



MDC Associates, Inc.
180 Cabot Street
Beverly, MA 01915 USA
www.mdcassoc.com

CAREER OPPORTUNITY

Project Manager, Quality Systems

Position

We are looking for a motivated Quality Systems Project Manager with quality assurance experience to join MDC Associates. As part of our consulting team you will help both startup and established IVD and medical device companies develop their quality systems, certify them to FDA and ISO standards, perform Internal Quality Audits (IQA) services and generally support their quality and regulatory needs to get and keep their devices on market.

Successful candidates will be natural troubleshooters with the curiosity to fully understand a quality assurance or product related issue and have an open mind to discover and recommend creative solutions. You should feel comfortable interacting with executives and support staff alike and have strong presentation skills to ensure you can clearly communicate Quality Systems concepts and influence clients. If you are a self-starter and independent worker with a high sense of organization and ability to manage multiple projects at once you will be very successful at MDC.

About MDC Associates

For over 30 years MDC has helped innovators and entrepreneurs bring In Vitro Diagnostics (IVD) and Medical Devices to market that impact the lives of millions of patients around the world, every year. Our mission is to continue to support these innovators by applying our expertise in Quality Systems, Regulatory Affairs, Training, and other consulting services to help them launch new advances that promote and protect the health of our global and local communities.

By joining MDC you will experience opportunities to grow your skillset and advance your career in a culture where we value everyone, and where we know our success is directly tied to your success. We hope you take the next step to explore your opportunity at MDC by applying for this position.

Location

Beverly, Massachusetts

Offices are within easy walking distance from the Beverly Depot allowing for a green commute from Boston and the NorthShore (both Newburyport and Rockport lines)

Reports to

Vice President, MDC Associates

Responsibilities

The Project Manager will initially work side-by-side with other Project Managers and the Vice President to become familiar with requirements and regulations that apply to MDC clients in anticipation of independent work with clients within 3-6 months of hire. At that time your responsibilities will be to:

- Develop and manage project timelines for a variety of project scopes.
- Develop policies, procedures and forms, using MDC templates when possible, to strategically and incrementally introduce quality systems concepts to clients and client staff until a fully compliant system is implemented and used.
- Train clients and client staff on concepts and implementation of quality systems process documents.
- Monitor quality systems processes to ensure clients' clear understanding of each process and adjust as needed to suit each client's needs.
- Engage with Research & Development personnel and teams to ensure Design Control and Risk Management documentation is successfully and clearly developed and controlled.
- Engage with Operations personnel and teams to ensure Transfer to Manufacturing is successfully completed and quality control processes and other supporting processes demonstrate compliance with defined specifications.
- Participate in design review meetings and management meetings to demonstrate compliant processes.

Qualifications

- 2-4 years in the *In Vitro* Diagnostic or Medical Device industry in Quality Assurance. 4+ years in Aerospace industry will be considered for the position
- Successful completion of 2- or 4- year college/university program
- Required knowledge of the following quality systems and regulatory requirements:
 - 21 CFR including 21 CFR part 820
 - 21 CFR related sections to IVDs
 - ISO 13485:2016
- Working knowledge of requirements to train employees and executives within their scope of work for their organization.
- Demonstrated ability to navigate between quality systems and regulatory requirements to inform quality system requirements for MDC clients.
- Computer skills: Microsoft Word, Excel, PowerPoint, MS Visio, Dropbox/Box

Additional Information

- 50% travel – primarily within the US with occasional travel outside the US.
- Travel includes road travel to local clients.
- Training provided.

Compensation

MDC Associates offers competitive salary and benefits, including health/dental, HRA, and 401k with match. We also support an engaging work environment that provides everyone the opportunity and structure to learn and grow.



How to Apply

Please submit an updated Resume/CV and a brief summary of why you want to do Quality Systems consulting and why you want to work for MDC Associates.

Contact

Joanne Lebrun

Vice President, MDC Associates

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