OncoResponse

JOB TITLE: **Associate Director CMC – Immuno-Oncology**

SUMMARY: We are seeking an experienced and proactive CMC 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. Make a big contribution to novel cancer therapies in a small company environment.

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. Please visit http://www.oncoresponseinc.com/

Responsibilities include:

- Play a key role in advancing experimental therapeutic molecules to the clinic by providing expertise in CMC-related activities; including but not limited to cell line development, process development (upstream, downstream, formulation), analytics, and stability for drug substance and drug product.
- Manage CMC activities outsourced to CDMO's including process development, cGMP manufacturing and other supporting efforts.
- Contribute to CDMO evaluation and selection, as well as subsequent management of contracts and agreements with these external partners.
- Provide input into CMC-related documents such as IND's, ensuring that they are complete, well written, and meet all relevant agency requirements and standards.
- Proactively identify CMC risks and provide recommendations on mitigation.
- Ensure that CMC activities remain within projected timelines and budget.
- Ensure that CMC activities meet regulatory requirements, both domestic and international.
- Work closely and cooperatively with Clinical, Quality, Regulatory and CMC team members.

Qualifications:

- BS in biology, biotechnology or related field. Minimum of 8 years of relevant industry experience including early and late stage trials.
- Well grounded in regulatory environment including compliance and strategy.
- Good writing skills.
- Experience evaluating, contracting with and collaborating with external development partners.
- Excellent interpersonal and collaboration skills.

OncoResponse offers a team-oriented, stimulating work environment. Competitive compensation, benefits and stock options are offered. Please email your resume with cover letter to: **careers@oncoresponseinc.com** for consideration.

OncoResponse offers a diverse, inclusive environment, and is an equal opportunity employer