	Description
Function	Director Quality Assurance
Location / Contact	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne careers@acimmune.com
Percentage	100%
Reporting Line	The Director QA reports directly to the Senior VP Regulatory Affairs & QA
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. • 160+ 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 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 which are in clinical phases.
Key responsibilities	• Lead the QA team • Develop the annual quality plan. Monitor progress via Quality Councils. • Lead the continuous development and maintenance of the QMS in collaboration with other Functions, including the development and review of procedures • Support concerned departments with the implementation of processes to ensure full GxP compliance (internal audit) • Review and approve quality related documentation (protocols, reports, technical agreements, specifications, change controls, deviations and CAPAs, CSV documentation…) • Oversee the vendor qualification and monitoring activities (external audits) • Represent QA on Project teams by providing GxP QA expertise to Clinical, Technical Operations and Research • Lead and manage inspection readiness, including hosting inspections • Monitor the evolving regulatory/quality landscape • Oversee archiving activities at the company level
Qualifications & skills	*Required:* The candidate must have the following qualifications: • Graduate degree in pharmacy, chemistry or equivalent education in a technical/scientific subject. • At least 15 years of proven experience in QA in the Pharmaceutical Industry GxP environment for chemicals and/or biologicals: - Expertise of GMP, GCP and GLP standards

	- 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 of Investigational Medicinal Products - Strong experience in GMP manufacturing and quality control of New Biological Entities - Knowledge of (Bio)-analytical method qualification and validation - Conduct of internal / external audits • Personal features include: - Demonstrated ability to synthesize, analyze and communicate key information - Strong interpersonal skills for building networks with key experts and ensuring the interface with internal departments - Ability to adapt priorities to meet company needs while maintaining effectiveness - Leadership and project management skills - Good spoken and written English are required *Would be a big plus:* • Knowledge/expertise of Computer System Validation • Experience in the manufacture and testing of radiolabeled product for human use