MethodSense, Inc. Is Hiring!

MethodSense, Inc. is a medical device and combination product regulatory affairs and quality assurance advisory firm and the developers of LuminLogic, a proprietary medical product lifecycle management solution. MethodSense is deeply committed to driving the business value of our clients through developing and implementing regulatory strategies, quality systems, operational and technology processes.

MethodSense is seeking to grow its incredible team of professional consultants with people who want to be a part of and help lead effective working teams, who want an environment that can accelerate their professional careers, and who want to make a direct impact that benefits patients and health care providers in the field of medical device consulting.

MethodSense Job Opening: Compliance Engineer Lead

Job Summary:

The Compliance Engineer Lead collaborates with Regulatory and Quality stakeholders in support of customer projects, serves as a project lead/co-lead interacting with customers, mentors other engineers and for select projects, takes responsibility for the client relationship

Essential Functions:

In a collaborative team environment, the Compliance Engineer Lead:

For Quality Projects-

- Prepares QA gap assessments
- Customizes Client QMS based on client strategy and business needs
- Mentors and performs Peer Reviews of Client Quality management systems (QMS) and QMS components
- Performs as a Lead Auditor of supplier and client audits and prepares audit reports for review and/or mentors and performs peer review of client audits reports
- Performs investigation of client audit findings, nonconforming product, and CAPAs including identifying root cause, analyzing risk, and proposing actions
- Trends, analyzes, and reports quality data that facilitates client process improvements,
- Leads management review meetings
- Creates, Reviews and Evaluates quality records for compliance with regulatory requirements.
- Implements effective complaint management systems via review, revision, investigation and determination of MDR reportable events and MDR submissions to regulatory bodies.\
- Applies design controls principles to client processes and technical file documents
- Trains clients and peers on QMS, design controls processes and technical file documents
- Performs peer reviews of Quality and Design Control records
- Implements and trains client on the document control system, e.g. Device Master Records (DMR), Device History Records (DHR), Quality Records, etc.

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For Regulatory Projects:

- Prepares strategies and authors regulatory roadmaps and assessments
- Prepares regulatory or QA gap assessments
- Prepares and presents presentations and related material for regulatory meetings to clients and management
- Prepares Risk files and assessments, trains, mentors and reviews peer or client completed risk assessments and related documents for compliance with US and EU regulatory and safety requirements (e.g. IEC 60601-1 series of Standards)
- Prepares pre-submission and submission regulatory meeting; writes and reviews meeting minutes
- Develops, authors and/or implements and reviews the work of other peers related to:
    - Technical documentations for preparation of technical files (including Design History Files), protocols and data analysis for usability studies or human factors and human engineering studies
    - Medical device or combination product submissions for clearance or approval for US or global medical device markets
- When leading project activities – is responsible for assisting in or organizing project activities and confirming that tasks are completed on time and within budget as expected
- Anticipates client current and future needs and proactively brings needs to the attention of clients and senior management
- Responsible for meeting client deadlines and ensuring timely completion of deliverables for the client projects
- Proactively communicates with Management if timeline or billable hours could be missed by them or team members working with

As a Mentor and Project Lead:

- Proactively identifies MethodSense process needs and discusses with management
- Communicates with Management strengths/weaknesses/successes and challenges of team members involved in projects with the Compliance Engineer Lead and offers recommendations to Management
- Actively contributes to position and white papers, blogs, website content, etc.
- Supports management with the development of statements of work for clients, which may include definition of tasks, hours and team members

Additional Expectations:

- Anticipates and seeks opportunities for new projects from existing clients and discusses the opportunities with Senior Management
- Proactively communicates with management about challenges or needs of peers mentored or seen within the company to continue improve morale and job satisfaction
- Displays positive work attitude
- Adheres to billable expectations and confirms that mentored team members have enough activities to help them adhere to billable expectations

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- Proactively stays on top of Quality and Regulatory issues and identifies areas where clients will benefit from understanding or utilizing certain regulations
- Proactively seeks opportunities to utilize LuminLogic functions with clients to enable adherence and effective utilization
- Identifies topics and actively participates in writing blogs and other marketing material to highlight company and individual competencies
- Participates and presents webinars and similar technical activities to demonstrate subject matter experience
- Demonstrates attention to detail
- Able to manage competing priorities in a fast-paced environment
- Proactively communicates process improvements with management and supports implementation of such
- Proactively notifies clients of quality and regulatory responsibilities (e.g. reminders for Supplier Qualifications)
- Ensures information and documentation is consistently accurate

MINIMAL REQUIREMENTS:

- Minimum of a bachelor's degree in biomedical engineering or alternative engineering degree
- 4 to 6 years of medical device or combination device industry experience
- Experience building, submitting and defending medical device submissions for FDA clearance / approval or CE mark acquisition
- Experience developing, implementing Quality Management Systems and defending them during inspection or audit
- Ability to demonstrate effective verbal and writing skills
- Ability to proactively seek out and leverage resources responsibly
- Strong time management skills with experience meeting project timelines

PREFERRED:

- Experience working as a consultant or in a strong consultative role
- General understanding of Software Development Lifecycle and Software Design

Interested applicants should send their resume to or contact:

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