**Job Title: Assistant Director/Director, CMC**

**Department: Regulatory Affairs**

**Location: Shanghai**

***Responsibilities***

* Provide regulatory CMC guidance to the project teams to ensure development activities are compliant with relevant guidelines and governmental regulations
* Support the preparation of CMC regulatory submissions namely INDs/BLAs applications including scientific and technical review for accuracy, soundness and regulatory appropriateness
* Ensure timely preparation and management of all necessary documentation for regulatory submissions
* Ensure that the content and format of regulatory submissions comply with applicable regulations and guidelines
* The candidate is expected to maintain up-to-date knowledge and expertise of relevant ICH guidelines, CFDA, FDA, and EMA regulations
* Responsible for establishing and maintaining internal filing template and ensure submission quality and consistency
* Represents WuXi Biologics in interactions with Regulatory Agencies and clients’ RA CMC representatives.

***Qualifications：***

* The candidate must demonstrate solid working knowledge of biologics development processes.
* Thorough understanding of FDA and EMA regulatory requirements and GMP regulation is required
* The candidate must be detail oriented with strong project management, problem-solving, negotiating, interpersonal, and communication skills (both written and oral).
* The candidate must have expertise in Chinese FDA regulations and experience interacting with CFDA. The candidate must be fluent in Chinese both written and oral
* Minimum BS degree in one of the relevant life sciences is desirable. Advanced degree and RAC certification are pluses.
* BS degree with 8-10 years’ experience
* MS degree with 5-8 years’ experience
* PhD degree with 3-5 years’ experience

***How to apply:***

1. With the subject of “Apply for *Job Title*, *Department*”
2. Please sent you C/V to WuXiBIO\_Recruiting\_Oversea@wuxiapptec.com

**Job Title: Senior/Executive Director, Quality Control**

**Department: Analytical Science**

**Location: Shanghai**

***Responsibilities***

* Lead Quality Control Organization including Biochemistry, Physicochemistry, Microbiology and Environmental Monitoring, and Stability groups to perform in-process, lot release and stability testing for early and late stage programs.
* Provide guidance and oversee method qualification/validation, troubleshooting, laboratory and OOS investigation and promote collaboration with partner organizations.
* Comply with Good Manufacturing Practices (GMP) and Good Documentation Practices (GDP). Strong knowledge of GMPs and quality systems with experience managing deviation, change control, and CAPA. Assist regulatory audit and inspections.
* Lead quality control system improvement initiatives. Projects may include writing and reviewing QC SOPs, designing and implementing systems (LIMS, E-notebook etc.).
* Develop training program. Ensure all staff receive training in basic cGMP training, applicable techniques and SOPs.
* Develop talent, inspire innovation and operational excellence and foster a continuous learning and improvement environment.
* Draft and review of relevant CMC sections for regulatory submissions including INDs and BLAs.
* Should be an effective communicator of ideas, project goals and results to cross-functional team members.

***Qualifications：***

* Requires a Ph.D. in analytical chemistry, biochemistry, or related life sciences degree and 12+ years of relevant experience that demonstrates an expertise in assay qualification/validation, release and stability testing and QC operations.
* Extensive hands-on experience in biochemistry, HPLC/CE and QC operations in cGMP environment.
* Excellent communication skills (both verbal and written) and interpersonal skills are required. Fluent in English and Chinese.
* Managerial experience by providing on-going mentoring, supervision, and yearly performance review and appraisal of a large group of scientists.
* Experience interacting with clients and health authorities (CFDA, FDA, EMA etc.) preferred.

***How to apply:***

1. With the subject of “Apply for *Job Title*, *Department*”
2. Please sent you C/V to WuXiBIO\_Recruiting\_Oversea@wuxiapptec.com

**Job Title: Associate Director/Director, Biochemistry Lab**

**Department: Analytical Science**

**Location: Shanghai**

***Responsibilities***

* Lead Biochemistry Lab in development of immunoassay and DNA assays activities for protein therapeutics for early and late stage programs, including method development, qualification/validation, method transfer to QC, and strong collaboration with partner organizations.
* Lead the efforts in applying high-throughput workstation and analytical technology to support process development.
* Contribute to draft and review of regulatory submissions including INDs and BLAs.
* The applicant will manage a large group of scientists, he/she should be an effective communicator of ideas, project goals and results to group members.
* Strong knowledge of GMPs.
* Hands-on technical leadership of all aspects of anti-host cell protein ELISA, anti-product ELISA and qPCR assay development.
* Direct scientists in the initiation and execution of laboratory experimentation, considering economic, regulatory and safety factors.

***Qualifications：***

* Requires a Ph.D. in biochemistry, or immunology and 8+ years of relevant experience that demonstrates an expertise in assay development and scientific accomplishments.
* Industry experiences in the development and validation of ELISA and DNA assays for CMC applications.
* Experiences with high throughput workstation and its applications.
* Record of scientific technical writing skills as demonstrated by peer-reviewed publications in science and technology journals.
* Excellent communication skills (both verbal and written) and interpersonal skills are required. Fluent in English and Chinese.
* Experience interacting with health authorities (FDA, EMA etc.) is a plus.

***How to apply:***

1. With the subject of “Apply for *Job Title*, *Department*”
2. Please sent you C/V to WuXiBIO\_Recruiting\_Oversea@wuxiapptec.com

**Job Title: Senior Manager/Assistant Director, Project Management**

**Department: Analytical Science**

**Location: Shanghai**

***Responsibilities***

* Collect and analyze resource allocation and utilization data on all projects within Department of Analytical Sciences to help planning and operational efficiency
* Establish system to track project progress and help assure that critical deadlines are met
* Familiarize and understand various aspects of analytical development activities for biologics development
* Regularly interact with management team including department head and various laboratory heads and project analytical leads
* Facilitate management team meetings and coordinates cross-functional team meetings
* Keep detailed records and follow up on action items to ensure timely execution
* Cooperative and respectfully communicate with external and internal customers

***Qualifications：***

* MS or Ph.D. in Chemistry, Biochemistry or other related life sciences degree with 3+ years of biopharmaceutical industry experiences
* Excellent understanding of project management processes and procedures
* Strong critical thinking, scientific reasoning and problem solving skills
* Be proactive with demonstrated leadership
* Excellent in time management, organizational and multitasking skills
* Excellent oral and written communication skills in both English and Chinese
* Strong Microsoft Project, Word, PowerPoint and Excel skills and other computer skills

***How to apply:***

1. With the subject of “Apply for *Job Title*, *Department*”
2. Please sent you C/V to WuXiBIO\_Recruiting\_Oversea@wuxiapptec.com

**Job Title: Director, Downstream Development**

**Department: Clinical Manufacturing**

**Location: Wuxi**

***Responsibilities***

* Design the downstream processes that are efficient, robust and scalable for the clinical manufacturing.
* Execute and/or oversee the process scale-up and technology transfer between the process development team and manufacturing team.
* Lead and execute the preparation of dossiers and data packages to assist with the interactions with Regulatory agencies.
* Assist the functional head to coordinate the work between the downstream development group and other functional groups to meet the project objectives and timelines.
* Coach and lead his/her team staff on the process development and validation.
* Manage his/her team effectively in a fast paced environment.

***Qualifications：***

* MS with 8+ years, or PhD with 4+ years downstream process development experience.
* At least 2 years’ people management experience and having strong management and leadership skills.
* Good communication skills (verbal and written) in Chinese and English.
* Skilled in Downstream process development, knowing all modes of chromatography, various modes of filtration (dead end filtration, tangential flow filtration, viral removal filtration), and how to assemble various steps into a purification process.
* Skilled in Design of Experiments.
* Have a good deep understanding of the limitations of manufacturing when designing purification processes.
* Skilled in downstream process scale-up, technical transfer, and production troubleshooting.
* Experience in downstream process characterization and validation.
* Skilled in working with the cross-functional teams.
* Familiar with budgeting processes for projects, personnel, equipment and lab space.
* Experience in regulatory submission to CFDA, FDA, and EMA.
* Interest in exploring cross-functional career opportunities

***How to apply:***

1. With the subject of “Apply for *Job Title*, *Department*”
2. Please sent you C/V to WuXiBIO\_Recruiting\_Oversea@wuxiapptec.com

**Job Title: Associate Director/Director,**

**Department: Business Strategy and Operation**

**Location: Wuxi**

***Responsibilities***

* Support the formulation of strategic initiatives that drive continuous growth for the company in the next 5-10 years. Interact and align with internal stakeholders to ensure the effective execution of action plans.
* Contribute to the development and execution of global expansion plan for the company through external partnership and acquisition.
* Host client and investor visit and present overview of company introduction and technology capability, lead a general facility tour if needed.
* Manage and coordinate business operation activities of CEO Office, including but not limited to senior staff and board meetings, corporate events, client and investor visits, and business improvement initiatives.

***Qualifications：***

* Advanced Degrees in life science or engineering with 2-5 year experience in the pharmaceutical or biotech industry, prior business training is a plus.
* Basic understanding of biological drug development with solid experience in one or more of the following fields: discovery, development, and manufacturing. Experience within in a fast-paced and matrix environment is preferred
* Ability to work independently with limited supervision and as a team member.
* Excellent verbal and written communication skills, strong multi-tasking and prioritization capability
* Interest in exploring cross-functional career opportunities

***How to apply:***

1. With the subject of “Apply for *Job Title*, *Department*”
2. Please sent you C/V to WuXiBIO\_Recruiting\_Oversea@wuxiapptec.com

**Job Title: Associate Director, Validation**

**Department: Process engineering and validation**

**Location: Shanghai/Wuxi**

***Responsibilities***

* Support the formulation of strategic initiatives that drive continuous growth for the company in the next 5-10 years. Interact and align with internal stakeholders to ensure the effective execution of action plans.
* Contribute to the development and execution of global expansion plan for the company through external partnership and acquisition.
* Host client and investor visit and present overview of company introduction and technology capability, lead a general facility tour if needed.
* Manage and coordinate business operation activities of CEO Office, including but not limited to senior staff and board meetings, corporate events, client and investor visits, and business improvement initiatives.

***Qualifications：***

* Advanced Degrees in life science or engineering with 2-5 year experience in the pharmaceutical or biotech industry, prior business training is a plus.
* Basic understanding of biological drug development with solid experience in one or more of the following fields: discovery, development, and manufacturing. Experience within in a fast-paced and matrix environment is preferred
* Ability to work independently with limited supervision and as a team member.
* Excellent verbal and written communication skills, strong multi-tasking and prioritization capability
* Interest in exploring cross-functional career opportunities

***How to apply:***

1. With the subject of “Apply for *Job Title*, *Department*”
2. Please sent you C/V to WuXiBIO\_Recruiting\_Oversea@wuxiapptec.com

**Job Title: Group Leader/Assistant Director/Associate Director**

**Department: Project Management**

**Location: Wuxi**

***Responsibilities***

* Leads the project team to fulfill the contract requirement and meet the client’s need for
* CMC development or manufacturing projects as appropriate.
* Tracks the progress of projects and coordinates WuXi's staff and resources to meet project deadlines in a timely and efficient manner.
* Disseminates and facilitates information flow/exchange among WuXi departments and between the client and WuXi.
* Manage scope change in project execution and assist to sign supplementary agreement for it.
* Holds regular internal project meetings to discuss and plan the projects.
* Holds regular meetings with clients to update progress via teleconference or site visits as appropriate.
* Maintains records to document all relevant communications related to projects.
* Copies files and mails final reports.
* Help Service Department to generate invoices and send them to the client.
* Maintains the WuXi standard quality and format of communications (e.g. letters, proposals, reports, etc.) and overall harmonization of documentation at the corporate level.
* Monitors timeline and contract for accuracy and follows up on any discrepancies with clients and/or internal personnel.
* Assists with training of team members as appropriate.
* Tracks and confirms client materials transfer information.
* Performs other duties as required.

***Qualifications：***

* BS/MS with major in Biological Sciences, Chemical engineering, or equivalent training plus 1 or more years project management experience or equivalent training and/or experience.
* Ability to accomplish the described duties through the use of appropriate computer equipment and software (i.e. Microsoft Word, Excel, PowerPoint, Project and Outlook) and general office equipment (i.e. photocopier, fax machine and phone equipment).
* Ability to accurately and reproducibly perform arithmetic calculations including fractions, decimals and percentages.
* Ability to use judgment as dictated by complexity of situation.
* Ability to work under limited supervision and to handle problems of a more difficult nature.
* Ability to interpret written instructions and to write form letters and routine correspondence.
* Ability to understand and follow verbal or demonstrated instructions.
* Ability to receive and comprehend and to effectively communicate detailed information through verbal and written communication.
* Ability to prioritize tasks in fast paced work environment.
* Ability to work effectively as part of a team and to exhibit effective interpersonal skills.
* Ability to build rapport with internal co-workers and clients in such a way as to maximize quality of client service..

***How to apply:***

1. With the subject of “Apply for *Job Title*, *Department*”
2. Please sent you C/V to WuXiBIO\_Recruiting\_Oversea@wuxiapptec.com

**Job Title: IND-enabling Program Management**

**Department: Discovery**

**Location: Shanghai**

***Responsibilities***

* Manage, direct and lead preclinical projects in a team environment; Work with clients to proactively identify the right strategy based on their unique program and help clients to select right studies, smartly coordinate the studies to move forward efficiently
* Monitor closely the progress of the project, coordinate with sponsors and internal expertise to design appropriate studies to meet regulatory requirements, ultimately to meet the project needs. Stay on the top of project with continues scientific and technical support. Proactively identify potential issuers and input the constructive suggestions
* Interact with clients, other key functions/business units within WuXi AppTec to facilitate the project development; Communicate directly (visiting host, holding TC and auditing, etc.) with national and international sponsors
* Service as an expert for all TOX-related discipline within TAD; Prepare documents package for IND filing; Search and prepare scientific references for project needs.
* Initiate issue-oriented agendas to facilitate effective team meeting discussion and able to summarize and provide guidance on follow-up strategies to ensure timely resolution of outstanding items.

***Qualifications：***

* PhD or equivalence in biomedical/ pharmaceutical science with at least 5 years experience in pharmaceutical/biotech industry in preclinical development with strong toxicology expertise.
* Demonstrated successful leadership, planning and organizational skills with strong knowledge in pharmaceutical R&D from discovery to clinical development and regulatory registration;
* Familiar with relevant FDA, ICH, EMA/OECD and CFDA guidelines/regulation with hands-on experience on planning and execution of IND/CTA programs
* Team oriented work ethic and ability to work in cross-functional teams
* Excellent written and oral communication skills
* Regulatory writing experience and PMP certification will be a pluss.
* Ability to build rapport with internal co-workers and clients in such a way as to maximize quality of client service

***How to apply:***

1. With the subject of “Apply for *Job Title*, *Department*”
2. Please sent you C/V to WuXiBIO\_Recruiting\_Oversea@wuxiapptec.com

**Job Title: Assistant director-B cell and NGS**

**Department: Discovery**

**Location: Shanghai**

***Responsibilities***

* The candidates will have extensive theoretical knowledge as well as bench level experience in the identification and characterization of mAb using various techniques, such as library display (e.g. yeast, phage, etc), B- cell cloning and NGS method
* The candidate will be responsible for establishing and executing novel antibody discovery platform for generating antibody leads.
* The candidates will have good organizational and documentation skills and the ability to plan and simultaneously execute multiple antibody discovery projects.
* Industry experience is strong preferred but not absolutely required for the position

***Qualifications：***

* MS with > 5 years or PhD with > 2 years of relevant experience in therapeutic antibody lead generation through cell-based methods. Expertise in one of the following areas:
* B cell repertoire analysis using Next Generation Sequencing and molecular biology for antibody discovery.
* Hand on experience on cell culture and B cell cloning techniques for antibody discovery.
* Experience in the development of novel antibody discovery platforms.
* FACS sorting, single cell RT-PCR or B cell culture.
* A strong motivation in pursue science in drug discovery.
* Adaptable and productive in a fast-paced environment
* Good communication skills required, including writing notebooks and presentation in English.
* Strong team-working spirit and excellent communication and inter-personal skills.
* Doctor degree in related Life Science subjects with >2-3 years related experience, or Master degree with > 5 years of industrial.
* Knowledge in immunology，especially B cell immunology
* Applied knowledge of library construction and library display.
* Experience in antibody affinity maturation or humanization.
* Proficiency in applications of deep sequencing technologies.

***How to apply:***

1. With the subject of “Apply for *Job Title*, *Department*”
2. Please sent you C/V to WuXiBIO\_Recruiting\_Oversea@wuxiapptec.com