

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 /03/ADBS/2018

Name of the post / Emoluments	Quality Manager (ADBS Study) (Up to Rs. 80,000 per month, consolidated) for 36 Months subject to annual performance review.
Location	NIMHANS, Bengaluru
Job profile	<p>The roles & responsibilities of Quality Manager are as follows but not limited:</p> <p>The Quality Manager, in consultation with the QM oversight lead at CDSA and the Principal Investigators (PIs), conduct monitoring at the study site (NIMHANS) to ensure compliance with GCP / applicable study requirements and provide recommendations for highest standards of study conduct, recording and reporting. This will include:</p> <ul style="list-style-type: none">• Manages study operational plan – project timeliness and quality of deliverables.• Ensure that assigned study is conducted in accordance with sponsor protocols, GCP guidelines, applicable regulatory requirements.• Develop and maintain GCP/ICH 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• Actively lead or assist activities in the areas of Internal Quality improvements and CAPA (Corrective and Preventive Actions).• Prepare study monitoring plan and required SoPs for the quality monitoring• Lead or assist with identifying non-conformances with requirements, provide suitable recommendations and facilitate ongoing quality improvements using risk-based methodology.• Proactively identify the project risks and assist in providing training to study staff in good clinical and documentation practices.• Manage and maintain databases for the quality systems.• Maintain the study master file and review the site master file for the appropriate updation throughout the study span• Prepare and assist in preparing annual reports and quality trending reports.• Participate in study management team meetings and represent the QM team.• Work closely with other teams at CDSA and the study site
Qualifications and Experience	<ul style="list-style-type: none">• MBBS/BDS/MPH /Allied medical degree from recognized university with at least 3 years of clinical research experience OR• Post – graduate degree in life-sciences / Clinical Research, nursing, or related fields with minimum 3 years of clinical research experience, with 2-3 years as Team lead/ Project Manager for clinical trials/ research project.

	<ul style="list-style-type: none"> • Candidate with monitoring and/ or M&E experience of the public health study will be preferred.
Age limit	<ul style="list-style-type: none"> • Not exceeding 40 years
Skills	<ul style="list-style-type: none"> • 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.
5. Interested candidates may please send their current CV (Resume) along with the application form (attached on CDSA website) 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 “Quality Manager (ADBS Study)”** to cdsa_admin@thsti.res.in. **Applications will be accepted up to 22nd April 2018.**
6. **Email application without clear subject line and incomplete applications will be summarily rejected.**
7. Only shortlisted candidates will be contacted for further discussion
8. 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.
9. **This position is strictly project-based.**
10. All results will be published on our website and all future communications will be only through email
11. Candidates (Including SC/ST and other backward classes) are not entitled for the travel reimbursement or any other reimbursement.
12. This position will be based out of NIMHANS Bengaluru with frequent travel to CDSA office, THSTI, Faridabad
13. Canvassing in any form will be a disqualification.

Last date of receipt of applications will be up to 22nd April 2018. Those who have applied earlier need not apply again.