

	Description
Function	Clinical Supply Chain Lead
Location / Contact	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne hr@acimmune.com
Percentage	100 %
Reporting Line	Chief of Technical Operations Officer
Company Profile	<ul style="list-style-type: none"> 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 140+ Employees, 20+ nationalities, IPO in 2016, listed on NASDAQ AC Immune SA is a progressive, equal opportunity employer
Job description	In this role, you will be the main point of contact liaising internal and external stakeholders to ensure continuous supply of Investigational Medicinal Products (IMP) to clinical centers in alignment with study protocol, Interactive Response Technology (IRT) and in compliance with regulatory and quality requirements.
Key Responsibilities	<p><u>Clinical Supply Chain</u></p> <ul style="list-style-type: none"> Design, implement and maintain strategic plans to forecast and supply study drug to clinical trials using sound supply chain techniques Plan and manages execution of initial supplies and resupplies Collaborate to the IMP needs estimation process and define a supply strategy in cooperation with the CMC Project Leader and the Clinical Project Manager (CPM) Set-up and operationalize the packaging, labelling, storage, and management of IMP with the internal and external stakeholders Ensure deviation process (e.g. temperature excursion) is executed in compliance with GxPs regulations. Proactively identify potential supply chain issues, provide analysis, and recommend solutions Ensure appropriate inventory control and management of shelf-life to guarantee supply, increase efficiencies and reduce wastes Ensure return and destructions processes <p><u>IRT</u></p> <ul style="list-style-type: none"> Provide input into user requirement specifications of IRT IMP management Review IRT strategy to ensure it supports the strategic supply plans and ensures settings are adjusted to optimize the supply chain Execute and documents IRT User Acceptance Testing <p><u>Project management</u></p> <ul style="list-style-type: none"> Serve as main point of contact between internal and external stakeholders Manage the Contract Manufacturing Organization (CMO) performing the operational activities from packaging design to on site delivery, return, reconciliation and destruction Perform study close out activities including returned good reconciliation, inventory destruction processing, and file archiving Coordinate the Sponsor and Qualified Person release of IMP in collaboration with both internal and external stakeholders Update and maintain the long-term budget plan related to clinical supply <p><u>Quality</u></p> <ul style="list-style-type: none"> Ownership of deviations, changes and liaise with different stakeholders Maintain and update relevant Clinical Supply Chain SOPs

Qualifications & Skills	<i>Required:</i> <ul style="list-style-type: none">• Bachelor or Master's in supply chain, Business Administration or equivalent• >5 years of experience in supply chain in the pharmaceutical industry• Good understanding of regulatory and compliance requirements (GxPs)• APICS, LEAN Six Sigma certification or equivalent preferred• Personal features include:<ul style="list-style-type: none">○ 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○ highly developed negotiation, influencing and diplomacy skills,○ self-motivating○ team player• Fluency in English is a must; French and a third language are assets
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