	Description
Function	**Formulation and Drug Product Development Lead**
Location / Contract	AC Immune SA, EPFL Innovation Park Building B, 1015 Lausanne hr@acimmune.com
Percentage	100% - available immediately
Reporting Line	CMC & Program Management Group
Overview	AC Immune is a Swiss Biotech Company focusing on the development of vaccines and immunotherapeutics against Alzheimer's Disease. AC Immune is seeking a **Formulation and Drug Product Development Lead** to support its CMC product development programs. The **Formulation and Drug Product Development Lead** is responsible for the design, formulation and all phases of product development from concept to scale-up of the company NBE and NCE. The range of activities goes from pre-formulation, formulation development and characterization, production of scale-down batches and scale-up for clinical supply. Typical spectrum of formulation ranges from solid oral dosage forms to parenteral liquid injectable. In this position, he/she interfaces with Analytical labs (internal and/or external) for testing of excipient compatibility, raw material qualification, and drug product stability. He or she will direct studies to define optimal pre-formulation, formulation development and DP development approaches in collaboration with identified CMOs. In addition, he/she evaluates/interprets data and communicates results to management and the CMC team as required. He/she contributes to the introduction of scientifically/quality driven approaches such as QbD or DoE (Design of Experiments).
Job Description	**Formulation and Drug Product Development Lead** • Ensure transition of Research manufacturing processes into Development • Establish solid scientific approach in the development of DP manufacturing processes • Define formulation and DP development strategies in collaboration with the CMO and develop suitable and scalable DP manufacturing process(es) • Identify and manage allocated budget and resources requirements • Responsible for production of small-scale / pilot-scale batches
Qualifications	The candidate should have the following qualifications: • Doctorate (PhD) in Chemistry, Chemical Engineering, or Pharmacy and relevant industry experience • Has at least 10 years of experience working across a broad range of oral solid and non-sterile liquid manufacturing technologies. Experience with high protein concentration formulation is a plus • Has experience with GMP requirements • Must be forward-thinking and be able to lead and contribute to scientific/technical discussions • Has strong communication skills including verbal, written, and scientific data presentation • Has strategic thinking and work collaboratively within and outside of the group