	Description
Function	Director Regulatory Affairs
Location / Contact	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne hr@acimmune.com
Percentage	100 %
Reporting Line	The Director Regulatory Affairs reports directly to the VP Regulatory Affairs & Quality Assurance.
Company Profile	• AC Immune is a clinical stage Swiss biotech company focused on the development of innovative therapeutics and diagnostics for Alzheimer's and other neurodegenerative diseases • 140+ Employees, 20+ nationalities, IPO in 2016, listed on NASDAQ • AC Immune SA is a progressive, equal opportunity employer
Job description	AC Immune is seeking a Director Regulatory Affairs accountable for the development and execution of global regulatory product strategies for early-stage innovative products through to registration and life-cycle management. A proven expert in the field, the Director Regulatory Affairs will be responsible for defining innovative regulatory plans in alignment with the department and company's goals and achieving timely regulatory approvals with competitive product labels. The Director Regulatory Affairs will provide oversight of the content and preparation of all regulatory documents/submissions related to applicable programs and mentor junior members of the regulatory team.
Key Responsibilities	• Act as the global regulatory expert for the assigned therapeutic area(s) or product(s) working in close collaboration with the VP Regulatory Affairs and retain the strategic and operational overview across projects • Lead the development of regulatory product strategy, product knowledge, global and regional regulatory requirements, including assessment and inclusion of innovative regulatory pathways to achieve timely regulatory approvals in alignment with AC Immune's strategic milestones and business model • Responsible for the maintenance of regulatory product strategy, proactively identifying emerging issues that may impact development plans and AC Immune business. Adjustment of the strategy and implementation plan in response to new information or changes in the competitive landscape. Communicate issues to management as appropriate • Provide leadership and guidance to senior executives on product regulatory matters and develop cross-functional partnerships with internal stakeholders • Maintain knowledge of current global regulatory guidance and procedures and assesses newly issued Health Authority guidance to ensure impact and strategic recommendations are included in the regulatory product strategy • Lead the preparation and content of high quality regulatory documents and dossiers (e.g., scientific advice requests, orphan medicinal product designation applications, pediatric investigation plans, BLA/MAA) in compliance with global and regional regulatory requirements • Lead interactions with global Health Authorities (FDA, EMA, National Competent Authorities) for product related discussions and disease or product related policies • Responsible for the organization of ad hoc Regulatory Advisory Boards as required

	• May act as a mentor for other RA team members. • Responsible for planning and monitoring the budget for the assigned projects • Establishes and maintains regulatory procedures required to meet legal and regulatory obligations
Qualifications & Skills	The candidate must have the following qualifications: • Graduate degree in scientific discipline or equivalent required; advanced degree preferred • A minimum 10 years' experience in regulatory affairs, including a good understanding of the drug development process and the roles of the different functions and stakeholders involved • Regulatory experience and knowledge in multiple phases of drug development from first-in-human through to registration, with a proven track record of successful BLA/MAA • Significant experience in global RA with an in-depth knowledge of the EU & US registration process and direct experience of leading innovative regulatory strategy development and execution required • In depth knowledge of current global regulations and guidances (e.g. US, EU, ICH etc) essential as they relate to the overall global regulatory strategy • Demonstrated experience in strategic planning, preparing and leading complex global dossier submissions (e.g. US, EU. etc.) • Demonstrated ability in data interpretation, to use and understand scientific data and contribute to innovative clinical study designs • Demonstrated ability to anticipate, analyze and resolve regulatory issues • Willingness to challenge the status quo and take risks through innovation. • Strong negotiation and influencing skills • Results driven and team orientated with the ability to influence outcomes • Excellent interpersonal and communication skills • Good spoken and written English are required