	Description
Function	Quality Control Lead
Location / Contact	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne careers@acimmune.com
Percentage	100 %
Reporting Line	Analytical Development & Quality Control (ADQC) Group Leader
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 highly qualified Quality Control Lead to support its CMC product development programs. The candidate must possess a strong background in Analytical Chemistry or equivalent and must have extensive Quality Control experience, preferably in the (bio)pharmaceutical industry and in the interface with Quality Assurance and Regulatory Affairs functions.
Job description	• Lead and manage analytical method transfer, qualification and/or validation activities to/at external partner(s) or Contract Research Organizations (CROs), including revision and approval of required documentation, for Drug Products, APIs and raw materials • Ensure that Release, Characterization and Stability testing by partners or Contract manufacturing Organizations (CMOs) and CROs is performed in compliance with cGMP/GLP/ICH/USFDA/ISO guidelines and aligned with internal and industry quality standards. • Manage and/or support the OOS/OOT/OOE and any other analytical related Deviations, CAPAs, Change Control, etc in close collaboration with QA /RA department and ADQC team. • Prepare, review and evaluate internal and third party SOPs, WIs, procedures and guidelines • Ensure high quality analytical documentation for submission to Health Authorities • Train regularly the ADQC team on quality control measures and requirements regarding analytical testing procedures, equipment qualification, data recording, laboratory management, etc
Qualifications	• Ph.D. or equivalent in Analytical Chemistry, Biochemistry or related discipline applied to the analysis of large molecules • Quality Control or analytical QC-related expertise (≥ 10 years) in the pharmaceutical/biotech field preferably interacting within multi-disciplinary teams • Deep working knowledge of method development and validation of analytical methods for New Biological Entities • Successful record of interaction with Regulatory Affairs and expertise in applicable regulations in the field of analytics (i.e. Ph.Eur./USP monographs and chapters, and cGMP/GLP/ICH/USFDA/ISO guidelines) • Personal features include: • Team spirited with strong organizational, problem-solving and analytical skills • Autonomous with good judgment and ability to make decisions in a timely manner • Demonstrated ability to manage multiple tasks at once • Strong interpersonal skills to build efficient relationships and communication within the team and at the interface with other departments • Proven Leadership ability and project management skills • Good spoken and written English are required *Would be a plus:* • Expertise in the Quality Control of New Chemical Entities • Experience in Quality Assurance