Position: Principal Scientist – Cell Therapy (Failure Modes and Effects Analysis)

Location: Worcester, MA

We are seeking a highly motivated Analytical Development Scientist, Failure Modes and Effects Analysis (FMEA), to join our Analytical Development team. The successful candidate will take the lead on the analytical activities of establishing and documenting the robustness of Mustang's qualified and/or validated analytical methods through failure modes and effects analysis, lead the lifecycle management of analytical procedures, work closely with cross-functional colleagues in the company to support the late stage development of drug product, prepare for pre-approval inspection, and support regulatory BLA filing.

Responsibilities:

- Apply expertise in molecular biology, cell biology and/or immunology to analytical development, the lifecycle management of analytical procedures and FMEA.
- Lead a team of scientists for the development of analytical processes, equipment and control systems used for the cGMP lot release and in-process testing of drug substance and drug product.
- Lead continual improvement across the entire lifecycle of the analytical procedure through commercial.
- Lead the technology transfer of analytical methods to QC and analytical method qualification and validation through commercial acting as a liaison between analytical and quality departments.
- Support deviation management, CAPA, and change control activities as required. Serve as Analytical SME to Quality, Manufacturing and other functions. Support manufacturing investigations, including OOSs, and prepare for pre-approval inspection.
- Author and review technical documents such as methods, qualification/validation protocols and reports.
- Serve as an analytical SME to solve technical challenges and support laboratory investigations.

Qualifications:

MS, PhD preferred with 10+ years of relevant industry experience, in molecular biology, virology, cell biology, immunology, pharmaceutical sciences and a minimum of 3 years in a managerial capacity.

- Strong technical skills in molecular biology, including but not limited to PCR, qPCR, cloning and ELISA.
- Experiences working with retroviral/lentiviral vector is a plus.
- Experienced and knowledgeable in quality control and cGMP regulations.
- Strong documentation, attention-to-detail, and procedure writing skills suitable for a cGMP environment.
- Critical thinking, scientific reasoning and problem-solving skills.
- Comprehensive knowledge of risk management including experience using F.M.E.A is a plus.
- Experience in cGMP pertaining to the pharmaceutical and biological industries.