Aiden Kelly

Risk Manager

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Summary

Highly skilled and experienced Risk Manager with extensive knowledge of ISO 13485 QMS in medical device/IVD product development, leading and documenting product risk management processes, and coordinating and facilitating across quality, regulatory, and multi-disciplinary technical teams. Adept at developing and managing a process for the identification and management of risks outside of regular risk-focused sessions, ensuring compliance with IVD regulatory standards. Possesses excellent communication and interpersonal skills and is proficient in Word, Excel, PowerPoint, etc.

Experience

Osler

Oxford

Risk Manager

2018 - 2022

Planned and coordinated risk management activities in accordance with IVD regulatory standards throughout the product development lifecycle. Created and maintained risk documentation within an ISO 13485 QMS across multiple projects and jurisdictions. Worked collaboratively with QARA, R&D, and Production to drive identification, analysis, and control of product risks.

- Developed and managed a process for the identification and management of risks outside of regular risk-focused sessions resulting in more effective and efficient risk management.
- Coordinated and facilitated across quality, regulatory, and multi-disciplinary technical teams to ensure compliance with IVD regulatory standards resulting in successful regulatory activities and market launch of the Osler Origin product.
- Led and documented product risk management processes, such as FMEA, FTA, Hazard Analysis, resulting in the identification and control of potential product risks.

Medtech Innovations

London

Quality Assurance Manager

2015 - 2017

Developed and implemented quality management systems in compliance with ISO 13485 standards. Coordinated internal and external quality audits and ensured compliance with regulatory requirements. Managed the CAPA process and ensured timely closure of non-conformities.

- Developed and implemented quality management systems resulting in the successful certification of the company to ISO 13485 standards.
- Coordinated internal and external quality audits resulting in successful audits and compliance with regulatory requirements.
- Managed the CAPA process resulting in timely closure of non-conformities and improved quality metrics.

Biotech Solutions

Bristol

Quality Assurance Engineer

2013 - 2014

Conducted quality audits and risk assessments to identify areas for improvement. Developed and implemented corrective and preventive actions to improve product quality. Trained employees on quality systems and regulations.

- Conducted quality audits and risk assessments resulting in the identification of areas for improvement.
- Developed and implemented corrective and preventive actions resulting in improved product quality.
- Trained employees on quality systems and regulations resulting in increased awareness and compliance.

Strengths

Risk Analysis

Identified and mitigated risks in multiple projects resulting in a 20% reduction in overall risk

Collaboration

Facilitated communication across multi-disciplinary teams resulting in a 15% increase in productivity

Regulatory Compliance

Ensured compliance with ISO 13485 QMS resulting in successful product launch and regulatory approval