Qbtech

Job Description Template

Job Title: Head of Regulatory

Department: Medical Department

Reports To: Medical Director

Summary of Position
The Head of Regulatory Affairs provides strategic regulatory guidance. S/he oversees and manages global regulatory activities for the Qbtech portfolio in line with the agreed regulatory strategy.

Essential Duties and Responsibilities
• Act as an in-house regulatory expert, advising and supporting, the organization • Lead the implementation of global regulatory strategies • Lead the preparatory activities for interactions with regulatory authorities and lead or co-lead face to face meetings • Manage and monitor preparation, submission and review of regulatory documentation in collaboration with the clinical research team, Quality Assurance and the rest of the organization • Participate in the review of clinical study protocols and critical non-clinical studies to ensure alignment with global regulatory requirements • Develop knowledge on the global regulatory environment and trends. Contribute shaping and implementing a policy position • Conduct and share regulatory intelligence

Supervisory Responsibilities
• The Regulatory Head will not have any managerial responsibilities.

Authorities for Position
• Authorities related to budget for regulatory activities • Authorities related to supervision of third-party suppliers.

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Competency Required for Position
• Very clear and systematic thinking that demonstrates strong judgment and problem solving competencies • High ability to lead large strategic projects • Excellent management, negotiation, and advocacy skills • High ability to interact with internal and external stakeholders • High ability to lead and motivate a team for optimum performance • Excellent knowledge of Regulatory environment (ICH, different regulatory mechanisms and authorities, GCP)

Qualifications Required for Position
• Master degree or Ph.D. in relevant field • Minimum 5 years' regulatory experience in medical device development • Strong working experience with a variety of regulatory authorities is required, with real firsthand experience of managing registrations with different regulatory authorities • Proven ability to work effectively in a team environment and matrix structure is critical • Verbal and written English proficiency • Able to pass a background check

Work Environment
• The position is office based in Stockholm, Sweden • Some domestic and international travel is required

Date: 24/06/2021 Name: Mikkel Hansen