

BeamOne LLC

Quality Assurance Manager

BeamOne LLC, an electron beam medical device and pharmaceutical sterilization service center is currently seeking a Quality Assurance Manager to join our dynamic team. BeamOne utilizes electron beam radiation to sterilize a wide variety of medical device and pharmaceutical products. We are looking for an individual to manage the quality systems at the Denver service center. More information on our services is available on www.beam-one.com.

SUMMARY

Assure compliance to the BeamOne Quality System. Oversee quality assurance matters and review production documentation for release. Conduct GMP, ISO & EN training as required for all employees.

DUTIES AND RESPONSIBILITIES include the following.

- Act as deputy management representative for ISO and EN audits.
- Oversee QA matters for the facility and provide quality improvement recommendations as well as corrective and preventive action as appropriate.
- Ensure production records are reviewed for accuracy and compliance with customer requirements (SPSAs) and BeamOne procedures (SOPs).
- Oversee the review and release of production lots by quality assurance personnel.
- Ensure BeamOne procedures (i.e. documentation system) are maintained in a manner to facilitate easy retrieval for reference, that all procedures are controlled and reflect the latest revision, that old versions are promptly removed to avoid confusion, the appropriate review and approval process is documented and personnel are trained to the procedures appropriate to their job description.
- Ensure that product and process deviations are properly documented and investigated in a timely manner. Investigations should include one or more corrective actions that should be tracked and completed in a timely manner to prevent reoccurrence of the deviation.
- Oversee the customer complaint system to ensure accurate documentation, corrective action, and timely response. Provide a follow-up to the customer within 30 days of completion of the corrective action to assess customer satisfaction and document this follow-up in the corrective and preventive action log.
- Ensure that all personnel are adequately trained, and where required, certified for the job. Ensure that training is appropriately documented and witnessed by signature/date. Maintain training records in an orderly manner that facilitates easy retrieval and review.
- Ensure that production materials are tested for acceptability in accordance with written procedures.
- Perform internal and external quality audits.
- Facilitate and implement facility management review as it relates to the BeamOne Quality System.

EDUCATION AND/OR EXPERIENCE

Bachelors of Science specializing in microbiology or biology, and three to five years of related experience and/or training in a FDA registered company; or equivalent combination of education and experience. Experience in quality auditing is required.

HIRING DETAILS

- This is a full-time, permanent position that reports directly to the Director of Quality.
- This is a salaried position with competitive pay.
- The company offers a benefit package including health and dental insurance. Paid time off for vacation and sick leave is provided.

WORK LOCATION

BeamOne
6750 E. 46th. Ave. Dr. Suite 100
Denver, CO 80216

CONTACT

Please fax/email resume with cover to:
Doug Myers, Director of Quality
Fax 303-320-6777
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