We rely on a great team!

cunesoft
compliance delivered

career

We are looking for:

Title: Director Regulatory Projects m/f
Reports to: CTO
Location: Munich (Germany) or Remote (European Wide)
Location: Full time

We are hiring a Director Regulatory Projects who manages, facilitates and tracks medium to large scale software development and implementation projects in highly regulated pharmaceutical environments. The position is based in Europe, can be remote or from our European Headquarter in Munich and reports to the CTO (Chief Technology Officer).

Job Responsibilities:

- Partner with technical leads, to provide PMO support and oversight for mid – large size, complex projects with multiple project components
- Facilitate effective decision making through presentation of key information and recommendations
- Execute well-defined project analysis, including cost benefit and structure analysis
- Provide financial oversight
- Ensure high levels of client satisfaction for assigned projects. Regularly solicit feedback regarding performance
- Analyze and resolve problems associated with technical issues, project resources, and project integration issues
- Analyze and resolve problems associated with computer system validation planning, validation execution and validation documentation
- Prepare reports for Steering and Stakeholder level decision making and decision support
- Develop risk mitigation plans and manage customer expectations and resolve cross-functional issues
- Facilitation between technical and business teams, technical experience is required
- Computer system validation experience in the life sciences domain is required
- The environment we work in is a .NET and Machine Learning/AI based, having experience in this space is desirable
- Defining technical engagement strategies with stakeholders
- Running and managing projects with clients, examples include running evaluation and pilot programs, benchmarking, and measuring success using analytics, overseeing ongoing distribution with clients

Minimum Previous Experience

- Experience and knowledge of regulations on eCTD, IDMP and xEVMPD
- Experience and knowledge on GxP and GAMP conform system validation
- Overall 10+ years of experience and 3 – 4 years of relevant experience
- Experience should include overseeing multiple system implementation projects
- Experience in managing both Waterfall and Agile initiatives
- Experience in life science, regulatory compliance domain is a must

Minimal Additional Knowledge:

- Microsoft .NET / C# as well as AI technology experience is a plus
- Microsoft Visual Studio as well as Microsoft Team Foundation Server experience
- Six Sigma, PMP, PRINCE2 and/or SCRUM certification preferred
- Proficiency with Microsoft Office Suite, MS Project, Visio and Visual Studio Team Foundation Services
- Resource management, including resource estimation and allocation

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Other Skills:

- Analytical
- Problem Solving
- Excellent Verbal & Written Communication
- Team Leader, must be flexible, independent and self-motivated
- Punctual, Regular and consistent attendance

Education:

- Bachelor of Engineering / Master of Computer Application / Master of Science in Computer Science

Should you be interested in joining Cunesoft, please contact
Talent Management team:
talent@cunesoft.com