ट्रांसलेशनल स्वास्थ्य विज्ञान
एवं प्रौद्योगिकी संस्थान
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/14/2022 **Dated: 23rd December 2022**

1. Translational Health Science and Technology Institute (THSTI) is an autonomous Institute ofthe 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 industrysupported by well-trained teams of research and laboratory staff. This foundation has helped pursuit of thematic research programs 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 for project positions at Clinical Development Services Agency (CDSA) center. CDSA is a niche center 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 developmentas 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

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

1.	**Name of the post & Project**	**Program Manager (DTRC)**
	Number of posts	One
	Emoluments	Rs. 1,00,000/-
	Duration	06 Months (likely to be extended)
	Age	45 Years
	Minimum Educational Qualification and Experience	**Essential qualification and work experience**: • MBBS/ BDS/ Allied Medical degree with 5 years of work experience including at least 2 years in Clinical Project Management and/or Clinical trial/Study monitoring OR • Ph.D. in clinical sciences/ life sciences/ pharmacy/ public health/ healthcare, or other related disciplines with at least 2 years of work experience in Clinical Project Management and/or Clinical trial/Study monitoring OR • Master's degree in life sciences/ pharmacy/ public health/ healthcare, or other related disciplines with at least 5 years of work experience in Clinical Project Management and/or Clinical trial/Study monitoring. • Experience of a clinical trial or public health project management in a recognized organization/institute (academic clinical trials unit, CRO, pharmaceutical, biotechnology, or device company). **Desirable experience**: • Experience of a clinical trial or public health project management in a recognized organization/institute (academic clinical trials unit, CRO, pharmaceutical, biotechnology, or device company). • 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 Program Manager will lead the Program Management Unit formed within CDSA for operational oversight and to ensure smooth administration of the Dengue TRC across all member institutions of the consortium. The activities of the Program Manager will aid management, monitoring and outreach for TRC activities. The position is responsible for oversight, management, and operational execution of the program. Timely delivery of key tasks, while maintaining high quality standards are: - 1. Regular tracking of project and financial milestones. 2. Compiling clinical data and research data received from all participating institutions. 3. Ensuring the upload of all data on publicly available servers. 4. Maintaining details of publications, talks and other communications for the TRC. 5. Risk Management for the TRC. 6. Archiving program related documents, reports and others. 7. Compiling annual progress reports for the TRC, with input from project partners and administration. 8. Organizing annual and other interim meetings of consortia partners and other

		stakeholders. 9. Supporting external stakeholder communications for the TRC via websites and social media. 10. Supporting outreach to DBT BIRAC on behalf of the TRC. 11. Compiling a final report of milestones achieved and information delivered. **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 National Ethical guidelines Indian Clinical Trials Regulations, ICH and CDSCO Good Clinical Practice • Effective communication skills that include the provision of timely and accurate information to stakeholders, proficiency 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 • 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
2.	**Name of the post & Project**	**Quality Manager** **(DTRC)**
	Number of posts	One
	Emoluments	Rs 80,000/- (Consolidated)
	Duration	06 Months (likely to be extended)
	Age	45 years (Flexible for exceptional Candidates)
	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	**<u>Responsibilities:</u>** • 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)

- Last date of receipt of the application: 13th January 2023.
- The application will be scrutinized/shortlisted and processed for further selection.

GENERAL TERMS & CONDITIONS: -

a) These are short-term positions and extensions will be granted subject to the satisfactory performance of the incumbents and the 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 qualifications 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) Closing date of online application will be the **CRUCIAL DATE** for determining eligibility with regard to age, essential qualification etc.

e) The 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 posts notified, they can be offered lower post / lower emoluments on the recommendation of the Selection Committee.

4. 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 departmentalcandidates. **6.** For Ex-servicemen up to the extent of service rendered in defense forces (Army, Navy & Air force) plus 3 years provided they have put in a minimum of 6 months attested service.

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

g) In case a large number of applications are received, screening will be done to limit the number of candidates to those possessing higher/relevant qualification and experience.

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

i) Canvassing in any form will be a disqualification.

HOW TO APPLY:

1. **Documents to be kept handy before filling up the online application:** all thedocuments except (i) should be in pdf format: -

   i) A soft copy of your passport size photo and signature. (jpeg/jpg/png format)
   ii) A comprehensive CV containing details of qualification, positions held, professional experience / distinctions etc.
   iii) Matriculation certificate (equivalent to 10th Standard) / Mark sheet)
   iv) Intermediate certificate (equivalent to 12th Standard) / Mark sheet)
   v) Graduation/Diploma degree certificate / Mark sheet

vi) Post-Graduation degree certificate & Mark sheet (if applicable)
vii) PhD/MD Degree (if applicable)
viii) Relevant experience certificates (if applicable)
ix) Caste / Disability certificate in the format prescribed by the Govt. of India, ifapplicable

2. Procedure for filling up online application:

i) The eligible and interested candidates may apply online at the Institute's website www.thsti.res.in/career. Applications through any other mode will not be accepted.
ii) The following will be the step wise procedure-
A) Step 1 : Details of applicant
B) Step 2 : Uploading of documents
C) Step 3 : Payment of application fee
- The payment can be made by using Debit Card / Credit Card / Internet Banking / UPI.
- Once payment is made, no correction / modification is possible
- Candidates are requested to keep a copy of the provisional receipt forfuture reference.
- Fee once paid shall not be refunded under any circumstances.
- Details of fees to be paid are as shown below:

S. No	Applying on direct recruitment	Application fee amount
1.	Unreserved, OBC & EWS candidates	Rs 590/-
2.	SC/ST/Women/PwBD	Rs 118/-

D) Step 4 : Submission of application form

iii) On successful submission of application, an auto-generated email containing the reference number will be sent to the email address provided. Please keep a note of the reference number for future correspondence.
iv) Candidates are required to keep a printout of the online application form by using the print button on the dashboard for future reference.
v) Candidates must ensure that he / she fulfils all the eligibility criteria as stipulated in the advertisement. If it is found that he / she does not fulfil the stipulated criteria during the recruitment process, the candidature of the candidate will be cancelled. If the same is noticed after the appointment, the candidate will be terminated following due process.
vi) Incomplete applications shall be summarily rejected and no correspondence in this regard shall be entertained.
vii) In case of difficulty in filling up the online form, please send e-mail to **hr.cdsa@thsti.res.in** along with the screenshot of the error displayed (if any).

"Government strives to have a work force which reflects gender balance and women candidates are encouraged to apply"

(M.V. Santo)
Head-Administration

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