

PKS Integration Operations Manager

Job ID
REQ-10086460
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Индия

Сводка

As an Integration Operational Manager working across non-GxP and GxP environments, you will support the integration of M&A activities and asset acquisitions across all modalities. You will work closely with a dedicated team, including PKS Expert and its SMEs (BA, ADME, ...) and a BR Line Function Integration Lead, to drive key operational activities. These include facilitating scientific deep dives and gap analyses, managing inventories of studies, study samples, reference substances, critical reagents, e-data, and raw data archives, and supporting the review of business partners, contracts, and invoices. Under the supervision of the PKS Integration Ops Lead, you will manage several M&A and asset integrations in parallel while maintaining clear and consistent communication with your line manager. This role is critical to ensuring the seamless integration of acquired assets into the Novartis BioMedical Research Pharmacokinetic Sciences (PKS) department.

About the Role

Key Responsibilities

- Guide and support the PKS subteam on the integration process
 - Review of relevant documents (BioA, ADME etc...)
 - Bioanalytical reports (MVR, TKR, BDR, IG, analytical plans).
- Prepare the "FDA" tabulated summaries and highlight missing validation steps and gaps
- Work on the inventories of studies, study samples, drug, reference substances and critical reagents, work closely with the BA SME to provide recommendations on what needs to be transferred to Novartis.
Get a clear understanding about the nature, volume and current location of the raw data.
- Contribute to data transfer to Novartis repositories
- Contribute to Source Data Verification
- Liaise with Biomedical Research integration office representative
- Liaise with Procurement, IT, Legal and other LF related to M&A

Essential Requirements

- PhD with at least 3 years of industry experience, or a master's degree with at least 6 years of industry experience, in biochemistry, chemistry, pharmaceutical sciences, or a related field. Project management experience or skills are preferred; an MBA is an asset.
- Prior experience as a bioanalytical scientist in a GCP-regulated environment is preferred.
- Strong understanding of GxP guidelines, FDA regulations, and ICH guidance related to sample management, laboratory documentation, and lab operations.
- Familiarity with general PK sciences, including ADME, PK, and bioanalysis, is a plus.
- Strong communication and organizational skills, with the ability to work independently and collaboratively across multiple projects while meeting timelines.
- Willingness to take on additional responsibilities as needed, with the flexibility to adapt to changing priorities and strategies.

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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Дивизион
Biomedical Research
Business Unit
Development
Место
Индия
Сайт
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

Accessibility and accommodation

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