Quality Assurance Officer – Medical Devices		
Job Title: **Quality Assurance Officer – Medical Devices**	Reporting to: **Regulatory Affairs Manager**	Deputy: n/a

Job Purpose:

Responsible for supporting the day to day management of the QMS to ISO 13485:2016 along with continuous improvement to the existing system.

Key Responsibilities:

1. Transfer from MDD to MDR
2. Maintenance and continuous improvement of the Quality Management System for Medical Devices. Including updating and writing SOPs, risk management files, post market surveillance documents, and clinical evaluation reports.
3. Efficient administration and management of Regulatory Technical Files.
4. Raising CAPA's, Change Controls, Non- conformances, Supplier Corrective Actions (SCARs) and providing resolution where applicable to support maintenance of certification/ standards.
5. Involved in raising, documenting and investigating product complaints.
6. Review and approve validation documents
7. Review and approve PQRs (Product Quality Reviews reports)
8. Liaise with subcontract manufacturers/ suppliers regarding quality/ regulatory issues.
9. To ensure compliance to applicable medical device regulations and standards, including the MDR requirements. (Ensure the company's products meet the regulations of the MHRA)
10. keeping up to date with guidelines/ regulations for medical devices. (UK/EU)
11. Work closely with other functions to ensure product can be compliantly distributed to market in support of product demand.
12. Review and approve Certificates of Analysis.
13. Writing clear, accessible product labels and patient information leaflets.
14. Specifying storage, labelling and packaging requirements.
15. Proof reading and approval of product labels.
16. Preparation and participating /hosting of audits by certification bodies/ regulatory agencies.
17. Performing internal and external audits.
18. Preparation and presentation of trending reports and graphs.
19. Advise the Regulatory Manager of any regulatory/ quality gaps/ issues within the organisation.
20. Managing archiving systems within quality/ regulatory.
21. To provide a medicines information service. Handle Medical Information enquiries and update the medical information log.
22. Complying to GDP- Ensuring that outsourced activities are correctly defined, agreed and controlled. Responsibility for ensuring quality agreements are in place, carrying out due diligence checks, monitoring and reviewing of performance of contract acceptor and any improvements required.
23. To work with the team and line management to deliver quality improvements.
24. To support line management to meet the company objectives.
25. Assist in solving any issues, queries, or problems within the department and across other business functions.
26. Provide and maintain staff training records.
27. Support the Management Representative to ensure continual compliance and improvements within our supply chain for Labour Standards Assurance Systems
28. To be cognisant of obligations for Health and Safety of self and fellow employees.
29. Responsible for own development opportunities and CPD where applicable.
30. Undertake other related responsibilities commensurate with the evolving objectives of the post as may reasonably be expected.

Territory scope:

Territory scope: Company core product range. This role will require occasional travel to the company's distribution outlets. There may also be a requirement for other UK and international travel on occasions. When the Quality Assurance Officer is absent, the Regulatory Affairs Manager will take over responsibility for these roles.

Qualifications and personal attributes:

- Degree in Life Sciences.
- Significant and demonstrable experience of working in a similar Quality Assurance related role within the Pharmaceutical Industry.
- Excellent working knowledge of ISO 13485: 2016, MDD and MDR 2017/745.
- Excellent oral and written communication skills and ability to present at different levels of the organisation.
- Strong interpersonal skills with the ability to work cross functionally across the business, with suppliers and customers.
- A proven track record to meeting highly challenging targets/ deadlines.
- Ensures high quality and accurate work with high attention to detail.
- Self-motivated and proactive with the ability to work under minimal guidance / supervision.
- Decisive thinker, ability to multi-task, remain calm under pressure.
- Strong work ethic and high levels of resilience.
- Good numerical and analytical skills.
- Full driving licence is desirable.

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