CLINICAL DEVELOPMENT SERVICES AGENCY

Ministry of Science & Technology, Govt. of India
3rd Floor, THSTI Building, 3rd Milestone, Gurgaon-Faridabad Expressway,
Faridabad – 121001
(An extra mural unit of THSTI, Department of Biotechnology)

Recruitment Notice No. CDSA/CORE /01/2018

Particulars	Details
Name of the post	Director Clinical Portfolio Management –One Position
Age Criteria	Up to 45 years
Emoluments	Up to Rs. 1,25,000/- per month consolidated
Duration	One year and likely to be continued
Location	CDSA, Faridabad
Essential Functions	• Provide overall project management including quality monitoring and clinical operations for clinical studies.
Responsibilities	**A. Leadership and Strategy** • Support the CDSA Director in the development of overall strategy • Contribute to developing the clinical trials/studies portfolio • Lead on the development of systems for overseeing and reporting on clinical trials / studies and medical device portfolio (including mechanisms for prioritizing clinical trials/ studies and for ensuring full cost recovery and income generation). • Analyze and formally report data and information on trends related to research sponsorship activities • Ensure consistent application of core CDSA policies and operating procedures across the CDSA sponsored trials/ studies portfolio • Act as the lead on behalf of CDSA for projects and committees, meeting with internal and external partners (academic and industry collaborations, vendors, sponsors and manufacturers and regulators) • Continually review and respond to changes required to shape the infrastructure, functionality and standards of clinical trials/ studies management, including the development and implementation of systems, operating procedures and policies. • Effect change and/or ensure dissemination of regulatory effective change management systems are implemented to facilitate the

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	changing clinical trials management environment in India and CDSA, in particular the operational implications of new clinical trials and CDSCO/ ICMR regulations and policies. • Provide expert support to projects with regards to compliance, policy, sponsorship and high-risk studies • Represent CDSA at regulatory inspections and meetings as required • Act as a key advisor on regulatory matters, collating project reports and writing position papers as well as advising on "higher risk" studies • With the Administrative Manager and Consultant Regulatory Affairs, oversee and draft Memorandum's of Understanding (MoU's) or other documents to outline the delegation of duties from the sponsor office to CDSA and other stakeholders of the projects • Actively contribute to or lead on initiatives related to the development of CDSA including resourcing, skills and training, systems and aligned risk assessments and strategies • Lead for escalations and trouble shooting where issues or concerns are raised by researchers with regards to trials and "higher" risk studies • Ensure the dissemination of information for CDSA staff on the CDSCO/ ICMR Clinical Trials Regulation and its implications, regulatory requirements, research governance and Good Clinical Practice (GCP). **B. Operations Management** • Oversee the preparation of client proposals • Participate in business development activities. • Participate in clinical review meetings (teleconferences live meeting and or face to face) and document preparation meetings as required • Solicit expert advice, develop collaborative relationship with key experts and investigators • Organize meeting with Client to understand the scope of the contract and any Master Services agreement in place for the client • Review the Project contract exhibit with appropriate functional heads to identify staff necessary for the project team • Develop project plan, including all elements listed in the project plan template as appropriate for project (Roles & Responsibilities, Communication Plan, Risk Analysis etc.) • Oversee preparation of initial budget for the project • Review and finalize responses to IEC and regulatory agencies • Responsible for reviewing study protocols, investigator's brochure, clinical study reports, IND sections • Revise SOPs or suggest process improvements for consideration. May draft new SOPs for review and act as reviewer for Clinical SOPs, as assigned and appropriate.

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	• Provide input as necessary to Feasibility Studies, Data Safety Monitoring Committee (DSMC) and other committees, clinical/ product development planning meetings • Provide or arrange for project-related training as needed for team members • Initiate the project following Best Practices in Project Management • Ensure the project is progressing according to quality standards, SOPs, regulations, and guidelines • Use project plan as a management tool to record and measure progress, updating as necessary • Track resources and actual time spent on each project task for all team members to evaluate project progress and profitability • Review metrics reports regularly and follow through on actions required • Determine the cause of project overruns, recommend and institute corrective action, with input from functional Primaries • Attend and represent project management/ contracted services at internal meetings and investigator meetings • Ensure information entered into management system is accurate, and updated on a regular basis • Ensure the project is completed within the budget, schedule, and according to contract specifications • Takes a leading role in preparing or contributing to the production of any type of clinical document, for either internal CDSA customers or external clients, for investigational drugs, biologicals, or medical devices • Provide consulting services to assist in the development of new drugs or devices under the direction of the Head of Organization **C. Quality Monitoring** • Work with investigators prior to start of project on incorporation of quality management processes into the scientific and operational design of the trial • Develop a monitoring plan with project investigators that is tailored to the specific human subject protection and data integrity risks of the trial • Agree predefined quality tolerance limits to identify systematic issues that can impact subject safety or reliability of trial results • Provide advice and support for site feasibility • Performs the duties of Project Director for all contracted clinical studies • Oversight for quality monitoring as per the approved plans. • Visit sites and participating institutes as and when required **D. Communications**

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	• Serve as primary contact for the project • Communicate to team members the scope of work, timeline and project goals, technical information, and input from client throughout the project • Inform team members of any new information or modification of project-related issues which may affect specific responsibilities of team members • Work with appropriate Managers on any anticipated need for addition or re-assignment of resources • Communicating with study investigators for evaluation of status of patient recruitment and progress to study timelines; supporting safety reporting and IEC submissions; maintaining and reporting metrics for clinical site performance • Provide Line Manager with input regarding team members' performance as needed for employees' periodic Performance Review • Prepare administrative reports and submit to clients as required by the contract exhibit, and other resource reports • Communicate fiscal, contractual, resource, deliverable and client-related issues to HoD as appropriate **E. Training** • Develop project specific and protocol specific training • Provide guidance and operational area training for project team members and staff as required • Act as mentor for CPM staff and oversight for their training and development. • Faculty for training programs conducted by CDSA
Educational Qualifications	**Essential Qualifications**: • Biomedical professional qualification recognized by relevant regulatory authority in India or • Post graduate degree in a science or health related discipline **Desirable**: • Postgraduate degree in Public Health • MD recognized by relevant regulatory authority in India • PhD in a science or health related discipline
Work experience	Essential: • 8 or more years of experience in clinical project management and/or drug development • Significant experience of clinical trial or public health project management in a recognized organization/institute (academic

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	clinical trials unit, CRO, pharmaceutical, biotechnology, or device company) leading/directing a clinical study / R&D team Desirable: • 12 or more years of years of clinical project management and/or drug development • Demonstrated application of project management concepts • Demonstrated ability to understand, explain and communicate project concepts (project life cycle, scope planning, scheduling, implementation of project plan), and manage project conduct (schedule, quality, and cost control, risk and change management) using standard tools and templates
Skills	• Leadership skills that include the ability to build effective medical and project teams, ability to motivate others, delegation, drive and timely/quality decision making • Personal qualities that include the ability to gain trust and confidence with a variety of clients, good learning ability, managerial courage, action oriented and resilience in a fast-paced and rapidly changing environment • Business/ Operational skills that include customer focus, commitment to quality management and problem solving • Influencing skills including negotiation and teamwork • Effective communication skills that include the provision of timely and accurate information to stakeholders, proficient in English, strong written and oral communication skills • Ability to develop and deliver presentations, prepare technical reports and contribute effectively in the manuscripts • Ability to develop novel concept and techniques in clinical monitoring • Ability to develop and implement monitoring plans and SOPs • Ability to make evaluative judgments, remain flexible as projects and priorities change • Demonstrated ability to prioritize workload in order to meet multiple deadlines • Ability to work independently with minimal guidance as well as collaboratively within a team setting •

GENERAL TERMS & CONDITIONS:

1. All educational professional and technical qualification should be from a recognized Board/ University and full-time.
2. The experience requirement specified should be experience acquired after obtaining the minimum educational qualifications required for the post.

3. Persons working in Govt. or Public Sector undertaking should produce "No Objection Certificate" at the time of Interview.
4. The qualification, experience and other requirements for the posts can be relaxed at the discretion of the competent authority, in case of candidates who are otherwise suitable. Candidates not found suitable for the posts notified, can be offered a lower post on the recommendation of the Selection Committee.
5. No TA/DA will be admissible to appear in the interview, including (SC/ST candidates).
6. **Only candidates who can join immediately needs to apply, as the position is to be filled on an urgent basis.**
7. This position will be purely on temporary/contractual basis for the specified period of time and based on project.
8. In case large number of applications are received for each post, screening will be done to limit the number of candidates to those possessing higher/relevant qualification.
9. **Only shortlisted candidates will be called for Written test/Interview. Request for change in Written test/ Interview schedule will not be entertained under any circumstances.**
10. The salary is a consolidated sum without any other benefits and it is based on experience, qualifications, skill set, etc. of the candidates.
11. Interested candidates may please send their current CV along with application form (attached on CDSA website) with a recent color photo and cover letter indicating their motivation for the position applied for in 150 words and three references by e-mail with subject line mentioning "Application for the position **"Director Clinical Portfolio Management"** to cdsa_admin@thsti.res.in.
12. Incomplete applications will stand summarily rejected without assigning any reasons thereof.
13. All results will be published on our website and all future communications will be only through email.
14. Canvassing in any form will be a disqualification.

Applications will be accepted up to February 23, 2018.

Note: In case a suitable candidate is not found, the call for application will remain open till suitable candidate is found. As soon as suitable candidate is found, this recruitment notice will be closed on our website.
