## Department: Cell Therapy

### Position: Director of QC and Analytical Development

**Report to:** VP of Operations

### Date: July 15, 2015

### Location: Shanghai

### Responsibilities:

Job functions including but not limited to,

1. Lead a group of scientists to perform analytical method development/optimization, qualification/validation under cGMP.
2. Manage the overall QC operations to support cell production GMP operations.
3. Communicate with other functional areas and clients to ensure timely completion of QC activities to meet project timeline.
4. Review and approve technical documents such as methods, qualification/validation protocols and reports.
5. Serve as technical lead to solve technical challenges and support laboratory investigations.
6. Assist higher management to schedule resources, coordinate laboratory activities, improve data and document quality to meet client expectation.
7. Lead the technology transfer of analytical methods, testing protocols, etc.

### Qualification:

1. Graduate degree in analytical chemistry, biochemistry, immunology, molecular/cell biology or related fields.
2. Relevant industrial working experience, 5-10 year for candidates with MS degree, 3-5 year for Ph.D. candidates.
3. 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
4. Strong communication skills in English and Chinese, fluent in speaking, writing and reading in both languages.
5. Critical thinking, scientific reasoning and problem solving skills.
6. Experience on training stafs and team building
Competencies (Refer to Company Leadership Competency Model):

职位说明书

Department: Cell Therapy

Position: Director of Quality Assurance

Report to: CEO or General Manager

Location: Shanghai Date: July 15, 2015

Responsibilities:
Job functions including but not limited to,
1. Establish and manage newly established Cell Therapy Quality Assurance department and quality system
2. Responsible for reviewing and approving SOPs, batch records and ensuring the operation complies with GMP regulations.
3. 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.
4. Responsible for reviewing and approving deviation investigation and changed control,
5. Oversee the investigation, documentation and communication of GMP nonconformity and enforce CAPA.
6. Recruiting and training QA staffs
7. Provide GMP training to all Cell Therapy operations employees
8. Manage any regulatory agency audit and customer audit

Qualification:

1. Must have 8+ years experience in GMP quality assurance management in Biologics, vaccine and cell therapy industries; experiences with US FDA GMP compliance and quality management is preferred.
2. Must be trained in or have experience with the requirement of SFDA, FDA GMP regulation.
3. Good understand of Quality System regulations and requirements and ability to assess and implement
quality assurance system.

4. Advanced degree in a science discipline with experience or training in Biologics, vaccine or cell therapy experience.

5. Strong organization, communication and teamwork skills to be able to effectively interact within multidisciplinary groups.

6. Strong team building ability and experience.

7. Good spoken and written skill in both Chinese and English.

**Competencies (Refer to Company Leadership Competency Model):**

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**Responsibilities:**
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8. Lead a group of scientists to perform analytical method development/optimization, qualification/validation under cGMP.

9. Manage the overall QC operations to support cell production GMP operations

10. Communicate with other functional areas and clients to ensure timely completion of QC activities to meet project timeline.

11. Review and approve technical documents such as methods, qualification/validation protocols and reports.

12. Serve as technical lead to solve technical challenges and support laboratory investigations.

13. Assist higher management to schedule resources, coordinate laboratory activities, improve data and document quality to meet client expectation.

14. Lead the technology transfer of analytical methods, testing protocols, etc.
Qualification:
7. Graduate degree in analytical chemistry, biochemistry, immunology, molecular/cell biology or related fields.
8. Relevant industrial working experience, 5-10 year for candidates with MS degree, 3-5 year for Ph.D. candidates.
9. Extensive knowledge and hands-on experience in the following areas:
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10. Strong communication skills in English and Chinese, fluent in speaking, writing and reading in both languages.
11. Critical thinking, scientific reasoning and problem solving skills.
12. Experience on training staffs and team building

Competencies (Refer to Company Leadership Competency Model):

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Report to: CEO or General Manager

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**JOB DESCRIPTION**

**Job Title:** Senior Director of Cell Therapy cGMP Manufacturing Operations  
**Department:** Cell Therapy  
**Reports To:** CEO/VP of Operations
JOB SUMMARY

Responsible for the daily operations in cell therapy manufacturing and facilities. Knowledge of cell culture / aseptic operations / cell and gene therapy manufacturing and support systems is essential. Demonstrated managerial skills and a strong working knowledge of the regulatory compliance requirements for the production of biologicals used in clinical studies and commercial manufacturing are essential. Responsible for hiring, training, supervising and evaluating staff. Remains current regarding technical manufacturing requirements and develops / modifies production methods to fully address such issues. Prepares validation protocols, SOPs, material specifications and develops new client master batch records. Manages cell manufacturing operations assuring customer satisfaction and compliance with appropriate regulatory standards including but not limited to the U.S. and China GMP regulations.

POSITION RESPONSIBILITIES:

- Responsible for representing Manufacturing in the build-out, commissioning and validation of the GMP cell therapy facility in Shanghai WaiQiaoQiao Free Trade Zone.
- Determining staff and equipment resources.
- Staffing and training of the assigned Manufacturing group to be competent in current Good Manufacturing Practices (cGMP).
- Interacts with Engineering, Maintenance, Validation, Quality Assurance, Quality Control, and Materials Management groups. As needed, interaction will be required with material/equipment vendors and clients.
- Supervises, plans and reviews operations for assigned staff, including responsibility for training, managing and evaluating as well as coordinating, scheduling and assigning work and maintaining facility's standards.
- Recommends hire/transfer/promotion/discharge and salary changes and acts on employee problems.
- Conducts employee performance appraisals in a timely and objective manner.
- Maintains production schedule to meet customer and business goals.
- Provides accurate production forecasting methods with continuous improvement through capacity optimization and cost reduction programs.
- Implements and maintains personnel policies, procedures and production control systems.
- Ensures cGMP compliance, ensuring that all production equipment is properly validated and production processes meet quality standards.

Position Qualifications:

- Minimum of 8 years supervisory experience and 10 years’ experience in biologics manufacturing is required.
- 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.
• Demonstrated leadership skills.
• Ability to evaluate technical data and write technical documents.

Location: Shanghai, China
Domestic travel is required.

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POSITION RESPONSIBILITIES:
• Responsible for representing Manufacturing in the build-out, commissioning and validation of the GMP cell therapy facility in Shanghai WaiQaoQiao Free Trade Zone.
• Determining staff and equipment resources.
• Identification and development of Standard Operating Procedures (SOPs), Master Batch Records, and Product Specification Sheets.
• Staffing and training of the assigned Manufacturing group to be competent in current Good Manufacturing Practices (cGMP).
• Interacts with Engineering, Maintenance, Validation, Quality Assurance, Quality Control, and Materials Management groups. As needed, interaction will be required with material/equipment vendors and clients.
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