ब्रिक–ट्रांसलेशनल स्वास्थ्य विज्ञान और प्रौद्योगिकी संस्थान
BRIC-Translational Health Science and Technology Institute
(An Institute of the Biotechnology Research and Innovation Council, Govt. of India)
NCR Biotech Science Cluster, 3rd Milestone, Faridabad – Gurugram Expressway,
P.O. Box No. 04, Faridabad – 121001

भर्ती नोटिस सं. : टीएचएस-सी/आरएन/16/2025 **दिनांक: 12 अगस्त 2025**

RECRUITMENT NOTICE NO.: THS-C/RN/16/2025 **Dated: 12th August 2025**

भर्ती अधिसूचना/ RECRUITMENT NOTIFICATION

1. BRIC-Translational Health Science and Technology Institute (THSTI), जैव प्रौद्योगिकी अनुसंधान और नवाचार परिषद, जैव प्रौद्योगिकी विभाग, विज्ञान और प्रौद्योगिकी मंत्रालय, भारत सरकार का एक संस्थान है। भारत का यह संस्थान फरीदाबाद में स्थित इंटरडिसिप्लिनरी एनसीआर बायोटेक साइंस क्लस्टर का एक अभिन्न अंग है, जिसमें अभिनव ट्रांसलेशनल अनुसंधान करने और मानव स्वास्थ्य में सुधार के लिए अवधारणाओं को उत्पादों में ट्रान्स्लेट करने के लिए विषयों और व्यवसायों में अनुसंधान सहयोग विकसित करने का मिशन है।
   BRIC-Translational Health Science and Technology Institute (THSTI) is an Institute of the Biotechnology Research and Innovation Council, Department of Biotechnology, Ministry of Science & Technology, Govt. of India. The institute is an integral part of the interdisciplinary NCR Biotech Science Cluster located at Faridabad, 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. ब्रिक-टीएचएसटीआई ने अनुसंधान और प्रयोगशाला कर्मचारियों की प्रशिक्षित टीमों द्वारा समर्थित उद्योग के साथ कई अंतर-संस्थागत सहयोग और कनेक्टिविटी का निर्माण किया है। टीएचएसटीआई ने विभिन्न केंद्रों की स्थापना की है जैसे (क) मातृ और बाल स्वास्थ्य केंद्र, (ख) वायरस अनुसंधान, चिकित्सा और टीका केंद्र (ग) तपेदिक अनुसंधान केंद्र (घ) माइक्रोबियल अनुसंधान केंद्र, (ड़) इम्युनोबायोलॉजी और इम्युनोथेरेपी केंद्र (च) ड्रग डिस्कवरी केंद्र (छ) नैदानिक विकास सेवा एजेंसी (ज) कम्प्यूटेशनल और गणितीय जीव विज्ञान केंद्र (झ) बायो-डिजाइन और निदान केंद्र। इन केंद्रों को कई मुख्य सुविधाओं द्वारा मजबूत किया गया है जैसे कि बायोएसे लेबोरेटरी, बायोरेपोजिटरी, बायोसेफ्टी लेवल-3 लैब, डेटा मैनेजमेंट सेंटर, इम्युनोलॉजी कोर लेबोरेटरी, मल्टी-ओमिक्स सुविधा, प्रयोगात्मक पशु सुविधा, वैक्सीन डिजाइन और विकास सुविधा, बायोडिजाइन में नवाचार का स्कूल आदि। जो THSTI के अनुसंधान कार्यक्रमों और राष्ट्रीय राजधानी क्षेत्र बायोटेक साइंस क्लस्टर और अन्य शैक्षणिक और औद्योगिक भागीदारों के लिए विशाल संसाधनों के रूप में काम करते हैं। ब्रिक-टीएचएसटीआई कई महत्वाकांक्षी और वैश्विक रूप से प्रतिस्पर्धी शैक्षणिक पाठ्यक्रमों के माध्यम से वैज्ञानिक लीडर की अगली पीढ़ी को प्रशिक्षित करता है जो बहु-विषयक शिक्षाविदों-उद्योग साझेदारी के माध्यम से अनुसंधान और नवाचार को बढ़ावा देता है ।
   BRIC-THSTI has built several inter-institutional collaborations and connectivity with industry supported by well-trained teams of research and laboratory staff. THSTI has established various centres namely (a) Centre for Maternal and Child Health, (b) Centre for Virus Research, Therapeutics and Vaccines (c) Centre for Tuberculosis Research (d) Centre for Microbial Research, (e) Centre for Immunobiology and Immunotherapy (f) Centre for Drug Discovery (g) Clinical Development Services Agency (h) Computational and Mathematical Biology Centre (i) Centre for Bio-design and Diagnostics. These centres are strengthened by many core facilities viz. Bioassay Laboratory, Biorepository, Biosafety Level-3 Lab, Data Management Centre, Immunology Core laboratory, Multi-Omics facility,

Experimental Animal Facility, Vaccine design and Development facility, School of Innovation in Bio design etc. that serve as huge resources for the research programmes of THSTI and also the National Capital Region Biotech Science Cluster and other academic and industrial partners. BRIC-THSTI trains the next generation of scientific leaders through many ambitious and globally competitive academic courses which promotes research and innovation through multi-disciplinary academia-industry partnerships.

3. यह भर्ती क्लिनिकल डेवलपमेंट सर्विसेज एजेंसी (CDSA) केंद्र में परियोजना पदों की रिक्तियों को भरने के लिए की जा रही है। CDSA, THSTI का एक विशेष केंद्र है, जिसे सार्वजनिक स्वास्थ्य रोगों के लिए किफायती स्वास्थ्य उत्पादों के विकास को सुविधाजनक बनाने के उद्देश्य से स्थापित किया गया है। यह देश का एकमात्र सार्वजनिक केंद्र है जिसे लाभ-न कमाने वाले तकनीक-आधारित प्रीक्लिनिकल और क्लिनिकल उत्पाद विकास के साथ-साथ सार्वजनिक एजेंसियों द्वारा किए जाने वाले क्लिनिकल अनुसंधान को समर्थन और पोषण देने के उद्देश्य से बनाया गया है। यह प्रशिक्षण और सीखने के एक इको-सिस्टम के विकास की दिशा में काम करता है और सार्वजनिक क्षेत्र की संस्थाओं तथा छोटे और मध्यम उद्यमों (SME) के साथ मिलकर नवाचारपूर्ण तकनीकों को जनहित में चिकित्सीय उत्पादों में बदलने का कार्य करता है। 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 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.

CDSA के मुख्य उद्देश्य निम्नलिखित हैं:

a. एक अकादमिक क्लिनिकल रिसर्च यूनिट के रूप में, अध्ययन योजना, सेटअप, संचालन, परियोजना प्रबंधन, निगरानी, डेटा प्रबंधन, सुरक्षा रिपोर्टिंग, विश्लेषण और रिपोर्ट लेखन में अन्वेषकों और SMEs को अंत-to-अंत क्लिनिकल अध्ययन समर्थन प्रदान करना।
b. क्लिनिकल विकास/प्रयोजन और नियमन के क्षेत्र में उच्च गुणवत्ता वाले प्रशिक्षण के माध्यम से शोध क्षमता और क्षमता का निर्माण करना।
c. देश में क्लिनिकल रिसर्च पर्यावरण का समर्थन और सुदृढ़ करना।
d. नियामक विज्ञान और नीति समर्थन: शोधकर्ताओं, नियामकों, स्वास्थ्य नीति निर्माताओं और उद्योग को समर्थन देने के लिए उपकरण और दृष्टिकोण प्रदान करना।

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. यह भर्ती निम्नलिखित परियोजनाओं के तहत ब्रिक-टीएचएसटीआई की रिक्तियों को भरने के लिए है:
   This recruitment is to fill up the vacancies of BRIC-THSTI under the following projects:

<u>पद के लिए आवश्यक शैक्षिक योग्यता और अनुभव /Educational Qualification and Experience required for the post:</u>

1.	**पद का नाम/Name of the post**	**सलाहकार - गुणवत्ता आश्वासन (क्लिनिकल रिसर्च)**/ Consultant- Quality Assurance (Clinical Research)
	पदों की संख्या/Number of the post	01
	वेतन/Emoluments	Rs. 1,50,000/-
	उम्र/Age	Upto 45 years
	न्यूनतम शैक्षिक योग्यता और अनुभव/Minimum Educational Qualification and Experience	**Essential qualification and work experience:** • Doctorate in life sciences or biomedical sciences or Pharmacy or Clinical Sciences OR Master's degree in life sciences or biomedical sciences or pharmacy or public health or clinical research OR MBBS/ BDS/ BHMS/ BAMS/ BPT/BVSc (Experience as above). • <u>WITH</u> at least 5 years of demonstrated experience in the area of Quality Control, Quality Assurance in clinical research <u>and</u> GCP/ GCLP trained and certified. **Desirable:** • Auditing and Inspection experience preferred • Proven track record of managing quality systems in clinical trials and laboratory settings. • Hands-on experience with regulatory inspections and audit readiness. • Strong understanding of Indian regulatory guidelines (DBT, ICMR, CDSCO) and International GxP standards. • Experience of monitoring of laboratory-based activities/research. • Proven experience in team leadership and people management. • Familiarity with global regulatory framework like EMA, FDA and WHO. • Knowledge of QA tools.
	कार्य प्रोफ़ाइल/Job profile	The Sr. Manager - Quality Assurance (Clinical Research) will oversee and drive quality management activities across CDSA-supported clinical research and laboratory operations. This role ensures that all the CDSA processes adhere to the applicable regulations and institutional standards, and contribute in the overall process improvement are implemented in a risk-based framework. **Clinical Research Quality Management** • Lead or support internal quality improvement initiatives and CAPA processes, identifying non-conformances and facilitating risk-based corrective actions. • Review the Quality Monitoring Plan, Data Management Plan, Statistical Analysis Plan, Safety Management Plan etc. • Conduct internal and external audits of clinical sites, laboratories, and other relevant areas to assess compliance with regulations, protocols, and institutional procedures.

		• Evaluate the quality systems, identify areas for improvement and ensure adherence to quality standards. • Ensure all clinical research activities are conducted in compliance with applicable regulatory requirements (e.g., GCP, FDA, EMA) and institutional SOPs. • Monitoring and assessing data quality and integrity throughout the clinical research process and provide real-time quality advice. • Developing and maintaining Standard Operating Procedures (SOPs) for all aspects of QA functions and reviewing SOPs of various functions under CDSA. • Collaborating with internal team, vendors, sponsors and other stakeholders to ensure quality and compliance. • Preparing for and participating in regulatory inspections (e.g., CDSCO, FDA, EMA) and sponsor audits. • Managing the overall quality assurance program, including staff, processes, and continuous improvement initiatives. • Coordinate and participate in monitoring visits, audits and inspections (internal and external), and manage follow-up on findings. • Review and provide guidance on study-related documents (protocols, CRFs, manuals, training materials) to ensure consistency with protocol and regulatory requirements. • Collaborate with internal team members to track milestones, timelines and emerging quality risks. • Provide QA support during both study start-up and close out ensuring proper documentation. **Laboratory Quality Oversight** • Provide oversight and guidance to CDSA staff and investigators on laboratory quality matters for ongoing studies. • Provide guidance on and contribute to laboratory training sessions for ongoing studies, including workflow evaluations of phlebotomy and sample transport, etc. • Review site-specific SOPs for sample collection, processing and handling; provide guidance and feedback to site teams. • Oversee quality assessments at central laboratories, ensuring harmonized standards. • Ensure GCLP compliance for overall study conduct. **Systems and Documentation** • Establish and maintain QA procedures and document control systems across **all CDSA functions** (clinical operations, laboratory activities, data management, regulatory affairs, etc.). • Ensure all standard operating procedures, work instructions, and quality records are updated promptly and distributed to relevant stakeholders. • Implement robust version control for all SOPs and critical documentation to track changes and maintain document integrity • Support development and implementation of electronic quality management systems and tools (e-QMS). • Generate periodic quality metric reports and present to senior leadership for continuous improvement.

		• Ensure system validation of different electronic systems used by CDSA like CTMS, CDMS etc **Cross-Functional Collaboration** • Establish and lead a cross-functional Quality Oversight Forum with clinical operations, laboratory, data-management and regulatory teams to review key metrics, oversee CAPA implementation and drive continuous improvement. • **Act as the primary QA liaison** between CDSA (Clinical Portfolio Management, Data Management), THSTI (Laboratory, Regulatory Affairs) and external partners to ensure alignment on quality standards and deliverables. • **Lead proactive risk management**, identifying potential quality issues early, coordinating root-cause analyses and deploying mitigation strategies. • **Embed QA expertise** in protocol development, study plan, CRF design and study-specific logs and forms and other governance forums to safeguard compliance at every stage. • Faculty for MSc (Clinical research) and PG Diploma in regulatory science course.
	कुशलताएँ/ज्ञान/ अभिरुचि **Skills/Knowledge/ Aptitude**	• Effective communication skills that include the provision of timely and accurate information to stakeholders, proficient in English, strong written and oral communication skills • Excellent training skills • Proficiency in quality management software and Microsoft Office suite • Strong analytical and problem-solving abilities • Meticulous attention to detail and documentation • Ability to work collaboratively in multidisciplinary teams • Demonstrated ability to prioritize workload in order to meet multiple deadlines • Ability to develop and deliver presentations, prepare technical reports and contribute effectively in the manuscripts

उपरोक्त पदों के लिए /For posts mentioned above-

- ऑनलाइन आवेदन प्राप्त करने की अंतिम तिथि: 01 सितमबर 2025/Last date for receipt of online application for posts: **01 September 2025.**
- आवेदनों की जांच/छंटनी की जाएगी तथा आगे की चयन प्रक्रिया हेतु उन्हें अग्रेषित किया जाएगा। The applications will be scrutinised/shortlisted and processed for further selection.

सामान्य नियम व शर्तें/ GENERAL TERMS & CONDITIONS:

a) These are the short-term positions and extension will be granted subject to 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. The candidates are required to satisfy themselves, before applying /appearing for the selection process, that they possess the minimum eligibility criteria as laid down in the recruitment advertisement. No query will be entertained with regard to the eligibility criteria.

d) Closing date of online application will be the **CRUCIAL DATE** for determining eligibility with regard to age, essential qualification, experience 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.
f) 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. Institute employees will get the age relaxation to the extent of the service rendered by them as on closing date of advertisement. 6. For Ex-servicemen upto the extent of service rendered in defence forces (Army, Navy & Air force) plus 3 years provided they have put in a minimum of 6 months attested service.
g) All results/notifications will only be published on our website. Therefore, the candidates should essentially visit THSTI website, regularly.
h) All communications will only be made through email.
i) 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.
j) The no. of vacancy indicated above may change subjected to the actual requirement at the time of Written test/skill test/interview.
k) With regard to any provisions not covered in this notification, the bye laws of THSTI / Govt. of India rules/ guidelines shall prevail.
l) Canvassing wrong information in any form will be a disqualification.

उपरोक्त तालिका में उल्लिखित पदों के लिए आवेदन कैसे करें/ HOW TO APPLY FOR POSTS MENTIONED IN ABOVE TABLE:

1. **Documents to be kept handy before filling up the online application:** (all the documents 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 degree/certificate (if applicable)
   viii) Relevant experience certificates (if applicable)
   ix) Caste / Disability certificate in the format prescribed by the Govt. of India, if applicable

2. **Procedure for filling up online application:**

   i) The eligible and interested candidates may apply online at the Institute's website. 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 for future reference.
   - Fee once paid shall not be refunded under any circumstances.
   - Details of fees to be paid are as shown below:

S. No	सीधी भर्ती पर आवेदन करना/ Applying on direct recruitment	आवेदन शुल्क राशि/ 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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