

Position:

Manager/Sr. Manager, Training, Quality Systems

About the Company:

Dren Bio is a privately held, clinical-stage biopharmaceutical company pioneering the discovery and development of first-in-class antibody therapeutics for the treatment of cancer, autoimmune disorders, and other serious diseases. Leveraging our wholly owned technologies, we have built a robust R&D pipeline, including two clinical-stage candidates currently being evaluated across multiple ongoing clinical studies. Our lead clinical candidate, dibotatug, is designed to induce antibody-mediated killing of a specific cell type implicated in a range of oncology and autoimmune indications. In addition, we have launched multiple programs from our proprietary Targeted Myeloid Engager and Phagocytosis Platform, a multispecific antibody-based technology engineered to selectively engage a novel phagocytic receptor expressed on myeloid cells (antigen presenting cells) for the targeted depletion of pathologic cells and other disease-causing agents. Data generated using the platform support its broad therapeutic potential, including initial programs focused on oncology, immunology, and neurology. Importantly, multispecific antibodies generated from the platform are specially designed to activate phagocytic mechanisms only in the presence of disease targets, potentially offering a superior safety profile compared to other immunomodulatory therapies. For more information, please visit our website at www.drenbio.com.

Function:

Quality

Level:

Manager/Sr. Manager

Location:

San Carlos, CA. This position is based onsite.

Reporting Manager:

Sr Director, Quality

About the Opportunity:

The Manager/Sr. Manager, Training, Quality Systems, will manage the GxP Training Program, act as the main Training System Administrator for the eLMS and lead the execution of all GXP Training activities, including but not limited to creation and processing of training content through the Electronic Learning Management System (eLMS), conducting and managing GxP on-boarding, creating training content as required, regular live and digital employee training via the eLMS, inspection support, creation of and reporting training metrics, continued development of training matrices across GxP functions. This role will be 1st point of contact for training, and other Quality Systems and Document Control-support as required.

Role and Responsibilities:

- Manage the GxP training program (guide, evaluate and implement the design and architecture of trainings within eLMS)
- Creation and revision of role-based training curricula to align with functional responsibilities
- Manage onboarding of new employees by facilitating Quality onboarding training, verifying account creation and assigning curricula in Dren Bio's eLMS
- Support the creation and revision of Training related SOPs, work instructions, training materials in collaboration with Subject Matter Experts (SMEs)

- Identify, review and implement digital learning resources, including but not limited to web-based training, videos/recorded content and SCORM files.
- Advise subject matter experts (SMEs) on conceptualizing and sharing content.
- Provide training and support for employees on the use of the LMS
- Responsible for the development of training material using instructional design principles that best suit various training objectives
- Facilitate GxP training for employees, as needed
- Oversight of training compliance across all departments, publish periodic training reports, and escalate compliance issues to management
- Collaborate cross-functionally to support LMS upgrades and change management
- Support /manage the other Quality systems and Document Control Activities and the timely closure of relevant Quality System records
- Identify and participate in initiatives to improve the training program, LMS and training content, and the Quality Systems
- Support development of Quality Management Review content to measure the effectiveness of the training program and the other Quality Systems
- Support audits and regulatory authority inspections by providing training reports/documentation or other assigned tasks related to all the Quality Systems
- Provide oversight and timely response of training and Quality Systems related inquiries
- Oversight of employees' resumes/CVs, and job descriptions to ensure compliance
- Ensure timely generation and review of content for periodic GxP refresher trainings
- Other duties as assigned

Education, Experience and Qualification Requirements:

- Min 5 years of experience in a GxP environment preferably in Document Control or Quality Systems role with a min of 2 years implementing, managing or working with GxP training
- Bachelor's Degree in related field preferred
- Experience in the administration of electronic learning management systems
- Experience in training program administration in the life sciences industry or other highly regulated industry
- Experience in electronic document and quality management systems required
- Experience with the transition from a development to commercial organization including regulatory inspections a plus

Core Competencies, Knowledge and Skill Requirements:

- Knowledge of GxP and Quality Systems principles with respect to US, EU, and other relevant regulatory guidance
- Ability to create accurate and engaging training materials a keen eye for detail and compliance.
- Superior organization skills with ability to manage competing priorities and meet aggressive deadlines
- Demonstrated ability to train GXP personnel one-on-one and in groups
- Works independently with minimal supervision
- Excellent team player with strong written and verbal communication skills
- Ability to work cross-functionally while providing excellent customer service
- Champions continuous process improvement
- Ethical and compliant
- Proficient with MS Office Suite including Word, Excel and PowerPoint

Salaries, Benefits and Other Employee Perks:

Dren Bio strongly believes in investing in, and rewarding, its employees. This philosophy is embodied in the Company's total rewards program, which includes competitive cash compensation, equity incentive awards, and employer sponsored benefit offerings. The base pay range for this position at commencement of employment is

expected to be between \$125,000 and \$165,000 per year. At Dren Bio, pay ranges are determined by role, level(s), and location. The range displayed in this job posting reflects the minimum and maximum new hire pay for candidates located across all United States job markets. Within the range, individual pay will be determined by work location and additional factors, including job-related skills, experience, and relevant education or training. During the hiring process, Dren Bio's Human Resources department can share more about the specific pay range based on the market location of the candidate.

Employment Practices:

Dren Bio is an equal opportunity employer. Employment decisions are based on merit and business needs. Dren Bio will not discriminate against any job applicant because of race, color, national origin, ancestry, gender, sexual orientation, age, religion, creed, physical or mental disability, gender identity, medical condition, pregnancy, marital status, veteran status, or any other characteristic protected by federal, state or local law.

Interested Applicants:

Please send resume and cover letter to careers@drenbio.com