

Job Description			
<b>Job Title:</b>	Head –Medical Affairs & Clinical Development		
<b>Function:</b>	Medical Affairs & Clinical Research	<b>Report to:</b>	CEO
<b>Location:</b>	MIDC Rabale, Navi Mumbai	<b>Position Type:</b>	Full Time
About Immunoadoptive Cell Therapy Private Limited.			
<p>ImmunoACT was incubated in IIT Bombay in 2018 and is doing cutting edge work in the space of cell and gene therapy to treat various diseases including cancer, auto immune disorders.</p> <p>It has set up a state-of-the-art GMP facility in Mumbai to scale its production and commercialize its patented product CAR T for lymphoma and leukemia treatment and a robust product pipeline.</p> <p>ImmunoACT’s Strategic Investor partner, Laurus Labs Limited is a leading Indian pharma company headquartered in Hyderabad with global presence and is listed on the Indian stock exchange with market cap of ~USD 3 Bn.</p> <p><b>Our Vision:</b> To be a Leader in Cell &amp; Gene Therapy for Patients’ Long-Term Cure through Translational Research in India &amp; beyond</p> <p><b>Our Values:</b></p> <ul style="list-style-type: none"> <li>• Accessible and affordable to all</li> <li>• Cutting edge research</li> <li>• Transforming ideas to reality</li> </ul> <p><b><i>Become part of this revolution in healthcare industry and grow your career with us.</i></b></p> <p><b>Website</b> – <a href="https://www.immunoact.com/">https://www.immunoact.com/</a> - Visit our website, understand about us.  <b>LinkedIn Profile</b> - <a href="https://www.linkedin.com/company/immunoact/">https://www.linkedin.com/company/immunoact/</a></p>			
Roles and Responsibilities			
<ul style="list-style-type: none"> <li>❖ Provide leadership to ImmunoACT’s Clinical Development Plan.</li> <li>❖ Ensure that the design of clinical studies under area of responsibility is in line with the objectives defined in the Clinical Development Plan.</li> <li>❖ Interface with Principal investigators of the clinical trial sites and assess their requirements, communicate protocols and ensure smooth operations at site.</li> <li>❖ Contribute to develop or coordinate development and approval of study documentation such as the study protocol, ICF, study-specific guidelines, regulatory documents, monitoring, data management and statistical analysis plans and clinical study report, in accordance with internal SOPs and GCP requirements</li> <li>❖ Work closely with internal Scientific and Technical teams towards streamlined operations to meet the clinical trial requirements and ensure study timelines and milestones are met.</li> <li>❖ Assess needs for External Service Providers (ESPs), identify and select ESPs, including negotiation of scope of work and budget and ensure that related contracts comply with internal SOPs and GCP requirements.</li> <li>❖ Close team working with internal or external functions such as Research &amp; Development, Manufacturing, Quality, Regulatory Affairs and any expertise required to implement and oversee the study according to GCP, the Protocol and the requirements of the Management Team.</li> <li>❖ Work closely with clinical trial project managers, site coordinators and regulatory affairs.</li> <li>❖ Contribute to the development of regulatory documents, responses to Health Authority, Regulatory and DSMB questions.</li> <li>❖ Oversee study approval processes for Health Authority, EC/IRB approvals for all study document as required.</li> <li>❖ Contribute to plan &amp; amp (accelerated medicine partnership), organize Investigator meetings, clinical trial related training &amp; review related material</li> <li>❖ Oversee monitoring activities and conduct co-monitoring visits to ensure data quality.</li> <li>❖ Closely monitor clinical trial budgets and patient / site level expenditures.</li> </ul>			

- ❖ Oversee post-infusion data management and ongoing translational studies.
- ❖ Assist in medical monitoring of trial conduct & amp, ensures that non-serious and serious adverse events are properly documented and reported.
- ❖ Ensure adequate trial resources in personnel and material are available cross-functionally and escalate issues if needed
- ❖ Provide study specific direction to study team members and ensure that they are regularly updated on the study progress, challenges and risks through-out the duration of the study.
- ❖ Ensure proper study documentation is maintained and archived in the TMF.
- ❖ Resolve issues in a proactive and timely fashion and escalate unresolved issues and identified risks to CEO as appropriate.
- ❖ Ensure tracking of study budget including revisions and perform final reconciliation at trial close out.
- ❖ Implement best practices and lessons learned and share outcome with the teams.
- ❖ Oversee database lock activities to ensure timely data availability and coordinate study close out with stakeholders as needed.
- ❖ Adhere to personal development plan and maintain training records to ensure appropriate level of competence in compliance with this job description including GCP and other compliances.
- ❖ Contribute to translational plan for cell & amp, gene therapy products
- ❖ Contributes to SOPs and relevant medical writing responsibilities
- ❖ Contributes to scientific & amp, medical liaison communications.

#### Qualifications and Educational Requirement

- ❖ MD (master's degree) in pharmacology or transfusion medicine or medical oncology.
- ❖ MBBS – Doctor of Medicine from a leading university in India, US or UK.
- ❖ Experience in haemato-oncology will be preferred.
- ❖ Minimum of 5 years relevant experience in clinical development and clinical trial management.
- ❖ Demonstrated expertise in clinical research & amp, development and project management (including risk management and contingency planning).

#### Desired Qualities

- ❖ Demonstrated project management experience and leadership skills (e.g., leading project teams) working in cross-functional (matrix) and multicultural teams.
- ❖ Experience in managing complex studies (e.g., large studies, difficult patient populations, involvement of many external service providers).
- ❖ Experience in executing a wide range of clinical trial activities and clinical trial operations (from initiation to clinical study report).
- ❖ Good understanding of managing clinical trial budgets.
- ❖ Pro-active and problem-solving attitude, very strong prioritization skills.
- ❖ Excellent planning and organizing skills.
- ❖ Excellent communication skills and relationship management with internal and external stakeholders.

<b>Compensation</b>	Compensation and other perquisites would not be a constraint for the right candidate
<b>Email Id</b>	<a href="mailto:jobs@immunoact.com">jobs@immunoact.com</a>