	Description
Function	Director Quality Assurance
Location / Contact	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne. hr@acimmune.com
Percentage	100%
Overview	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. AC Immune is seeking a Director QA responsible for providing strategic direction and leadership for the global QA function and drive for continuous improvement through embedding a quality culture across the company. A proven expert in the field, the Director QA will lead the continued development of the QA function in support of the company's activities and be responsible for the quality and compliance activities for its chemical and biological products. The Director QA reports directly to the VP Regulatory Affairs & Quality Assurance.
Job description/Tasks	• Lead the strategy and development of the quality plan • Responsible for the continued development and maintenance of the QMS, including the development and review of procedures • Support concerned departments with the implementation of processes to ensure full GxP compliance where applicable • Review and approval of quality related documentation (protocols, reports, technical agreements, change controls, deviations and CAPAs, CSV). • Lead the quality oversight of vendor management activities • Provide QA expertise to Research (bio-analytical assays, GLP, GCLP), Clinical (GCP), Manufacturing (supply, release, GMP) and Analytical (method validation) project teams • Preparation and execution of the annual audit plan (internal and external audits, i.e. manufacturers, distributors, packagers and labs) • Lead and manage inspection readiness, including hosting inspections • Monitor the evolving regulatory/quality landscape to ensure continued compliance of the company's regulated operations • Line management of QA team members
Qualifications	The candidate must have the following qualifications: • Graduate degree in pharmacy, chemistry or equivalent education in a technical/scientific subject. • 10 Years of proven experience in QA in the Pharmaceutical Industry GxP environment for chemicals and/or biologicals: - Expertise of GMP, GCP and preferably GLP standards and applicable guidelines

	- Experience in the Research and Development environment, including laboratory, analytical or manufacturing technical background - Good understanding of drug substance / drug product development, manufacturing process, quality control, packaging and distribution - Knowledge of (Bio)-analytical method qualification and validation - Conduct of internal / external audits - Knowledge of CSV an advantage • Ability to interpret and implement quality standards, pro-actively initiate and lead quality compliance activities and manage complex projects / tasks with competing priorities. • Excellent interpersonal and communication skills • Good spoken and written English are required