# Principal Scientist

Job ID
REQ-10002651
Apr 24, 2024
India

## Summary

Laboratory Excellence and Operation (LEO) and Biomarker Science and Operation (BSO) team in India are the key global resources for Line functions (LF) and Translational Medicine (TM) Clinical Trial Teams for biomarkers including biomarker outsourcing, scientific biomarker monitoring, vendor management, biomarker logistics, clinical site communication and sample coordination. LEO/BSO are working in close collaboration with clinical teams, LF technology experts, Biomarker Leads (BMLs) as well as external service providers (ESP) including central labs and clinical sites.

## About the Role

Your responsibilities include, but are not limited to:

- Independently provide operational support to Biomarker Study Experts and clinical studies focusing on biomarkers and including reviews of clinical study protocol, site operations manuals, informed consent forms, sample collection table, instruction manual, central lab protocol/manual, and eCRF and other biomarker sample operation logistics and coordination including study setup, sample tracking/reconciliation, assay and vendor set up, sample/data upload and study closure
- Partners with Biomarker Study Experts and BMD SME to set up, implement and monitor biomarker assays at external service providers (ESP) in one or more biomarker modalities (e.g. Immunoassay, LC-MS, Flow cytometry, genetics, tissues, digital endpoints etc.) in TM clinical studies
- Support data transfer and data flows in LIMS and DTS (e.g. study creation, data flow, data transfer, etc.) for managed biomarkers and studies. Update study and project information in relevant reports and IT systems
- Identify, escalate and resolve assay troubleshooting, sample management issues, ESP, quality or performance issues and engage LF experts/SME, clinical trial leaders and data management as needed.
- Lead best practices, process and continuous improvement initiatives and innovations in sample, vendor, data and assay monitoring function
- Collaborate with other TM, BMD and GCO functions

- Operational knowledge of *clinical trials: clinical study set up, clinical sample management, clinical sample analysis and managing external service provider (ESP) including central laboratories and/or specialized vendors*
- Laboratory background and knowledge immunoassay and/or bioanalysis
- Knowledge of the drug development process, clinical biomarkers and working with translation clinical research.
- Strong project and time management skills, problem solving, communication and leadership skills.
- Knowledge of regulatory requirements e.g. ICH/GCP, GLP, etc.

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We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

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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.

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