PERSON SPECIFICATION

Quality and Regulatory Affairs Manager

ESSENTIAL	DESIRABLE
QUALIFICATIONS • A Quality & Regulatory professional, educated to degree level (or equivalent), with at least 5 years' experience within a medical device related environment at management level. • Green Belt Lean and Six Sigma with demonstrable experience of DMAIC, 5S, process capability, DOE. • Internal auditor. • Computer literate with good working knowledge of Microsoft Word, Excel, PowerPoint.	**QUALIFICATIONS** • Minimum expectation is that the post holder will have relevant professional qualifications (e.g. Quality diploma). • Black Belt Lean and Six Sigma trained Membership of a recognised Quality or Engineering institute. • Lead Auditor
EXPERIENCE • Demonstrable working knowledge of relevant quality standards (e.g. BS EN ISO9001, BS EN ISO13485, BS EN ISO14001, ISO14971, IS010993 & ISO11137) within a medical device related environment. • Demonstrable working knowledge of the Medical Device Directive 93/42/EEC, the Medical Device Regulations EU/2017/745 and the creation of CE compliant technical files. • Working in a senior Quality Management and / or Regulatory Management role in a high volume manufacturing environment. • Responsibility for leading, managing, coaching and motivating QARA staff.	**EXPERIENCE** • Experience working in the medical device or pharmaceutical industry. • **Experience working in an regulatory advisory capacity to other group companies** • **Biocidal Products Regulation (BPR, Regulation (EU) 528/2012)**
KNOWLEDGE • Extensive understanding of current medical device legislation and the impact on the operations of a medical device manufacturer.	**KNOWLEDGE** • REACH regulations, CLP regulations. • Labelling and transportation of dangerous goods. • Cosmetics Directive (76/768/EEC) • **Biocidal Products Regulation (BPR, Regulation (EU) 528/2012)**
SKILLS & ABILITIES • Excellent problem solver • Ability for lateral thinking • Able to project manage, organise self and others. • Able to assess risks and make difficult decisions. • Ability to develop self and team. • Ability to interpret and apply regulations in a commercial environment.	**SKILLS & ABILITIES** • Engineering and or manufacturing background.
PERSONAL • Ability to work at a senior level providing guidance and leadership outside of the direct function. • Tenacious, assertive in driving standards and compliance	**PERSONAL** Leadership Team experience. Ability to combine a big picture view with drive to ensure the use of detail and data.

with a willingness to challenge the status quo. • Ability to build collaborative relationships with key stakeholders. • Organised and able to manage time effectively. • Strong Continuous Improvement mind-set. • Strong leadership qualities. • Data driven. • Ability to communicate well at all levels with both internal and external customers • Sense of humour.	