

Associate Director - PKS Drug Disposition, HYD

Job ID
REQ-10034036
Dic 13, 2024
India

Resumen

Contribute to the BR mission of discovering innovative medicines for unmet medical needs. Manage the PKS Drug Disposition team at Hyderabad in a matrixed structure. Create a culture aligned with Novartis Values and Behaviors. Collaborate with local CRO(s) on PKS assays to support the drug discovery portfolio and acts as local manager for Clinical BA teams. Contribute to the Integrated Drug Discovery efforts and Clinical Pharmacology activities in India. Liaise with local and global stakeholders.

About the Role

Major Accountabilities

1. Manage the PKS DD Unit team at Hyderabad, India in collaboration with line function managers (matrix leadership). Foster and role model a culture of inspired, curious and unbossed leadership.
2. Participates in PKS sub-team to define PKS strategy for compound progression and development.
3. Manages study timelines, objectives and budgets, ensures accuracy of project progress in company tracking tools.
4. Accountable for the timely and effective communication of data, strategy, results, impact to the project teams.
5. Ensure alignment of plans and strategies with sub-teams, project teams, manager and leadership team.
6. Contribute to the analysis and interpretation of the PK/TK, PKPD data during discovery, early and full development and present results and implications to the program.
7. Proactively identifies potential project hurdles, provides solutions and implements contingency plans.
8. Independently authors and prepares key pre-clinical/clinical/regulatory documents including, but not limited to: clinical study protocols, clinical study reports, modelling reports, investigator brochures, IND / IMPDs and NDAs within agreed timelines, and meeting all regulatory requirements
9. Leads cross-departmental teams, department-wide initiatives and work streams.
10. Provide PK Sciences expertise on due diligence and prepare appropriate documentation.
11. Publishes internally and externally as main contributor to enhance Novartis and PK Sciences visibility.

12. Mentors and trains other PK Science Associates.
13. Completes all required organizational trainings and requirements according to corporate timelines.
14. Adhere in strict accord to the appropriate SOP and GxP guidelines.
15. Act as External Relationship representative at Business level (ESP Oversight/Governance at business level)
16. Act as point of contact for PKS colleagues to initiate and support reporting of clinical deviations within PKS.

Job Dimensions

Number of associates

Locally:10-15; Indirect:0

Financial responsibility

None

Impact on the organisation

Internal impact: Enabling DC

External impact: Smooth operational execution

Ideal Background

Education

PhD in life sciences/healthcare

Languages

Fluent oral and written English

Experience/Professional requirement

- 10+ years in the pharmaceutical industry
- 10+ years of experience in drug discovery, development or a relevant environment (e.g. Drug Metabolism and Pharmacokinetics).
- Extensive and in-depth knowledge of drug metabolism and pharmacokinetics including, pharmacology PK and PK/PD evaluation,
- Demonstrated success of working in cross-functional project teams (preferably global) and sound awareness of recent developments in drug development sciences
- Knowledge of regulatory requirements and experience in dealing with regulatory authorities and experience conducting due diligence.
- Proficient with full range of techniques used in job and core area. Working knowledge of tools and processes used in drug design and development.
- Extensive library research skills and knowledge of problem-solving techniques.
- Extensive and in-depth knowledge of scientific discipline and relevant laboratory tools and procedures if responsible for lab associated activity
- Good understanding of management and training principles.

- Sound and robust list of scientific publications and external presentations.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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División

Biomedical Research

Business Unit

Pharma Research

Ubicación

India

Sitio

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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