medicalmetrics INC.
Insight from Imaging

JOB DESCRIPTION

POSITION TITLE: *Quality System Administrator*

REPORTS TO: *Director of Regulatory and Quality Affairs*

EXEMPT/NON-EXEMPT: Exempt

JOB SUMMARY:

This position will support an ISO 9001 and ISO 13485 compliant Quality Management System, driving compliance with QMS processes and continual improvement actions. Will oversee day to day activities of the QMS in fulfillment of company directives, policies and ISO standard requirements.

DUTIES AND RESPONSIBILITIES:

- Coordinate Quality Management System document control process that allows for efficient and controlled access to current approved documents.
- Track and coordinate documentation change requests, from approval through implementation.
- Assist with maintaining quality documentation such as training records, SOPs, audit files, validation documentation, etc. This would include reviewing, scanning, filing, and indexing of documents.
- Monitor and track training of MMI employees to ensure training process is compliant.
- Prepare, create or update reports and documents, as requested in support and with input from process owners.
- Train MMI employees on MMI Quality System procedures.
- Assist in developing training materials such as PowerPoint presentations and quizzes for company-wide procedures and processes to document effectiveness of training.
- Assist in tracking quality management system metrics in support of the company's Quality Objectives.
- Assist in maintaining the MMI corrective and preventive action systems and support MMI personnel in developing appropriate corrective actions for observed gaps or non-conformances.
- Assist in scheduling, facilitating, preparing and documenting the Management Reviews.
- Participate in the internal audit program which includes development of the internal audit schedule, prepare and conduct internal audits, summarize audit findings and report into MMI's corrective/preventive action program and at the Management Review/s.
- Coordinate and host sponsor, regulatory and registrar audits. Assist with MMI audit responses.
- Support Director of Regulatory and Quality Affairs with any quality related tasks and objectives in support of departmental or company functions.

- Understand MMI's Quality Policy and supports the achievement of quality objectives.
- Comply with MMI's policies and procedures, as well as ISO 9001:2015 relative to job tasks.
- Ensure compliance with HR policies and procedures.

EDUCATION AND EXPERIENCE:

- Four-year undergraduate degree (BA or BS) and/or combination of education and work experience in a Quality and/or regulated environment of over 4 years.
- ISO 9001, ISO 13485, GMP/GLP/GCP or other Regulatory or Quality Systems awareness.
- Familiarity with electronic Quality Management System platforms a plus.
- Experience with conducting internal audits.

SKILLS REQUIRED:

- Strong interpersonal skills
- Excellent verbal and written communication skills
- Excellent work ethic and attention to detail
- Effective time management and organizational skills
- Development of training materials and company documents (e.g., procedures, work instructions, etc.)
- Knowledge of Microsoft business applications (incl. Word, PowerPoint, Excel, Visio, etc.)

COMPANY & COMPENSATION:

- Medical Metrics Inc. (MMI) is a fast-growing, independent imaging core laboratory and medical imaging solutions company based in Houston, TX. MMI provides image analysis and consulting services to medical device, biologics, and pharmaceutical companies in support of their clinical trials and product R&D.
- Competitive salary, commensurate with experience and qualifications
- Excellent benefits package including medical, dental, and life insurance, 401(k) plan, and paid vacation and holidays

For further information, please contact:

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