

**CLINICAL DEVELOPMENT SERVICES AGENCY**  
**An extramural unit of Translational Health Science & Technology Institute**  
**(An autonomous institute under the Department of Biotechnology (DBT),**  
**Ministry of Science & Technology, Govt. of India)**  
**NCR Biotech Science Cluster at Faridabad Gurgaon Road, Faridabad.**

Clinical Development Services Agency (CDSA) mission is to create, develop, and nurture world-class clinical product development capacity in India. CDSA invites applications from high performing professionals with a desire to serve public health needs of the country for the below mentioned PTB Project position:

<b>Recruitment No:</b>	<b>CDS/RN/02/2014</b>
<b>Name of the post / Emoluments and Age</b>	<b>QUALITY MANAGER (in Pregnancy-infant cohort)</b> (Up to Rs. 50,000/- per month consolidated) up to <b>40 years</b> <b>Project-based position on contractual basis.</b>
<b>Qualifications and Experience</b>	Basic degree in life, medical or biomedical sciences or pharmacy with 4-5 years of demonstrated experience in the area of Quality Control, Quality Assurance and Clinical operations. GCP/ GLP trained personnel will be preferred.
<b>Skills/Desirables</b>	<ul style="list-style-type: none"> <li>• Extensive knowledge of GCP/GLP/ISO and appropriate clinical research regulations and guidelines.</li> <li>• Good team working skills, able to anticipate potential problems.</li> <li>• Able to facilitate open and honest communication</li> <li>• Good understanding of needs for project and department roles.</li> <li>• Effective communication skills</li> <li>• Good computer skills (MS Word, Excel, e-mail, etc)</li> </ul>
<b>Job profile</b>	<ul style="list-style-type: none"> <li>• Oversees quality management processes and provides guidance and support to project teams to meet quality standards.</li> <li>• Providing training to research team on interpretation of GCP/ethical requirements for quality management.</li> <li>• Overseeing and/or performing quality functions and executing quality programs (project management, clinical operations, clinical and genetics laboratory, data management, etc.)</li> <li>• Developing quality management plan and ensuring compliance</li> <li>• Ensure compliance with agreed upon documentation practices</li> <li>• Identifying areas of deficiency and trends in quality and escalating to appropriate personnel</li> <li>• Collaborate with clinical and project management team to ensure compliance with quality standards, timelines and appropriate follow-up in areas of deficiency</li> <li>• Coordinate expert monitoring visit/ audits as per project requirement.</li> <li>• Educating, training, and mentoring research team in quality improvement methods</li> <li>• Supervise quality management team to ensure efficient clinical monitoring (site preparedness, study initiation interim monitoring), reporting and follow-up for corrective and preventive action.</li> <li>• Travel up to 50%, as assigned</li> <li>• Work with CDSA team on their requirements as and when required</li> </ul>

## **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 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**" to cdsa\_admin@thsti.res.in Applications will be accepted up to 13 January, 2015.
6. Only shortlisted candidates will be contacted for further discussion
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
9. All results will be published on our website and all future communications will be only through email
10. In case we do not get a suitable candidate than we will only publish the advertisement on the CDSA & THSTI website as a rolling on advertisement
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 placed in CDSA Faridabad office at NCR Biotech Science Cluster at Faridabad Gurgaon Road, Faridabad.
13. Canvassing in any form will be a disqualification.

**Candidates who have applied for this position in response to the earlier advertisement need not apply again. Applications will be accepted up to 13 January 2015.**