

We rely on a great team!



We are looking for:

Title: Regulatory Consultant (m/f)

Reports to: Head of Client Success

Location: India, Bangalore Office

Starting as soon as possible

Job Responsibilities:

Position Summary:

As a Regulatory Consultant, a large portion of your time you will be working with customers, answering their questions and helping them to analyze regulatory and functional challenges they may be experiencing. As many customers are working with tight submission timelines, a strong customer focus is critical to success. You must stay in communication with the customer and manage the situation through to resolution.. A strong focus will be on Regulatory document management and eCTD submission publishing activities, helping customers to achieve technical eCTD compliance. You will also support pre-sales engagements as well as post-sales support activities.

As a Regulatory Consultant, you need to have strong verbal and written communication skills and strong interpersonal skills. You are required to communicate with internal technical staff, as well as communicate externally with the customer. You need to have a good knowledge of applicable regulations and regulatory guidances. Important are your problem-solving skills. Furthermore, you will be required to work within a global team, sharing information and supporting other team members in this role. You must have good analytical skills in order to troubleshoot the situation and identify different solutions.



Major Responsibilities:

- Work with customers to answer questions and/or resolve process or technology-related challenges within their Cunesoft environment.
- Analyze and respond to customer support tickets with solutions within established timeframes.
- Collaborate with the technical team to determine technical solutions.
- Actively communicate technical and regulatory solutions to customer.
- Document issues, status, and resolutions within established systems.
- Create and maintain online support documentation.
- Understand customer requirements and document these as business requirements for new software functionality.
- Train users via web meetings as required.
- Participate and assist with testing, configuration/release management, deployment as well as validation.
- Demonstrate software in support of requirements gathering as well as occasional sales support.

Minimum Requirements:

Experience/Skills:

- 2+ years of direct experience as regulatory consultant / support consultant with regulatory computer systems for eCTD and/or xEVMPD and/or RIM and/or DMS systems
- Understand regulatory requirements for eCTD publishing
- Understand and previous experience with GxP and/or 21 CFR Part 11
- Must be flexible, independent, and self-motivated



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- Ability to lead customer-facing web meetings with end users, but also senior level participants
- Punctual, regular, and consistent attendance
- Excellent verbal and written communication skills
- A good and solid understanding of regulatory processes and procedures
- A good understanding of regulatory software

Education:

- Bachelor Degree
- University Degree

Should you be interested in joining Cunesoft, please send your application to our

Talent Management team:
talent@cunesoft.com