



ब्रिक-ट्रान्सलेशनल 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, 3<sup>rd</sup> Milestone, Faridabad – Gurugram Expressway,  
P.O. Box No. 04, Faridabad – 121001

**RECRUITMENT NOTICE NO.: THS-C/RN/02/2025**

**Dated: 06<sup>th</sup> February 2025**

- 1) 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) 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 Viral 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 Biodesign 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.
- 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 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.

**Educational Qualification and Experience required for the post:**

1.	<b>Name of the post</b>	<b>Senior Program Officer (Regulatory Affairs)</b>
	<b>Number of the post</b>	01
	<b>Name of the Project</b>	Indian Regulatory Science Course Development Support
	<b>Emoluments</b>	Rs. 1,75,000/-
	<b>Age</b>	Not exceeding 50 years
	<b>Minimum Educational Qualification and Experience</b>	<ul style="list-style-type: none"><li>• Post graduate degree in Pharmacology or Regulatory science or a related field</li></ul> <b>Essential Experience:</b> <ul style="list-style-type: none"><li>• Minimum 8 years of professional experience in regulatory science, product development, clinical trials, or related fields</li><li>• Deep understanding of Indian regulatory frameworks (e.g., NDCT 2019) and international standards.</li><li>• Proven track record of collaborating with government bodies, academic institutions, and industry stakeholders</li></ul>
	<b>Job profile</b>	<p>CDSA-THSTI seeks a dynamic professional to spearhead the development of a <b>Regulatory Science Curriculum</b> for a Diploma program aimed at addressing India's evolving needs in regulatory science and clinical research. The position involves liaising with the <b>Central Drugs Standard Control Organization (CDSCO)</b>, organizing workshops, and driving capacity-building initiatives to strengthen India's regulatory science ecosystem.</p> <p><b>Key Responsibilities:</b></p> <ol style="list-style-type: none"><li><b>1. Regulatory Science program</b><ul style="list-style-type: none"><li>▪ <b>Curriculum Development:</b> Design a comprehensive regulatory science diploma curriculum that incorporates both Indian regulations and global frameworks (e.g., US FDA, EMA, ICH guidelines).</li><li>▪ <b>Stakeholder Collaboration:</b> Act as the liaison between regulatory experts, academic institutions, and industry leaders to align the curriculum with current regulatory challenges and best practices.</li></ul><p>Coordinate and work closely with all the niche centers and members of the Regulatory Landscape in India (DCGI, DBT, ICMR etc.)</p></li><li><b>2. Workshop Leadership:</b> Organize 2-3 high-impact workshops focused on critical topics such as regulatory strategies for product development, cGMP, etc.</li><li><b>3. Regulatory Support for Clinical Trials</b><ul style="list-style-type: none"><li>• Review and advise on clinical trial applications (CTAs) for submission to the Central Drugs Standard Control Organization (CDSCO) and any queries from regulatory bodies.</li><li>• Resolve queries in regulatory science received to CDSA-THSTI from academic investigators and SMEs'.</li></ul></li></ol>

		<ul style="list-style-type: none"> <li>• Develop a comprehensive repository of regulatory updates in CDSA DMS system for use by other stakeholders</li> </ul> <p><b>4. Teaching and Capacity Building.</b></p> <ul style="list-style-type: none"> <li>• Serve as a faculty member for MSc Clinical Science course and postgraduate diploma program in regulatory science.</li> <li>• Design and deliver training sessions and workshops for internal teams and external stakeholders.</li> <li>• Participate in relevant workshops, conferences, and training programs to enhance expertise</li> </ul>
	<b>Skills</b>	<ul style="list-style-type: none"> <li>• Comprehensive knowledge of clinical trial and regulatory processes.</li> <li>• Proficiency in tools and software for regulatory submissions and documentation.</li> <li>• Effective team collaboration and stakeholder management skills.</li> <li>• Strong organizational abilities to manage competing priorities and deadlines.</li> <li>• Ability to analyze and synthesize complex information from diverse sources.</li> <li>• Exceptional written and verbal communication skills, with a strong focus on detail and accuracy</li> </ul> <p>Demonstrated capacity to mentor and educate in the field of regulatory science</p>
<p><b>For posts mentioned above-</b></p> <ul style="list-style-type: none"> <li>➤ Last date for receipt of online application for posts: <b>26 February 2025.</b></li> <li>➤ The applications will be scrutinised/shortlisted and processed for further selection.</li> </ul>		

### **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 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.

**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	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](mailto: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**