



Curas Ltd is a British company with representative office in Penang, Malaysia. Curas is emerging as a new medical device brand in the world. In line with our expansion plan and to support our worldwide operations; we are seeking capable and dedicated individuals to join our dynamic organization for an exciting career in the below position. We offer challenging and supportive working environment with opportunities for career development.

QA/RA Executive

Responsibilities

- Responsible for developing, preparing, implementing and maintaining Quality system procedures according to standards and regulations
- Handles Quality Assurance and Regulatory Affair matters of a range of medical devices/disposables, including product complaints
- Work closely with manufacturers to resolve product quality problem and take preventive actions
- Control and maintain Quality documents, labelling requirements, MSDS, Technical files, etc.
- Assist other departments with documents and SOP to comply with regulatory requirement
- You will lead and coordinate problem solving activities, formulate and execute action plans on quality related issues
- Lead in yearly audit on quality system to ensure compliance to GMP and ISO/EN standards, CE, etc. Work with notified bodies, auditors, customers/distributors and suppliers/manufacturers

Requirements

- Degree in Business Administration, Science, Engineering or any other related field
- Preferably with at least 2 years working experience in Quality Assurance and/or Regulatory Affairs in manufacturing environment
- Good knowledge of QC tools, GMP, ISO9001, EN ISO 13485, CE and various other product standards and test requirements related to medical device
- Well verse and have interest and knowledge of the medical device industry preferred
- Good written and verbal communication skill and problem-solving ability
- Ability to work independently and self-motivated to learn new and changing regulatory requirements. Able to prioritize and handle multiple tasks and responsibilities
- Good interpersonal skill and ability to interact with people of all levels in the company and externally with notified bodies, auditors, customers and suppliers
- Ability to facilitate and provide leadership when interpreting regulatory standard and guidance
- Computer literacy in Microsoft Office application

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Salary will commensurate with your qualification and experience. Qualified and interested candidates are invited to apply via e-mail to hr@curas.com . Please include your resume and state your expected salary. Only short-listed candidates will be notified.

Note: Visit curas.com for further detail about the company and other vacancies