

MagArray Quality Manager Position

The role of the Quality Manager is to administer a comprehensive Quality Management System (QMS) that ensures MagArray provides quality diagnostic products and services for our customers. The implemented QMS is intended to enable effective planning, development, delivery, and monitoring of MagArray products to maintain our customers' trust, while ensuring compliance with applicable regulatory and legal requirements.

Responsibilities and Duties

- Ensure that processes needed for an effective QMS are established and maintained
- Ensure the QMS comprehends elements needed for compliance with FDA Quality System Regulation/Medical Device Good Manufacturing Practices and is consistent with ISO 13485 compliance.
- Ensure the QMS comprehends elements needed for achieving and maintaining CLIA certification of compliance for the testing laboratory by meeting all applicable CLIA regulations
- Implements and maintains programs and processes to ensure high quality products are developed and manufactured in compliance with current Good Manufacturing Practices (GMP)
- Serve as the administrator of the electronic document management, training, audit, and CAPA database modules used by all employees
- Manage the document control system including approval of document change requests, and facilitating timely document collaboration, review, and approval.
- Manage the part numbering system to issue part numbers and appropriate document types
- Administer the laboratory notebook policy and Good Documentation Practices policy
- Administer the lot numbering system and Work Order processes and serve as Quality Assurance review and approval of executed batch records and device master records
- Control of quality records
- Ensure the review of nonconformances and deviations at Material Review Board meetings and the outcomes and records meet the quality standards
- Reports to top management on the performance of the QMS and any need for improvement especially during the quarterly Management Reviews
- Manage the CAPA processes and ensure effective follow-up and closeout of CAPA
- Manage the internal and external audit processes to ensure effective follow-up and closeout

Qualifications and Skills

- B.S., M.S., or Ph.D. degree in biochemistry, molecular biology, chemistry or related field from an accredited university; or equivalent industry experience
- Minimum 3 years experience in a regulated laboratory environment with M.S., or PhD degree, and a minimum of 5 years with a B.S. degree
- Experience in a quality or regulatory related role responsible for implementing and/or maintaining a Quality Management System
- Demonstrated deep knowledge of Quality Management systems principles, industry practices, and standards
- Track record of accomplishments that demonstrate an ability to successfully carry out the responsibilities and duties listed above for this position
- Excellent verbal and written communication skills
- Strong interpersonal and collaboration skills enabling a positive influence on employees to achieve results in an open team environment
- Excellent document writing and editing skills; able to critically review procedures
- Expert knowledge of Microsoft Office programs (i.e. Word, Excel, PowerPoint)
- Familiarity with, or ability to learn, AssurX CATSWeb[®] document management system
- Knowledge of Japanese language and culture is a plus, but not required

Physical Requirements

The Quality Manager position requires an ability to frequently sit or stand and to talk and hear. The position involves spending extensive time at a computer keyboard writing and editing documents and navigating a database. Frequently, the employee will be required to use hands to handle, sign, and organize paper documents, labels and forms; reach with hands and arms, and climb stairs. Vision abilities required include close vision, depth perception, and ability to adjust focus.



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About MagArray, Inc.

MagArray, Inc. is a start up medical diagnostics company. We have developed a simple, ultra-sensitive, multiplex immunoassay system using a proprietary sensing technology. Originating out of Stanford University, the MagArray core technology brings new levels of sensitivity and ease of use to immunoassays through the use of magnetic nanotags and giant magnetoresistance (GMR) sensors. MagArray has designed the sensors along with the instrument system used by the clinical lab to obtain data from the sensors. This is an exciting time for the company as we enter a period of accelerated growth to launch diagnostic tests and services backed by stable funding, and we are looking for an energetic individual with the right skill set to join our team.

For more information or to apply, send an email to magarrayhr@gmail.com