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| **Job Description** | | | |
| **Job Title:** | Project Manager - Pharmacovigilance | | |
| **Function:** | Clinical Operation | **Report to:** | Head clinical operation |
| **Location:** | MIDC Rabale, Navi Mumbai | **Position Type:** | Full Time |
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| **About Immunoadoptive Cell Therapy Private Limited:** | | | |
| ImmunoACT is a pioneering cell & gene therapy company, currently in Phase II trials for India’s first indigenously developed CAR-T therapy for the treatment of refractory/relapsing B-cell malignancies (HCAR19), with an aggressive pipeline to treat liquid and solid tumors, With strong, strategic Research (IIT-Bombay) and Clinical (Tata Memorial Hospital) collaborations, ImmunoACT is paving the way towards affordable and accessible gene-modified cell therapies for resource-constrained economies.   Our first state-of-the-art GMP facility has been operational since mid-2022, as we scale-up and scale-out our production capabilities to serve the clinically unmet needs of patients across India.  **Our Vision:**  To be a Leader in Cell & Gene Therapy for the Long-Term Cure of Patients, through Translational Research in India & beyond  **Our Values:**   * Accessible and affordable to all * Cutting edge research * Transforming ideas to reality  *Become a part of this revolution in the healthcare industry - grow your career with us.* **Website** – <https://www.immunoact.com/> - Visit our website, understand about us.  **LinkedIn Profile** - <https://www.linkedin.com/company/immunoact/> | | | |
| **Roles and Responsibilities** | | | |
| * To build a good understanding of the Indian oncology space, cancer-site-specific patient burdens, operational details of the CART treatment and patient requirements. * To maintain and expand on partnerships with clinical team members of treatment centers, their administration, and auxiliary personnel – with the goal of providing expanded access to CAR-T therapies to patients and ensuring smooth clinical operations. * Maintain awareness of current state of cell & gene therapy (literature and competitive intelligence) and provide critical evaluations on the clinical operations.​ * Build and lead a team of executives for each of the current hospitals in their zone. * Lead and coordinate internal and external PV audits and inspections. * Monitor PV system performance and compliance of partners and distributors * Act as the responsible contact person in the region, internally and externally, for safety-related aspects and PV. * Ensure internal regulatory/PV processes and procedures are well documented and support compliant regulatory/PV activities. * Perform other duties as assigned. | | | |
| **Key Performance Indicators** | | | |
| * Meeting the clinical readiness of the site/hospitals * Meeting regulatory requirements as per GLP/hospital ethics guidelines * Training of the hospital personals (nurses/ other staff) on CAR-T products infusion and management * Positive satisfaction ratings from the clinical/hospital teams). * Leadership qualities in terms of training and motivating direct reportees * Stakeholder management internally and externally. | | | |
| **Qualifications and Educational Requirement** | | | |
| * Masters in Clinical Research/PG Diploma in Clinical Research * 3+ years of extensive, hands-on clinical trial and/or clinical settings of sponsor product * Experience with international and domestic regulatory submission, oncology experience, clinical trial experience | | | |
| **Desired Qualities** | | | |
| * Domain expertise in Cell Therapies, CAR-T, biologics manufacturing is plus. * Excellent verbal, written, presentation and interpersonal skills. * Strong analytical and problem-solving skills. * Proactive, creative, self-motivated, flexible to work in a small company environment and assume a wide variety of tasks. * Strong analytical and problem-solving skills. * Excellent written and verbal communication skills. * Ability to work independently and as part of a team. * Ability to manage multiple projects simultaneously. * Strong attention to detail. * Ability to work under pressure. | | | |

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| **Compensation** | Compensation and other perquisites would not be a constraint for the right candidate |
| **Email Id** | [*jobs@immunoact.com*](mailto:jobs@immunoact.com) |