

Position: Quality Systems Consultant

About the Job

PathWise, Inc. is a world-class management consulting and training firm that improves business processes of client companies. Our clients include the FDA as well as many top medical device and pharmaceutical organizations. PathWise provides instructor-led training programs and a variety of quality-based consulting services. The PathWise system of consulting and learning is designed to support the most critical factors for organizational and individual success within the Life Science industry. Our focus is on improving all aspects of quality systems and maintaining compliance with regulatory bodies.

PathWise is a values-based organization with a unique, family-like culture. A Consultant is responsible for providing scope and planning to consulting implementations and managing performance of an implementation. The Consultant will interact with the sales team, product development team, and training team internally. This individual will also interact directly with client teams.

Scope of Consultant

Responsibilities:

- Provide scope and planning to consulting implementations
 - Scope out new consulting projects
 - Develop implementation plans with Clients and Managers
 - Recommend process and procedural improvements.
 - Maintain and apply knowledge of current policies, regulations, and industrial processes.
 - Implement proposed improvements
 - Perform GAP analysis or audits of customer facilities or suppliers
- Work with internal and external customers to improve processes by providing technical guidance to quality teams, identify key work to be performed, build cross-functional and collaborative project teams, initiate action, lead efforts and achieve deadlines.

Travel Requirements: Approximately 50% to 70%. International travel may be required.

Job Competencies:

Technical competencies:

- Technical writing
- Procedure Writing
- Project Management
- Planning and organizing
- FDA and other country regulations and requirements

- Quality Systems Auditing
- Presenting to top level management

Business Skills:

- Ability to positively influence a team
- Strong Interpersonal skills
- Verbal and written communications skills
- Ability to learn technical information on their own
- Managing stress when faced with short deadlines and change
- Work alone in home office
- Communicates and works well in a virtual organization
- Ability to lead a virtual team
- Self-starter

Software Skills:

- MS Word (mid-level skills or better)
- MS Outlook
- MS Power Point (expert skill level)
- MS Excel
- Visio
- Ability to navigate the Internet
- SharePoint
- MS Projects or equivalent

QUALIFICATION REQUIREMENTS:

- BA in Life Science, Communications, Business, or equivalent experience (MS in a Life Science, Management, MBA, or PhD in a life science is preferred)
- Six Sigma Green Belt and/or Black Belt preferred
- CQE and/or CQA is Preferred
- High level of proficiency in Visio, MS Word, Excel, PowerPoint and Project
- Must effectively multi-task and manage time to meet deadlines under minimal supervision
- Experience in FDA remediation as well as other regulatory bodies remediation
- Possess a proven track record of leading consulting teams through the full cycle of the client implementations, GAP, Planning, Implementation, and Verification

Other Skills and Abilities:

Qualified candidates will possess excellent written and verbal communication skills, and have the ability to present, train, and consult on technical and non-technical information clearly and concisely. Successful candidates must be flexible. Must be able to relate to project managers and clients with diverse backgrounds and exp