	Description
Function	Manager Quality Assurance
Location/Contact	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne careers@acimmune.com
Percentage	100%
Reporting Line	Director 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. • 150+ Employees, 20+ nationalities, IPO in 2016, listed on NASDAQ. • AC Immune SA is a progressive, equal opportunity employer
Job description	The QA Manager will work in close collaboration with Technical Operations teams to ensure that all GMP requirements are fulfilled for Investigational Medicinal Products (IMP), used in clinical trials where AC Immune is the Sponsor. The QA Manager is responsible for supporting the Quality Assurance department in the execution, maintenance and improvement of the Quality Management System (QMS). The QA Manager will promote a strong quality culture by providing training and guidance on quality-related topics.
Key responsibilities	• Represent QA on Project teams by providing GxP QA expertise to Clinical, Technical Operations and Research, • Review and approve quality related documentation (protocols, reports, batch records, change controls, deviations, OOS/OOT and CAPAs, Specifications, Product Specification File, documents supporting IMP batch certification), • Act as QA representative in Technical Transfer Core Teams, • Provide guidance on quality requirements and support TechOps team and Contract Manufacturing Organizations in sterile/aseptic process validations, equipment qualification, risk assessments, root cause analysis, • Contribute to the maintenance of the QMS (including the development and review of procedures), • Perform vendor qualification and monitoring activities, • Perform internal audits, • Assist with preparation and provide support for inspections or audits, • Ensure GxP compliance is maintained within the evolving regulatory/quality landscape.

Qualifications & skills	Required: • Graduate degree in pharmacy, chemistry or equivalent education in a technical/scientific subject, • At least 5 years of proven experience in QA in the Pharmaceutical Industry and GxP environment for chemicals and/or biologicals, • Strong experience in GMP manufacturing and Quality Control of sterile Investigational Medicinal Products (New Biological Entities), including qualification and validation, • Ability to interpret and implement quality standards, pro-actively initiate and lead quality compliance activities and manage complex projects / tasks with competing priorities. • 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: • Experience in the manufacture and testing of New Chemical Entities and radiolabeled product for human use • Experience as a qualified external auditor