ट्रांसलेशनल स्वास्थ्य विज्ञान
एवं प्रौद्योगिकी संस्थान
thsti
TRANSLATIONAL HEALTH SCIENCE
AND TECHNOLOGY INSTITUTE

(An Autonomous Institute of the Department of Biotechnology, Govt. of India)
NCR Biotech Science Cluster, 3rd Milestone, Faridabad – Gurugram Expressway, P.O. Box No. 04, Faridabad - 121001

Recruitment notice no.: THS-C/RN/09/2023 **Dated: 25th May 2023**

1. Translational Health Science and Technology Institute (THSTI) is an autonomous Institute of the Department of Biotechnology, Ministry of Science and Technology, Govt. of India. The institute is an integral part of the interdisciplinary NCR Biotech Science Cluster located at Faridabad, and is designed as a dynamic, interactive organization with the mission to conduct innovative translational research and to develop research collaborations across disciplines and professions to translate concepts into products to improve human health.

2. THSTI has built several inter-institutional collaborations and connectivity with industry supported by well-trained teams of research and laboratory staff. This foundation has helped pursuit of thematic research programmes which can be broadly categorized as, (a) Infectious diseases and Immunology (b) Maternal and Child Health, (c) Non-communicable disease (d) Multidisciplinary clinical and translational research. These will be strengthened by four core facilities viz. Small Animal Facility, Data Management Centre, Biorepository and Bioassay Laboratory that will serve not only the research programmes of THSTI, but also the National Capital Region Biotech Science Cluster and other academic and industrial partners.

3. This recruitment is to fill up the vacancies under Clinical Development Services Agency (CDSA) of THSTI. CDSA is a niche centre of THSTI established to facilitate development of affordable healthcare products for public health diseases. It is the only public Centre in the country created with a mandate to support and nurture cost-effective, high quality, not-for-profit technology-based preclinical and clinical product development as well as support clinical research conducted by public agencies. It works towards development of an eco-system for training and learning and work with public sector institutions, and small and medium enterprises (SME) to translate innovative technologies into medical products for public good.

   The main objectives of CDSA are

   a) As an academic Clinical Research Unit, to undertake & provide end -to- end clinical study support for investigators and SMEs in study planning, set up, conduct: project management, monitoring, data management, safety reporting, analysis and report writing
   b) Build research capacity and capability through high quality training in the area of clinical development/trials and regulation
   c) Support and strengthen clinical research environment in the country
   d) Regulatory science and policy support: provide tools and approaches to support researchers, regulators, health policy makers& industry

4. Applications are invited from eligible candidates to fill up the following positions:

1	**Name of the post & No.**	**Quality Manager (01 Position)**
	Name of the Study	**DTRC**
	Age	45 years (Flexible for exceptional Candidates)
	Emoluments	Rs 80,000/-
	Duration	06 Months (likely to be extended)
	Location	CDSA, THSTI, NCR, Biotech Science Cluster, Faridabad
	Minimum Educational Qualification and Experience	**Essential qualification and work experience:** • Master's degree in life sciences or biomedical sciences or pharmacy or Public Health or Clinical Research. • At least 4 years of demonstrated experience in the area of Quality Control, Quality Assurance in biomedical research. • GCP/ GCLP trained **Desirable:** Experience of monitoring of laboratory-based activities/ research.
	Job profile	**Responsibilities:** • Oversees quality management processes and provides guidance and support to project teams to meet quality standards. • Actively lead or assist activities in the areas of Internal Quality improvements and CAPA (Corrective and Preventive Actions). • Ensure that the assigned study is conducted in accordance with study protocols, GCP guidelines, and applicable regulatory requirements. • Lead or assist with identifying non-conformances with requirements, provide suitable recommendations and facilitate ongoing quality improvements using a risk-based methodology. • Proactively identify the project risks and assist in providing training to study staff in good clinical and documentation practices. • Maintain GCP-compliant processes which control the quality of work at the study site • Conduct source document verification and case record forms for assessing the study trends • Develop quality monitoring plan and processes for clinical activities of data collection, laboratory-based activities of sample processing and storage, and running of the biorepository.

		• Overseeing and/or performing quality functions and executing quality programs (clinical operations, clinical laboratory, data management review) • Collaborate with clinical and project management teams to ensure compliance with quality standards, timelines, and appropriate follow-up in areas of deficiency • Coordinate expert monitoring visits/ audits as per project requirements. • Work with Clinical Portfolio Management and other internal departments on their requirements as and when required • Work with data management and other key departments (Laboratory) to track the process, and progress, and to ascertain the foreseen challenges proactively. **Skills :-** • Good understanding of needs for project and job responsibilities. • Extensive knowledge of GCP/GLP, observational studies and appropriate regulations and guidelines. • Ability to develop and implement clinical and laboratory monitoring plans, SOPs, database concepts, and formats • Ability to build effective project teams, ability to motivate others, delegation, drive and timely/ quality decision making • Operational skills including focus and commitment to quality management and problem solving • Influencing skills including negotiation and teamwork. • Effective communication skills to provide timely and accurate information to stakeholders • Ability to assess non-compliance situations and recognize potential or real wider strategic risk to project, escalates when needed. • Ability to identify systematic causes of complex quality problems and recommend long-term solutions • Fair and ethical. Creates a culture that fosters high standard of ethics. • Basic business computer skills (MS Word, Excel, e-mail).
2.	**Name of the post & No**	**Consultant Project Manager(01 Positions)**
	Name of the Study	**Digoxin Study**
	Age Limit	45 years
	Emoluments	Up to Rs. 70,000/-
	Duration	12 months
	Location	CDSA, THSTI, NCR, Biotech Science Cluster, Faridabad

	Minimum Educational Qualification and Experience	**Essential qualification and work experience:** • MBBS/ BDS/ Allied Medical degree **OR** Ph.D./Master's degree/ diploma in life sciences, pharmacy, public health, healthcare or other related discipline **AND** A minimum of 2 years' experience in Clinical Project Management and/or Clinical trial/Study monitoring Post Ph.D. **OR** • Masts degree in life science s with 5 years experience in clinical trials / study monitoring • Experience of clinical trial or public health project management in a recognized organization/institute (academic clinical trials unit, CRO, pharmaceutical, biotechnology, or device company). **Desirable qualifications and work experience:** • Postgraduate degree in Public Health • MD/DNB from a recognized Indian University/ recognized by MCI • Ph.D. in a health-related discipline • Demonstrable experience of line management, project management concepts and ability to understand, explain and communicate project concepts using standard tools and templates.
	Job profile	The position is responsible for Responsible for oversight, management and operational execution of assigned clinical studies and trials. Timely delivery of key tasks, while maintaining high quality standards are: - • The project manager will manage the performance of project team working on projects. • The management and cross-functional coordination of the project and work closely to develop and maintain the overall project plan and timelines, communicate project expectations to the respective resource/consultant and manage the overall projectbudget. • Support the team in the implementation of systems for resource planning, study / trial administration, implementation, oversight monitoring, quality assurance and documentation and record keeping • Establishment of procedures to ensure adherence to trial protocols and administrative requirements. • Develop project specific and protocol specific training or as requested. • Monitoring the trial progress to ensure compliance with and adherence to the project plan and to identify, evaluate and rectify problems • Understand the requirements of the various controlling bodies, agencies and frameworks, guiding the project in conforming to those requirements and coordinating any necessary audit processes. • Work with the Investigators to ensure that the trial is meeting its targets, is producing meaningful output and to predict and plan any changes that warrant requests to changes in protocol, funding, or timelines

		• Development, approval, and distribution of study-related documents including Case Report Forms (CRF's), study protocols, study manuals, and other study tools to investigational sites and review committees • Manage distribution, collection and tracking of regulatory documentation to ensure compliance with regulatory and project requirements and audit readiness • Work with data management and other departments to track progress, milestones and the challenges • Communicate to team members the scope of work, timeline and project goals, technical information or update. • Provide guidance and operational area training for project team members and staff as required • Faculty for training projects conducted by CDSA • Any other assignment with Clinical Portfolio Management team, based on project deliverables or exigencies.
	Skills: -	• Leadership skills that include the ability to build effective 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 • Comprehensive understanding of Indian Clinical Trials Regulations, ICH and CDSCO Good Clinical Practice • Business/ Operational skills that include 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 • Computer literacy in Word, Excel, PowerPoint, Access or other trial management systems • Ability to develop and deliver presentations, prepare technical reports and contribute effectively in the manuscripts • 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 • Knowledge of regulations and guidelines pertaining to the conductof clinical trials/ studies on human subjects

Interested candidates fulfilling the criteria as mentioned above may walk-in for written test/skill test/interview on 06th June 2023 at 11:00 am at THSTI, NCR Biotech Science Cluster, 3rdMilestone, Faridabad-Gurugram Expressway, Faridabad - 121001

GENERAL TERMS & CONDITIONS:

a) The position is short-term basis with a probation period of three months. The extension will be granted subject to the satisfactory performance of the incumbents and tenure of the project for which they are selected. Those appointed to these positions will not have any claim for regularization of their employment.

b) All educational, professional and technical qualification should be from a recognized Board/University.

c) The experience requirement specified above shall be the experience acquired after obtaining the minimum educational qualifications specified for the post.

d) The number of positions to be hired, age limit, qualification, experience and other requirements may be relaxed at the discretion of the competent authority, in case of candidates who are otherwise suitable. In case candidates are not found suitable for the postsnotified, they can be offered lower post / lower emoluments on the recommendation of the Selection Committee.

e) Age and other relaxations for direct recruits and departmental candidates: 1. By five years for candidates belonging to SC/ST communities. 2. By three years for candidates belonging to OBC communities. 3. For Persons with Benchmark Disabilities (PWBD) falling under the following categories: (i) UR - ten years, ii) OBC - 13 years (iii) SC/ST - 15 4. Age is relaxable for Central Government servants up to five years in accordance with the instructions or orders issued by the Central Government, from time-to-time. 5. There is no upper age limit for the Institute employees who are treated as departmental candidates.

f) All results will be published on our website and all future communications will be only through email

g) With regard to any provisions not covered in this notification, the bye laws of THSTI / Govt. of India rules / guidelines shall prevail.

h) Canvassing wrong in any form will be a disqualification.

i) The candidate may be transfer to site location as per the project requirement and management discretion.

M.V.Santo)
Head-Administration

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