07/05/2024

DANIMARCA	
Posizione	Drug Product Subject Matter Expert (SME)
Scadenza	31.05.2024

In Genmab's expansive growth, we are now looking for a Drug Product Subject Matter Expert (SME) to take upon the responsibility within the area of Compatibility and In-use for Genmab's portfolio products. You will work closely together with early/late stage project teams as well as Drug Supply and subject matter experts within the Science & Technology team. As a Drug Product SME specializing in Compatibility and In-Use, you will play a pivotal role in ensuring the integration of our pharmaceutical products within various healthcare environments. Leveraging your expertise in drug product formulation, you will assess compatibility with delivery systems, storage conditions, and patient needs.
You will be joining the "Pharmaceutical Development and Product Support" team in the Late Stage Manufacturing Development (LSMD) department in CMC operations. LSMD currently has 25 team members and is responsible for the late stage development activities of Genmab's portfolio projects and preparation of the CMC package for regulatory filings.
Key responsibilities include
- Oversight of Compatibility and In-use strategies for early/late stage clinical development programs to ensure alignment with product objectives and regulatory requirements
- Responsible for Compatibility and In-use studies conducted for Genmab portfolio projects, incl. preparing/reviewing protocols and reports
- Responsible for providing expert guidance and recommendations for Compatibility and In- use inquiries (in-side/out-side Genmab)
- Collaborate with cross-functional teams as Medical and Clinical to integrate Compatibility and In-use considerations into product development plans
- Support authoring and review of relevant CMC regulatory submissions documents for Compatibility and In-use
- Responsible for CMC input to clinical trial documents such as IMP/Pharmacy manual
- Support DP late stage development activities, incl. formulation development, drug product process characterization and validation activities
- Support DP activities performed at our partnered CMOs
Requirements
- Master's degree in natural science, pharmacy or similar
- You have at least 5-10 years of documented professional experience with chemistry, manufacturing, and controls (CMC) biologics product development in the Biopharmaceutical industry
- You have active experience within drug product formulation, Compatibility and In-use studies and a solid understanding of regulatory requirements
- Experience with multiple delivery systems is a plus
- You preferably have experience with lifecycle management and medical information requests
- Excellent communication skills in English written and oral
Moreover, you meet the following professional requirements:
- You are focused on achieving goals that are important for the team and our organization
- You have the ability to work successfully under pressure in a fast-paced environment and with tight timelines
- You are pro-active, take initiative and responsibility
You are a team player with demonstrated ability to collaborate with a diverse group of internal and external stakeholders
- With your positive attitude, you enjoy working in multicultural teams inside and outside of Genmab
This role is located in Copenhagen, Denmark.
About You
- You are passionate about our purpose and genuinely care about our mission to transform the lives of patients through innovative cancer treatment
- You bring rigor and excellence to all that you do. You are a fierce believer in our rooted-in-science approach to problem- solving
- You are a generous collaborator who can work in teams with diverse backgrounds
- You are determined to do and be your best and take pride in enabling the best work of others on the team
- You are not afraid to grapple with the unknown and be innovative
- You have experience working in a fast- growing, dynamic company (or a strong desire to)
- You work hard and are not afraid to have a little fun while you do so
Locations
Genmab leverages the effectiveness of an agile working environment, when possible, for the betterment of employee work-life balance. Our offices are designed as open, community- based spaces that work to connect employees while being immersed in our state-of-the-art laboratories. Whether you're in one of our collaboratively designed office spaces or working remotely, we thrive on connecting with each other to innovate.
How to apply: Directly at this website
https://genmab.wd3.myworkdayjobs.com/en-US/Genmab_Careers_Site/details/Subject-Matter-Expert--Drug-Product_R10311