

Position	Regulatory Affairs Manager
Reports to	tbc
Name of Job Holder	tbc
Key Responsibilities of Role	
<ul style="list-style-type: none"> • Oversight of all key Regulatory Operations within Vaccitech Limited • Preparation of submissions for investigational products to key regulatory agencies such as FDA and EMA • Oversight of the approval process when subcontracted to a Contract Service Provider • Coordinate and participate in preparation of different types of regulatory submissions (e.g. dossier, variations, scientific advice submissions, INDs) to competent authorities worldwide for approved and developmental products • Preferably experience of but definitely an awareness of the key electronic submission tools • Develop content, timelines and contingencies for submissions in collaboration with internal and external contributors • Ensure that submissions are of high quality, meet all regulatory requirements and are in compliance with corporate goals and directives • Provide regulatory feedback in project teams and to senior management • Participate in contacting competent authorities for respective projects/products and interact with internal departments • General regulatory and maintenance tasks • Strategic input into and development of operational strategy for Vaccitech programmes 	
Qualifications and/or experience required to perform the role	
<ul style="list-style-type: none"> • University degree in science (preferred) • 5 to 10 years' experience in regulatory affairs • Experience in Regulatory Life Cycle Management and eCTD is an advantage, although not required • A thorough understanding of ICH GCP, Regulatory requirements worldwide (particularly FDA and EMA) plus a knowledge of the EU directives 2001/20/EC, 2005/28/EC and 2003/94/EC and UK Statutory Instruments SI 2004:1031, SE2006:1528 and subsequent amendments • Excellent spoken & written English • Proficiency with standard Windows and Office programs 	



JOB DESCRIPTION

- Experience with electronic document management systems and IT knowledge
- Good social skills and ability to work in teams