PRISM MEDICAL UK

Job Title: **Quality System Engineer**
Reporting to: **Group QHSE Manager**
Based: **Prism North Wales**

Job Purpose:
Working within the Quality department this role will work with all areas of the manufacturing team in deploying and maintenance of the company's quality management system. Will be the lead in driving updates and changes to the system and ensuring all department managers understand requirements.

Responsibilities to include:

- Day to day technical / systems support to keep existing quality system up to date
- Control and creation of product technical files
- Report to management on company QMS system and update as required
- Create and control internal audit schedule for all manufacturing sites
- Support external QMS reporting to external bodies
- Support in producing company literature (user manuals etc.)
- Liaise with R&D department in the testing of new products

Skills and Attributes:

Essential:

- Experience of working in a manufacturing environment in accordance with the requirements of ISO 13485, ISO 9001, ISO 14001 & the EU Medical Device Directive
- A good general technical understanding, particular focus in medical products
- Able to learn and apply established procedures in a reliable and consistent manner.
- Anticipate what information is required by their colleagues and to disseminate it actively and efficiently.
- Enjoys working within multidisciplinary teams in the development of leading edge designs and technologies.
- Ability to plan, organise and prioritise own work with minimal supervision.
- Effective team worker.
- Excellent attention to detail.
- Willing to listen and take advice from others.
- Shows initiative and has ability to think for self.
- Excellent verbal and written communication skills
- Microsoft Excel, Word & PowerPoint proficient
- Can-do attitude, team player

Desirable:

- Lead auditor qualified
- FDA submissions experience
- Commercial awareness of costs
- Ability to lead / manage teams

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