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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.
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| **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.
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| **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
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| **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* |