CLINICAL DEVELOPMENT SERVICES AGENCY

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

Recruitment Notice No. CDS/RN /34/2017

Name of the post / Emoluments	Medical Monitor (Upto Rs. 75,000 per month, consolidated) for 6 Months
Location	NCR, Biotech Science Cluster, Faridabad
Job profile	The roles & responsibilities of Medical Monitor are as follows but not limited: • The MM, in consultation with Medical Director and safety oversight committees, will provide safety review during the execution of the clinical trial. This oversight includes reviewing safety information and providing applicable recommendations. • Interpretation of single and or grouped adverse events, serious adverse events, drug effect and attribution of causality, and disease condition • Educating, training, and mentoring research team in safety monitoring and reporting • Preparation of expedited and periodic reports. • Draft clinical narrative reports describing the event • Participates in development of CRF, statistical analysis plan (SAP), DMC charter and other documents as required by the study. • Participate in study management team meetings, Data Monitoring Committee (DMC) and steering committees as required. • Answer safety questions and review the literature as needed; provide input to safety issues and answer questions posed by IEC, DMC and regulatory authority etc. • Actively interact with investigative sites, respond to protocol/medical questions • Perform review of data generated by data listings or statistical analyses. • Review medical coding of safety data • Request additional tables or analyses where appropriate. • Review individual data with SAEs and potentially clinically important laboratory test or vital sign abnormalities. • Participate in all reviews and procedures required for database lock.

	• Provide Study Team with medical expertise during key activities • Contribute to, draft, and edit Clinical Study Reports (CSR) • Contributes to IB updates for the project • Assists in development of scientific meeting abstracts and presentations as well as manuscripts
Qualifications and Experience	• MD/MS or • Postgraduate diploma from recognized university with 1-2 years of R&D experience • MBBS or equivalent degree from recognized University with 2-3 years R&D experience or • BDS from recognized University with 5 years R&D experience Age limit: • Not exceeding 40 years.
Skills	• Ability to gain trust and confidence with stakeholders. • Operational skills including focus and commitment to quality management and problem solving • Influencing skills including negotiation and teamwork • Effective communication skills, the provision of timely and accurate information to stakeholders • Understanding of GCP, regulations and guidelines • Knowledge of adverse medical event investigation, analysis, and reporting procedures and standards • Fair and ethical. Creates a culture that fosters high standard of ethics. • Basic business computer skills (MS Word, Excel, e-mail)

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 post can be relaxed at the discretion of the controlling authority, in case candidates are otherwise well qualified.
   Interested candidates may please send their current CV with a recent photo and cover letter indicating their motivation for the position applied for (150 words) and three references along with the attached datasheet and excel sheet posted in the website. E-mail should be submitted with subject line **Application for the post of "Medical Monitor (bOPV Study)**" to **cdsa_admin@thsti.res.in. Applications will be accepted up to 25th December 2017.**
5. Only shortlisted candidates will be contacted for further discussion

6. Incomplete applications will stand summarily rejected without assigning any reasons.
7. The salary is a consolidated sum as per sanctioned order without any other benefits. Salary mentioned against the position is an actual and will be based on experience, qualifications, skill set, etc. of the candidates.
8. **This position is strictly project-based and hired only for 6 months.**
9. All results will be published on our website and all future communications will be only through email
10. Candidates (Including SC/ST and other backward classes) are not entitled for the travel reimbursement or any other reimbursement.
11. This position will be placed in CDSA Faridabad office at NCR Biotech Science Cluster at Faridabad Gurgaon Expressway, Faridabad.
12. Canvassing in any form will be a disqualification.

Last date of receipt of applications will be up to 25th December 2017. Those who have applied earlier need not apply again.

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.