Immatics US, based in Houston, Texas, is a highly innovative biopharmaceutical company developing adoptive cellular immunotherapies against novel cancer targets. For additional information about Immatics, please visit our website www.immatics.com. We are currently seeking applicants for the following position:

Director of Regulatory Affairs

Immatics US is currently seeking a Director of Regulatory Affairs. The position is based in Houston, Texas. The Director of Regulatory Affairs will work in an interdisciplinary environment with colleagues from pre-clinical and clinical development, business development and intellectual property and in close collaboration with the MD Anderson Cancer Center colleagues from various departments of Immatics Biotechnologies GmbH (Germany).

Essential Job Functions

- Lead and manage the US Regulatory Affairs Department.
- Experience with all aspects of the regulatory process including strategy (agency interactions, application planning), operations (meeting request, background packages, IND through BLA submissions), and regulatory cmc (minimum of supervision experience)
- Develop and recommend regulatory strategies for Immatics' cell therapy products and companion diagnostic devices to senior management, update based upon regulatory changes.
- Develop overall timelines and plans by working with team members in RA, research and development, QA, and clinical affairs to ensure regulatory requirements are properly covered and implemented as part of product development plans.
- Ensure compliance with regulatory requirements and timely preparation of organized and scientifically valid applications.
- Arrange, prepare for, and lead meetings with FDA (preIND meetings, Typ A meetings, preSubs, informal contacts).
- Interact as the company representative with external contacts for regulatory functions, including FDA, IRBs and scientific review boards, clinical and business cooperation.
- Lead and oversight of all regulatory operational processes and tasks, including authoring and compilation of regulatory submissions, coordination of regulatory CROs, TMF handling, trial insurance, clinicaltrials.gov registration.
- Participate in regulatory intelligence gathering activities and maintain knowledge of US and EU regulatory requirements
- Mentor, guide, and train direct reports and cross functional team members to increase regulatory affairs awareness.
- Other duties as required.

Minimum Required Education, Experience & Skills

- Minimum of 7 years of experience in operative regulatory affairs in pharmaceutical development in preclinical and clinical stage; experience in oncology and/or adoptive cell therapy is a clear plus.

- Experience with all aspects of the regulatory process including strategy (agency interactions, application planning), operations (meeting request, background packages, IND through BLA submissions), and regulatory CMC (minimum of supervision experience).
- Experience with FDA CBER and CDRH.
- Solid knowledge of US regulatory requirements for pharmaceutical development and companion diagnostic devices. Background in cell and gene therapy products is highly recommended.
- Experience in submissions and interaction with approval boards (i.e. IRBs, RAC, gene therapy committees etc.).
- Master's degree in Life Sciences or related field. Advanced degree preferred.

Please submit resume and cover letter to HR-US@immatics.com