



**Sr. Manager, Quality Systems Training**  
**Job Code 565YL**

**Description**

Fate Therapeutics is seeking a motivated, driven, experienced and talented Sr. Manager, Quality Systems Training, to support Fate's quality programs at Fate. The successful candidate will develop, implement, and maintain personnel qualification and training programs for Fate. The Sr. Manager, Quality Systems Training develops policies, procedures, and controls to cGMP/GxP documentation and established regulatory standards, delivers, and evaluates training programs that improve performance of employees and compliance to regulations. The Senior Manager, Quality Systems Training is also responsible for the overall management of training systems, content, and support materials in the company. This position requires an independent, proactive leader with a strong depth of understanding of the FDA and international regulations and guidance documents, and how they can be applied in a risk-based and appropriate fashion for a smaller company setting. This position will be responsible for the design, development, and delivery of new training programs and initiatives for the company as well as overseeing the activities of training. Candidates must have experience working in a GxP environment and have hands-on experience with Learning Management System (LMS), instructional design and EDMS. This is a full-time position, routinely interacting with other Quality Assurance functions, Manufacturing, Quality Control, MSAT; reporting to the Director, Quality Assurance, and is located at our corporate headquarters in San Diego, California.

**Responsibilities:**

- Facilitates the training needs of on-going training programs on a continuous basis, and also has responsibility to develop and deliver content to the departmental heads and management for the training curriculums at all levels of business.
- Conducts the tracking and reporting of the progress for all on-going training programs, training system metrics.
- Ensures that there is consistency in the quality of training programs, initiatives, and materials.
- Works with department leads in the approval and formulation of training strategies, initiatives, and materials that will address the identified training needs, to build compliance training and keep employees aware of best practices and relevant regulations.
- Drives innovative training program development through the facilitation of online resources, training toolkits, and mentorship programs.
- Establishes unique strategic plans for each department that improve the skills of employees in each department in a more personalized manner.
- Actively builds the capabilities of business employees, placing focus on critical thinking, business fundamentals, and leadership.
- Creates, designs, and continuously improves training content, for example, outlines and presentations, agendas, associated materials, and so forth.
- Highly collaborative, works closely with various departmental heads and management in developing training activities unique to their individual departments and that are aligned with individual department employee needs.



- Plays a major support role, coaching leadership and management principles within the business, leading training sessions and ensuring proper execution of training programs.
- Establishes metrics that measure the performance and success of ongoing training programs to identify points of improvement and develops solutions that improve the effectiveness of training programs.
- Maximizes the effectiveness of the training initiatives launched by staying up to date with current training practices, training methods, learning tools, and learning deployment devices and technologies.
- Develops and establishes SOPs taking into consideration risk-based approach
- Provides support, oversight, participates and serves as site Subject Matter Expert on GxP training program during audits and regulatory inspections.
- Develops, maintains and drives continuous improvements while providing quality oversight of the GxP training program which includes:
  - Develops and oversees quality orientation training for new GxP employees as part of the on-boarding process and annual GxP refresher training.
  - Develops and oversees of the “Train-the-trainer” program for delivery of instructor-led and on-the-job training/Skills Demonstration Assessments.
- Responsible for delivery of instructor-led training to team members in both virtual and traditional group presentation settings.
- Handles sourcing/producing, evaluating and administering of online learning resources when requested/applicable.
- Provides support to teams in defining/designing/delivering/deploying targeted training.
- Supervises, coaches and develops trainers across departments to ensure training effectiveness.
- Collaborates with process owners and departments to create effective training material.
- Maintains training records to meet all regulatory requirements.
- Partners with the global and site organization on the development of audit responses and corrective actions related to GxP training.
- Supports Document Control for workflow development and training issuance.

#### **Qualifications**

- Bachelor’s degree and 5+ years experience in positions of increasing Quality responsibility in a training and development capacity, planning, managing and developing compliance training programs to support organizational needs and conducting GxP training programs
- Instructional Design experience in a corporate, scientific and/or manufacturing environment
- Ability to quickly learn and understand complex technical and scientific information as it relates to training and compliance responsibilities
- Demonstrated ability to develop and implement key learning objectives and adult learning strategies and tactics
- Excellent presentation skills and a proven track record of delivering successful training and presentations
- Excellent knowledge and hands-on experience using EDMS, LMS Document and/or Training Management System
- Development of training plans, job aids, On-the-Job and Instructor Led Training, agendas, training curricula, as well as application of GMP principles, and working in an FDA regulated environment



- Progressive experience planning, managing training programs, developing programs to support organizational needs and conducting GXP training programs
- Critical analytical skills, strong verbal and communication skills
- Ability to work under pressure and analyze processes within scheduled timeframes
- Proficiency using PC software programs, including PowerPoint, Excel, Word, Visio, and LMS, in addition to virtual meeting platforms Teams, Zoom, GoTo
- Excellent presentation skills, including written and verbal communication and ability to work with others and influence in a positive and collaborative manner
- Ability to communicate effectively with people in diverse and different settings
- Ability to work independently, well organized, detail oriented, able to prioritize and complete activities in a timely manner and manage multiple projects at one time
- Good organizational, project management skills and ability to perform varied tasks in a functionally independent and consistent manner
- Strong technical writing skills
- 21 CFR Part 11 compliance auditing experience, and/or application to company processes, a plus
- Proficiency in Learning Management Software, electronic quality and operational systems strongly preferred

#### **Working Conditions and Physical Requirements**

- May require some travel (up to 10%)
- May require occasional evening and weekend work
- Subject to extended periods of sitting and standing, vision to monitor and moderate noise levels. Work is typically performed in an office environment, however there is consideration for a potentially mixed virtual/office situation.

The preceding job description indicates the general nature and level of work performed by employees within this classification. Additional and incidental duties related to the primary duties may be required from time to time.

For consideration send cover letter and resume to [careers@fatetherapeutics.com](mailto:careers@fatetherapeutics.com) and reference job code 565YL.

#### **About Fate Therapeutics, Inc.**

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit [www.fatetherapeutics.com](http://www.fatetherapeutics.com).