulations;
- Good team player; relevant project and personnel management experience is preferred;
- Good English reading and writing skills; excellent English speaking is preferred.

Floor QA Manager

Based in Hangzhou

Responsibilities:

- Review and approve quality system documents related to production;
- Review and approve master batch records;
- Review executed batch records and support batch disposition of drug substance product;
- Oversee critical operations during production;
- Participate in quality related incident and deviation investigation, follow up CAPA implementation and CAPA effectiveness;
- Participate in internal audit;
- Perform daily walkthrough in production areas;
- Participate technology transfer;
- Provide GMP training.

Qualifications:

- Bachelor degree or above in chemistry, biology, pharmacy or other related fields;
- 8+ years of experience in the pharmaceutical industry that includes 2+ years of QA experience;
- Familiar with GMP regulations; FDA and EMA audit experience and professional background in biopharmaceutical and aseptic production are preferred;
- Good team player and communication skills in both Chinese and English;
- Mostly working in the air-conditioned office with weekend holiday as well as occasional business trips and overtime;
- Frequently used equipment and tools include computer, calculator, stationery, folders and long-distance calls.

Principle / Senior Scientist, Bioassay/Bioanalytical Development

Based in Hangzhou

Responsibilities:

- As a senior member of Analytical Sciences organization, be responsible for the overall development strategy for bioassays and other bioanalytical methods, under the guidance of AS Head.
- Develop and qualify bioanalytical methods (e.g. ELISA and cell-based bioassays, high molecular weight impurity assays, binding affinity assays) to ensure their suitability for the intended use and ability to meet ICH and country-specific regulations.
- Manage a project team for analytical development or lead an analytical technology platform
- Responsible for the establishment and monitoring of product quality standards in assigned clinical-stage drug development programs or commercial stage process transfer/improvement programs
- Responsible for compliance to all applicable Data Integrity and Good Development Practices requirements for assigned methods and/or projects
- Responsible for method transfer to HJB Quality Control, and method transfer to/from external laboratory testing functions, for assigned methods/projects
- As a key Subject Matter Expert (SME) for Bioassay/Bioanalytical methods, contribute to complex laboratory investigations for related methods and manufacturing deviations e.g. OOS/OOE results
- Responsible for continuous improvement of established methods and development of new technology-based bioanalytical methods
- Coaching/leading junior members to enhance team capabilities.

Qualifications:

- Advanced degree (Master, PhD is preferred) in Life Sciences, Biology, Biochemistry, Analytical Chemistry, Immunology, or related disciplines
- 7+ years of relevant experience for Master degree holders; or 3+ years of relevant experience for PhD degree holders
- In-depth knowledge of large-molecule therapeutics in areas of biosynthesis, structure-function, bioanalysis, monoclonal antibody mechanism of action (MoA), cell signaling
- Good knowledge in modern analytical instrument in bioassay/bioanalytical applications.

Senior Scientist/Principle Scientist, Purification, Process Development

Based in Hangzhou

Responsibilities:

- Responsible for leading projects in protein purification process development under the supervision of the purification director.
- Lead a project team to design and execute experimental plans.
- Responsible for the development of a complete purification process to meet quality requirements on clinical and/or commercial production of biopharmaceuticals.
- Responsible for preparation of technical documents for regulatory filing of purification related sections.
- Develop novel technologies on protein separation and purification for continuous improvement.

Qualifications:

- Master's degree or above in biochemistry, molecular biology, chemistry, bioengineering, pharmacy, biochemical engineering or other relevant fields.
- Master's degree with 7+ years' experience or PhD with 3+ years of working experience in the industry with major in protein separation and purification.
- Strong analytical and problem-solving skills. Knowledge of the chemical properties of proteins and antibodies. Operational experience in various technologies and equipment for large-scale purification is preferred.
- Previous experiences in biomedical development projects that received clinical approval is preferred.

Principle Scientist, Analytical Development

Based in Hangzhou

Responsibility:

- As a senior member of Analytical Sciences organization, be responsible for the overall development strategy for analytical methods (separation sciences and advanced spectroscopy/spectrometry), under the guidance of AS Head.
- Develop and qualify analytical methods (e.g. HPLC- and CE-based purity/impurity methods, assay by UV, Multi-Attribute methods) to ensure their suitability for the intended use and ability to meet ICH and country-specific regulations.
- Manage a project team for analytical development or lead an analytical technology platform
- Responsible for the establishment and monitoring of product quality standards in assigned clinical-stage drug development programs or commercial stage process transfer/improvement programs
- Responsible for compliance to all applicable Data Integrity and Good Development Practices requirements for assigned methods and/or projects
- Responsible for method transfer to HJB Quality Control, and method transfer to/from external laboratory testing functions, for assigned methods/projects
- As a key Subject Matter Expert (SME) for Phys-Chem methods, contribute to complex laboratory investigations for related methods and manufacturing deviations e.g. OOS/OOE results
- Responsible for continuous improvement of established methods and development of new technology-based phys-chem analytical methods and/or characterization methods
- Coaching/leading junior members to enhance team capabilities

Qualifications:

- Advanced degree (Master, PhD is preferred) in Life Sciences, Biology, Biochemistry, Analytical Chemistry, Immunology, or related disciplines
- 7+ years of relevant experience for Master degree holders; or 3+ years of relevant experience for PhD degree holders
- In-depth knowledge of large-molecule therapeutics in areas of biosynthesis, structure-function, bioanalysis
- Good knowledge of modern analytical instrument for bioanalysis
- Experience in analytical method development/validation during large-molecule drug technical development; experience in leading analytical and/or CMC development project is highly preferred
- Rigorous, diligent, eager to learn and good team player; strong analytical and problem-solving skills;
- Highly proficient in spoken and written English and English-Chinese translation.

Senior Scientist, Cell culture

Based in Hangzhou

Responsibilities:

- Under the department technical director's guidance, responsible for the R&D planning for cell culture process, process optimization and scale up of the entire project and gaining a deep understanding of the technical background and features of the project.
- Independently lead the R&D work at project level; analyze and solve problems;
- Optimize process to maximize product yield, meet process quality requirements and reduce cost to meet quality and approval standards of clinical and commercial production of the biomedical industry nationally;
- Responsible for the integrity and quality of the project, including documents, data and materials needed for obtaining approval of the process;
- Develop new and more productive cell culture process technology and make continuous improvement.

Qualifications:

- Degrees in biochemical engineering, fermentation engineering, bioengineering and other relevant fields;
- Candidate with master's degree should be accompanied with 5+ years of experience; or PhD focusing on metabolic research of cell culture for proteins and antibodies, and on nutritional requirements cell growth;
- Rigorous, diligent, eager to learn, good team player and good at communication;
- Strong analytical and problem-solving skills; possess in-depth knowledge of cell culture and metabolic pathways, and operational experience in various techniques and equipment for large-scale cell culture or fermentation;
- Previous experiences in biomedical development projects that received clinical approval is preferred;
- Highly proficient in spoken and written English and English-Chinese translation.