

Position:

Quality Systems Consultant/ Trainer

About the Job

PathWise, Inc. is a world-class consulting and training firm that improves quality systems of client companies. Our clients include the FDA as well as many top medical device, pharmaceutical and biologics 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/Trainer is responsible for providing scope and planning to consulting implementations and managing performance of an implementation. He/she will deliver classroom training and will interact with the business development team, product development team, and training management team internally. This individual will also interact directly with client teams, help set up an effective classroom environment and conduct proper documentation activities under GDP.

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

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 industry 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.

Compliant, Effective, Efficient.

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866.580.PATH

Trainer responsibilities:

- Deliver exceptional classroom training and coaching to class sizes of 15 to 25 participants
- Provide individual coaching on skills and behaviors from classroom delivery
- Ensure training materials are approved prior to use
- Aid in delivering multiple, multi-site trainings in worldwide improvement projects
- Assist in and provide guidance to the development of training materials as a Subject Matter Expert

Job Competencies:

Technical competencies:

- Experience in the some or all of the following topics; CAPA and Investigations, Change Control, Quality Risk Management, Good Documentation Practices, Technical Writing, Quality System Regulations, Good Manufacturing Practices, Good Clinical Practices, Good Laboratory Practices, Validation, Root Cause Analysis.
- Understand adult learning principles
- Understand and apply FDA and other country regulatory requirements
- Experience in effectively planning and organizing a classroom environment
- Present to a range of audiences from floor level manufacturing/clinical/laboratory staff to top level management
- Proficient in technical and procedure writing
- Knowledge of classroom and exercise facilitation techniques
- Possess Project Management skills
- Adept in auditing

Business Skills:

- Strong Interpersonal skills
- Excellent verbal and written communication skills
- Ability to learn technical information independently
- Manage travel when faced with short deadlines
- Communicate and work well in a virtual organization
- Capacity to positively influence a team
- Skill to lead a virtual team

Qualification Requirements:

- Five or more years' experience in medical device, pharmaceutical and biologics organizations
- Bachelor's Degree in Life Science, Communications, Business, or equivalent experience (MS in a Life Science, Management is preferred)
- Six Sigma Green Belt and/or Black Belt preferred
- Effectively multi-task and manage time to meet deadlines under minimal supervision
- Experience in classroom training for broad audience base
- Competency (knowledge and ability) to clearly present and discuss GxP regulations and Quality System requirements in any company setting
- Training certifications or equivalent in the areas of adult learning

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 Project or equivalent