About Dragonfly

Founded in 2015 by Dr. Tyler Jacks, head of the Koch Institute at MIT, Dr. David Raulet, one of the world's leading experts in Natural Killer (NK) cell biology, and Bill Haney, a longtime tech entrepreneur and investor, Dragonfly Therapeutics was launched to harness the power of the immune system to provide breakthrough cancer treatments for patients – especially in areas where there are no effective treatments, today.

The company develops novel first-in-class therapeutics designed to harness Natural Killer cells and other cells of the innate immune system which can provide direct killing of cancer, mobilize T cells, and provide a unique therapeutic window beyond current T cell therapies. Our Scientific Advisory Board members are major figures in cancer biology and immunology, and along with the team are deeply committed to building game changing therapeutics to attack cancer.

Our mission is to to revolutionize cancer treatment by inventing natural killer cell-based therapies for vastly improved patient outcomes. We believe in a small team with a big impact.

Manager/Senior Manager, Quality Assurance

Dragonfly Therapeutics seeks an experienced and motivated Manager/Sr. Manager with a strong background in Quality Assurance to support the development of new biologic therapeutics. The successful candidate will report to the Senior Director and work with Dragonfly's team to manage the quality operations for clinical drug products.

Responsibilities:

- Maintain a phase-appropriate Quality Management System approach for GMP product manufacture and product development activities to ensure cGMP compliance of clinical trial material with internal standard operating procedures and applicable regulations.
- Lead and/or participate in process, compliance, and quality system improvement efforts.
- Lead disposition of drug substance and drug product for use in clinical trials.
- Author, review and/or approve documentation, including Master Production Records, SOPs, specifications, protocols and final reports in compliance with Good Manufacturing Practices.
- Review of protocols and reports for QC method qualification/validation and facility and equipment validation
- QA Representative on specific project teams, meetings, etc to provide input on QA topics. Serve as liaison between Dragonfly and CxO quality assurance departments.
- Proactively identify, inform, and help to resolve any potential quality issues to maintain program timelines and compliance.
- Participate/Lead product quality investigations and resolve quality issues.
- Quality planning for moving products from research to preclinical to clinical trials including specification development, batch record creation/approval, and test method qualification/validation.
- Maintain audit schedule of contracted organizations and ensure audits are performed as needed. Work with CMO and auditors to resolve any findings and ensure quality agreements are appropriate.

Qualifications:

- Bachelor's degree in biology, chemistry, life sciences or a related field preferred
- At least 5+ years of QA experience in the biopharmaceutical / pharmaceutical industry
- Thorough knowledge of EU, FDA, ICH, and other applicable regulatory requirements as well as industry standards
- Working knowledge with US and EU Pharmacopeia
- Ability to apply cGMP regulations, practices, and trends pertaining to biopharmaceutical/ pharmaceutical product development, manufacturing and testing in clinical manufacturing
- Excellent oral and written communication skills and ability to interact with all levels of the organization
- Ability to work on complex problems in which analysis of situations or data requires an in-depth evaluation of various factors. Can work through operational problems to ensure compliance is maintained while continuing to move programs forward. May require instructions in new situations.
- Ability to exercise judgment within broadly defined practices and policies in determining solutions and actions. Ability to interpret guidance documents and provide guidance to project teams on impact and best approaches.

Please apply by sending a cover letter and resume to Jobs@dragonflytx.com. (posted July 17, 2020)