

	<b>Description</b>
<b>Function</b>	Toxicologist & Safety Officer
<b>Location / Contact</b>	AC Immune SA, PSE-B, EPFL, 1015 Lausanne <a href="mailto:hr@acimmune.com">hr@acimmune.com</a>
<b>Percentage</b>	100 % - availability immediately
<b>Overview</b>	AC Immune is a Swiss Biotech Company specialized in the development of immunotherapeutics and small molecules (SME) against Alzheimer's Disease. AC Immune is seeking an experienced toxicologist responsible for the design and management of all non-clinical studies to support the preclinical and further development of AC Immune's research and development programs. The candidate will develop the design, preparation and implementation of in vivo and in vitro studies related to all non-clinical development activities to meet regulatory requirements for pre-IND/CTA and IND/CTA submission of biologics and SMEs.
<b>Job description</b>	<ul style="list-style-type: none"> <li>• Design and manage studies in toxicology, ADME, pharmacokinetics and other discipline as they relate to preclinical assessment of safety and efficacy.</li> <li>• Monitor and coordinate (from initial contract to archiving) outsourced studies to ensure common understanding, compliance with study protocol and regulatory requirements.</li> <li>• Act as primary contact person to external CROs for the management of out-sourced preclinical studies.</li> <li>• Interface and provide toxicology guidance to the internal clinical and research groups.</li> <li>• Write and present non-clinical parts for regulatory submissions.</li> <li>• Review of scientific literature relevant to preclinical product development.</li> <li>• Ensure compliances with GLP regulations in designing protocols, analyzing and interpreting the data and preparing relevant documentation.</li> <li>• Support the business development team on technical due diligence associated with in-licensing, acquisitions, and co-development agreements regarding regulatory aspects.</li> <li>• Cover the Safety aspects at AC Immune as Safety Officer by identifying potential safety and health hazards, developing prevention proposals, establishing safety documentation and the bases of decision for the management regarding safety (security) and the protection of the health at work</li> </ul>
<b>Qualifications</b>	The candidate should have the following qualifications: <ul style="list-style-type: none"> <li>• Ph.D. in Toxicology or Pharmacology, Biology or Immunology or alternatively 3-5 years of study director experience in a CRO.</li> <li>• At least 5-7 years of preclinical development experience in the biotechnology or pharmaceutical industry.</li> <li>• Supervisory experience in the biotechnology or pharmaceutical industry or a respective CRO.</li> <li>• Knowledge of GLP regulations, including writing SOPs and study reports.</li> <li>• Proven ability to meet deadlines.</li> <li>• Personal features include:                             <ul style="list-style-type: none"> <li>• excellent interpersonal, analytical and communication skills</li> <li>• ability to build effective working relationships within the company and with external partners</li> <li>• team player</li> <li>• fluency in English is a must; French and a third language are assets</li> </ul> </li> </ul>