OncoResponse

JOB TITLE: Director of CMC Quality Assurance – Immuno-Oncology

OncoResponse Inc., a Seattle-based privately held immuno-oncology company, has partnered with MD Anderson Cancer Center to deploy a unique and transformative approach to the discovery of cancer therapeutics. OncoResponse is leveraging the human immune system to identify fully human monoclonal antibodies and discover novel targets that will lead to the development of antibody-derived therapeutics for the treatment of cancer. Be part of an exciting discovery process in the fight against cancer. OncoResponse offers a team-oriented, stimulating work environment, along with competitive compensation, benefits and stock options. Join a small, growing company and make a big difference! Please visit www.oncoresponseinc.com.

Please note: We are following robust COVID infection prevention guidelines. All of our employees who work on site are required to present proof of full vaccination status.

To apply, please email your resume and a cover letter to HR@oncoresponseinc.com

Responsibilities:

OncoResponse seeks a proactive biotech CMC Quality professional. We offer the autonomy, excitement and ability to contribute offered in an early stage, small company moving into early and late phase clinical trials. Responsibilities will include:

- Lead the CMC QA function and work closely with clinical, regulatory and CMC teams
- Develop and lead efforts for QA oversight of the manufacture of pre-clinical and clinical product
- Ensure quality of products produced/maintained at contract organizations through review and approval of key activities
- Review and approve relevant documentation including deviation investigations and change control
- Ensure development of quality metrics at the contract organizations that support excellence in quality systems and processes; Manage any due diligence activities
- Write and review relevant sections of regulatory submissions including IND's; Assist in responses to regulatory questions
- Work as part of CMC team to ensure successful planning, execution and delivery of projects
- Ensure activities and deliverables are in compliance with FDA, EMA, local regulations and guidance, SOPs and industry best practices
- May participate in external collaborations to influence policy, practices and current guidance for the manufacture of biologics
- Assist the CMC and clinical teams as needed

Preferred Qualifications:

- BS in Chemistry, Biology, Biotechnology or related field
- Minimum of 10 years of relevant industry experience such as manufacturing, quality assurance, and/or quality control in biotechnology

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Preferred Qualifications (cont'd):

- Experience in all stages of clinical product development
- Well-grounded in the regulatory environment including compliance and strategy
- Good writing skills and experience contributing to the regulatory submissions
- Experience evaluating and collaborating with external development partners
- Excellent interpersonal and team skills