CLINICAL DEVELOPMENT SERVICES AGENCY

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

Recruitment Notice No. CDSA/CORE /01/2018

Particulars	**Details**
Name of the post	Director Medical Affairs and Medical Writing –One Position
Age Criteria	Up to 45 years
Emoluments	Up to Rs. 1,25,000/- per month consolidated
Duration	One year and likely to be continued
Location	CDSA, Faridabad
Essential Functions	• Provide medical leadership on clinical trials and clinical study projects • Serve as medical liaison to clients • Assist in marketing and sales of products and services • Provide medical guidance to new service/product development.
Responsibilities	. Medical Affairs • Provide medical leadership to clinical trial and clinical study projects • Participate in clinical review meetings (teleconferences live meeting and or face to face) and document preparation meetings • Edit responses to IEC and regulatory agencies on adverse events and Serious adverse events • Review and edit regulatory and safety documents for clinical consistency with data and standard of practice • Review and edit CSR for clinical consistency with data and standard of practice • Review all documents assigned for scientifically/ medically relevant issues including drug safety

Particulars	Details
	• Review and sign off technical documents written with respect to medically relevant matters with particular attention to those relating to drug safety • Provide support for the preparation of clinical protocols, integrated clinical and statistical summary reports, journal articles, and other documents • Attend and present material (such as therapeutic area training) as requested, at internal and external meetings (e.g. investigator meetings) • Provide input as necessary to Feasibility Studies, Data Safety Monitoring Committees (DSMC) and other committees, clinical/ product development planning meetings • Provide advice and support for site feasibility • Attend and present materials at internal meetings and investigator meetings • Solicit expert advice, develop collaborative relationship with key experts and investigators • Assist in the preparation of client proposals • Act as medical liaison with clients • Assist in the development of DSMB charters • Assist in the development of protocol specific procedure medical manuals • Engage medical experts as consultants/ advisers in various therapeutic areas as per the need of research project • Participate in business development activities • Provide consulting services to assist in the development of new drugs or devices under the direction of the Head of Organisation • Provide medical leadership in developing quality assurance programs B. Medical Monitoring • Performs the duties of Medical Monitor for all the clinical studies in which CDSA is involved • Interpretation of single and or grouped adverse events, serious adverse events, drug effect and attribution of causality, and disease condition • Edit clinical narrative reports describing the event; advise on individual subject cases as identified by the study team and identifying queries for the local monitors to complete.

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	• Ensure compliance with clinical safety and good pharmacovigilance practices and requirements • Provide support in preparation of Periodic Safety Update Reports (PSURs) • Review and sign off Data Management listings of safety data (including adverse events, laboratory data, vital signs data, medical history, physical examination, concomitant medication), • Assist the PI and DSM in establishing the presence or absence of clinically meaningful trends and, if noted, assisting in follow up as appropriate with the project team, sponsor, and Regulatory Authorities • Provide coding review of AEs, Past medical history, Concomitant medications or other medical data listings to verify and medically vet clinical data C. Medical Writing • Takes a leading role in preparing or contributing to the production of any type of clinical document, for either internal CDSA customers or external clients, for investigational drugs, biologicals, or medical devices • Acts as mentor for less experienced Medical Writers and assists in their training and development. • Participates in project teams and may provide service as an independent expert. May serve as writing lead and project manager for medical writing projects • Responsible for developing and managing writing style guides, templates such as, protocols, investigator's brochure, clinical study reports, IND sections • Proposes applications • Provides and manages internal and external writing activities • Responsible for developing or acquiring a document management system, establishing style guides, and generation of templates and processes • Revise SOPs or suggest process improvements for consideration. May draft new MW SOPs for review and act as reviewer for MW SOPs, as assigned and appropriate.

Particulars	Details
	D. Training • Provide medical guidance and therapeutic area training for project team members and staff as required • Develop training modules for therapeutic areas • Develop project specific and protocol specific training • Oversee development of training modules and project specific and protocol specific training in other therapeutic areas • Be a faculty for training programs conducted by CDSA
Educational Qualifications	**Essential:** MD in pre-, para- or clinical subjects, preferably clinical or pharmacology background
Work experience	Essential Experience: • Post MD/PhD experience of medical monitoring and medical writing (includes time spent as functional Primary or functional/ technical Lead), experience with a CRO, pharmaceutical, biotechnology, or device company • experience of drug development and clinical trial administration background • Experience in safety reporting and management • Experience in pharmacovigilance, medical coding and systems for adverse event review and reporting is preferred • Clinical practice experience of at least two years • Experience of medical monitoring and medical writing experience (includes time spent as functional Primary or functional/ technical Lead) experience with a CRO, pharmaceutical, biotechnology, or device company Desirable: • Demonstrated knowledge of drug development activities
Skills	• Leadership skills that include the ability to build effective medical and 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

Particulars	Details
	• Business/Operational skills that include customer focus, 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 • Ability to develop and deliver presentations • Ability to develop novel concept and techniques in medical monitoring • Ability to develop and implement monitoring plans and SOPs • Detail-oriented • Ability to 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 • Familiarity with basic computer applications: MS Word, E-mail, Excel, Internet • Knowledge of all regulations and guidelines pertaining to the conduct of clinical trials on human subjects • Ability to make evaluative judgments • Ability to develop and revise standard operating procedures • Knowledge of adverse medical event investigation, analysis, and reporting procedures and standards • Ability to develop technical reports and manuscripts • Ability to travel

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 posts can be relaxed at the discretion of the competent authority, in case of candidates who are otherwise

suitable. Candidates not found suitable for the posts notified, can be offered a lower post on the recommendation of the Selection Committee.

5. No TA/DA will be admissible to appear in the interview, including (SC/ST candidates).
6. **Only candidates who can join immediately needs to apply, as the position is to be filled on an urgent basis.**
7. This position will be purely on temporary/contractual basis for the specified period of time and based on project.
8. In case large number of applications are received for each post, screening will be done to limit the number of candidates to those possessing higher/relevant qualification.
9. **Only shortlisted candidates will be called for Written test/Interview. Request for change in Written test/ Interview schedule will not be entertained under any circumstances.**
10. The salary is a consolidated sum without any other benefits and it is based on experience, qualifications, skill set, etc. of the candidates.
11. Interested candidates may please send their current CV along with application form (attached on CDSA website) with a recent color photo and cover letter indicating their motivation for the position applied for in 150 words and three references by e-mail with subject line mentioning "Application for the position **"Director Medical Affairs and Medical Writing "** to cdsa_admin@thsti.res.in.
12. Incomplete applications will stand summarily rejected without assigning any reasons thereof.
13. All results will be published on our website and all future communications will be only through email.
14. Canvassing in any form will be a disqualification.

Applications will be accepted up to February 23, 2018.

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.
