Director of Cell Therapy Manufacturing Operations

**JW Therapeutics**, a new Biotech start-up in Shanghai, China, is on the hunt their Director of Cell Therapy Manufacturing Operations.

As the **Director of Cell Therapy Manufacturing Operations**, you will be contributing to building a world class cell therapy manufacturing operations team (hiring, training, supervising, and evaluating) while being responsible for the daily operations in cell therapy manufacturing and facilities. You will be integral in the development and training of your staff; determining equipment resources; the development of Standard Operating Procedures, Master Batch Records, and Product Specification Sheets to ensure full compliance with China cGMP regulations; Maintains production schedule to meet customer and business goals; Interacting with Engineering, Maintenance, Validation, Quality Assurance, Quality Control, and Materials Management groups to contribute to the success of JW Therapeutics.

*This is an exciting opportunity to join a company and have a direct impact on immuno-oncology cell therapy growth in China but also across the world while setting up this new company for success!*

**As a top candidate for this role, you will have:**

- Minimum of 8 years supervisory experience and 10 years’ experience in biologics manufacturing is required.
- Demonstrated leadership and managerial skills and a strong working knowledge of the regulatory compliance requirements for the production of biologics used in clinical studies and commercial manufacturing are essential.
- Knowledge of cell culture / aseptic operations / cell and gene therapy manufacturing and support systems is essential.
- Direct experience in cell therapy, vaccine clinical manufacturing preferred.
- Has a thorough understanding of cGMP requirements for clinical manufacturing.
- Experienced in commercial manufacturing requirements for biological or cell or gene therapy products.
- Excellent communication skills, both oral and written.
- Ability to evaluate technical data and write technical documents.

**About JW Therapeutics...**

JW Therapeutics is an independent Chinese biotech startup focuses on discovering, developing, manufacturing and commercializing immuno-oncology cell therapy products. The company is co-founded and backed by the world leading immune-oncology cell therapy company, JUNO and life science platform services company, WuxiAppTec. JW is located in Shanghai, China.

We are looking for a few good individuals who have the curiosity in latest sciences, demonstrated leadership and are interested in entrepreneurship to join us to build a great Chinese cell therapy company.
Director of Quality Control & Analytical Development

JW Therapeutics, a new Biotech start-up in Shanghai, China, is on the hunt their Director of Quality Control & Analytical Development.

As the Director of QC & Analytical Development, you will be contributing to building and leading a world class group of scientist that will perform analytical method development/optimization, qualification/validation under cGMP regulations; You will be integral to JW by managing the overall QC operations to support cell production manufacturing operations; Serve as a technical lead and review/approve technical documents such as methods, qualification/validation protocols and reports; assist upper management to schedule resources, coordinate laboratory activities, improve data and document quality to meet client expectation; lead the technology transfer of analytical methods, testing protocols, etc. This is an exciting opportunity to join a company and have a direct impact on immuno-oncology cell therapy growth in China but also across the world while setting up this new company for success!

As a top candidate for this role, you will have:

- A minimum of a Graduate degree in analytical chemistry, biochemistry, immunology, molecular/cell biology or related fields.
- Relevant industry experience (5-10 year for candidates with MS degree or 3-5 year for Ph.D. candidates)
- Extensive knowledge and hands-on experience in the following areas: Biochemical assays such as ELISA, qPCR, Western blot, enzyme activity testing; 5 years’ experience developing and characterizing cell-based analytical methods; 5 years flow cytometry analytical working and method developing experience
- Critical thinking, scientific reasoning and problem solving skills.
- Experience with training staffs and team building a must!
- Superior communication skills (verbal and written) in both Chinese and English - fluent in speaking, writing and reading in both languages.

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**Director of Quality Assurance**

**JW Therapeutics**, a new Biotech start-up in Shanghai, China, is on the hunt their **Director of Quality Assurance**.

As the **Director of Quality Assurance**, you will be contributing to building a world class quality assurance team (hiring, training, supervising, and evaluating) and quality systems; You will be integral in the review and approval of Standard Operating Procedures and Batch Records to ensure full compliance with China cGMP regulations; responsible for ensuring that raw materials, packaging materials and intermediate, bulk and finished product are approved or rejected, stored, distributed and subsequently handled according to the SOP and specifications; responsible for reviewing and approving deviation investigation and change controls; Oversee the investigation, documentation and communication of GMP nonconformity and enforce CAPA's; as well as provide GMP training to all Cell Therapy operations employees and manage any regulatory agency audit and customer audit.

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As a top candidate for this role, you will have:

- An advanced degree in a scientific discipline with experience or training in biologics, vaccines or cell therapy experience.
- Must have 8+ years’ experience in GMP quality assurance management in Biologics, vaccine and cell therapy industries; experience with US FDA GMP compliance and quality management is preferred.
- Must be trained in or have experience with the requirement of CFDA, FDA cGMP regulations.
- Must have a good understanding of Quality System regulations and requirements and the ability to assess and implement quality assurance systems.
- Strong organizational, communication and teamwork skills to be able to effectively interact within multidisciplinary groups.
- Strong team building ability and experience.
- Superior communication skills (verbal and written) in both Chinese and English.

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Head of Manufacturing Operations

JW Therapeutics, a new Biotech start-up in Shanghai, China, is on the hunt their Head of Manufacturing Operations.

As the Head of Manufacturing Operations, you will be building a world class cell therapy manufacturing operations team and commissioning/validating world class GMP cell therapy facilities. You will be integral in the development and training of your staff; the development of Standard Operating Procedures, Master Batch Records, and Product Specification Sheets to ensure full compliance with China cGMP regulations; Interacting with Engineering, Maintenance, Validation, Quality Assurance, Quality Control, and Materials Management groups to contribute to the success of JW Therapeutics.

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