	Description
Function	Drug Product External Manufacturing Operations Lead – NEW
Location / Contract	AC Immune SA, PSE-B, EPFL, 1015 Lausanne info@acimmune.com
Percentage	100% - available immediately
Reporting Line	Head of External Manufacturing and Clinical Supply
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. The DP External Manufacturing Operations Lead is responsible for leading the Contract Manufacturing Organizations to deliver DP clinical products in line with approved budget, volumes, plan and in compliance with GMP and regulatory requirements. He/she will collaborate with other functions of the Departments and TechOps teams to ensure fulfilment of expectations. In parallel, he/she establishes solid partnerships with the Contract Manufacturing Organizations.
Job Description	• Plan the manufacturing slots at the Contract Manufacturing Organizations in line with the CMC Development Plan. • Review and approve batch records, deviations, CAPA's, technical documents and Change Controls associated with the GMP production of clinical trial materials. • Ensure appropriate root cause investigations are completed and effective corrective/preventive actions implemented. • Provide support, where necessary, to the Contract Manufacturing Organizations, for technical transfers, scale-ups, sterile/aseptic process validations or other specific projects, to perform risk analyses, to purchase new manufacturing equipment, define user requirement specifications, IQ/OQ/PQ protocol development, review, execution and approval. • Compile, analyze, and present manufacturing process data to internal and external teams. • Collaborate with Technical Operations and Quality Assurance for batch record review and batch release within agreed timelines.

Qualifications	The candidate should have the following qualifications:
	• Graduate degree in Life Sciences subject or Chemical Engineering
	• At least 10 years of experience in GMP manufacturing of sterile products (injectables)
	• At least 10 years of experience in multidisciplinary project management in the pharmaceutical industry which should cover:
	• demonstrated ability to manage complex projects within agreed timelines, budget and quality standards (GMP Annex 1)
	  ○ experience in pharmaceutical CMC and process tech transfer to CMOs
	• Personal features include:
	  ○ ability to partner across functions to deliver best solutions
	  ○ ability to communicate clearly and efficiently at all levels, within the company and with external partners
	  ○ quality and compliance oriented mindset
	  ○ highly developed negotiation, influencing and diplomacy skills
	  ○ self motivating
	  ○ team player
	  ○ fluency in English is a must; French and a third language are assets