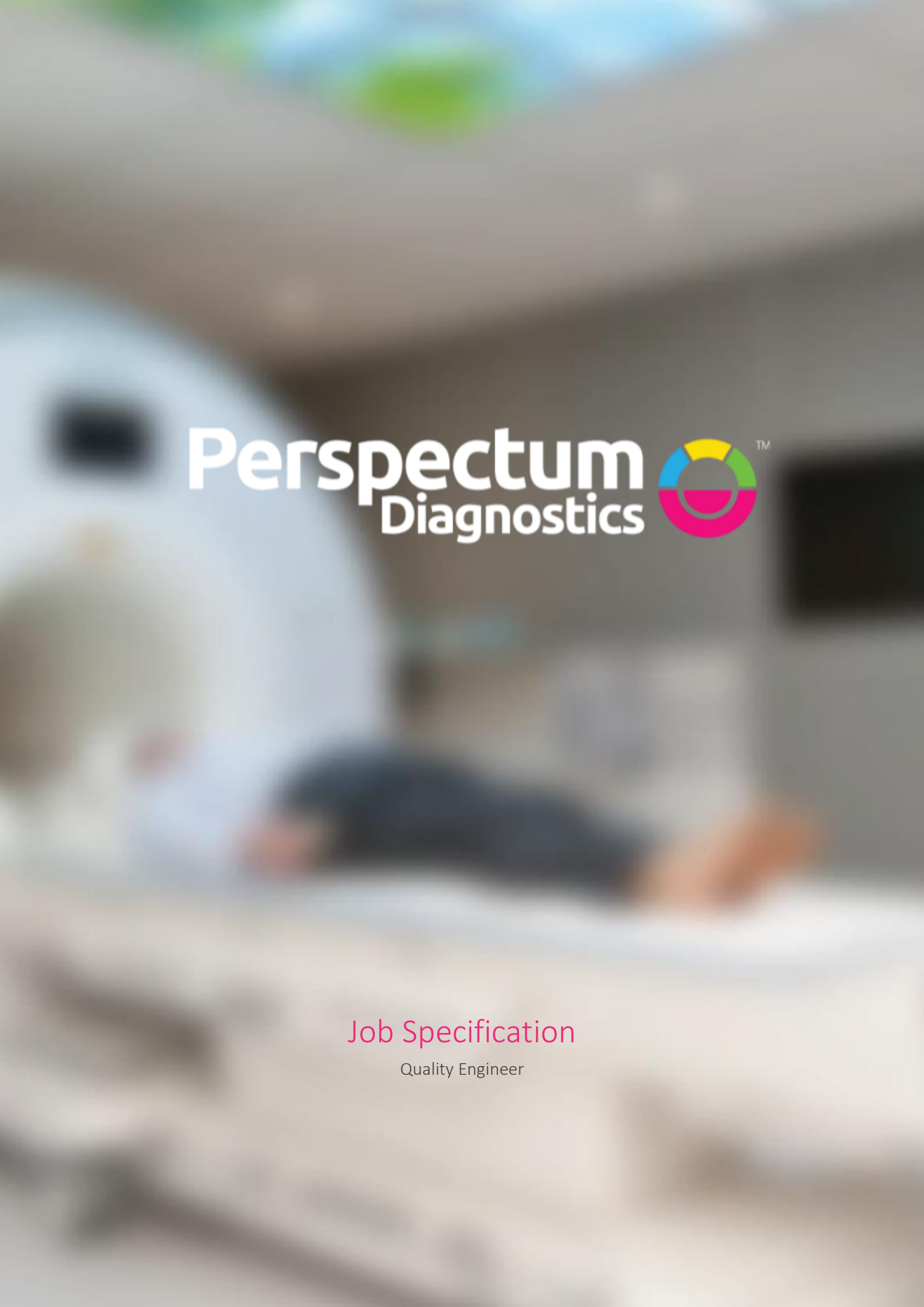

Job Specification

Quality Engineer

About us

Perspectum Diagnostics has been founded by physicians, scientists, and engineers with patented technology and know-how to develop solutions for major unmet needs in diagnostic medicine. We focus on the detection and accurate, quantitative measurement of liver, gallbladder and pancreatic disease, including precancerous and cancerous states.

The role

This is a unique opportunity to help refine and maintain a quality management system to ensure that the products developed and services delivered by Perspectum Diagnostics is fit for purpose, consistent and meets both external and internal requirements. This includes legal compliance and customer expectations.

You will be pivotal in ensuring and managing the activities required to meet various quality standards, including ISO 13485, ISO 27001, ISO 14971, IEC 62304 and 21 CFR Part 11 (FDA).

Responsibilities

- As a quality engineer, you will be responsible for establishing and maintaining Perspectum's quality policies, processes and maintaining the QMS
- Work alongside a cross-functional team to review customer requirements to ensure that they are clear and unambiguous
- To assist with Process Improvement and to provide practical assistance in the implementation of agreed processes
- Conduct Internal audits and participate in external audits
- Participate in Defect Handling Boards
- Tracking and closure of actions arising from Internal / External audits
- Training staff as necessary so that they fulfil the requirements of the quality management system
- Other duties as assigned by the Head of Quality and Regulatory

Skills and requirements: essential

- Experience in a Medical Device environment
- Experience performing internal audits
- Flexible attitude and ability to perform under pressure
- IT skills including a good working knowledge of Microsoft Office - Specifically Word and Excel
- Ability to work independently
- Ability to mentor members from other teams on how to follow the processes prescribed by the quality management system
- Not afraid of documentation!

Skills and requirements: desirable

- Auditing qualification such as Lead auditor
- Experience of medical device quality standards such as IEC 62304, ISO 13485 and ISO 14971
- Experience of information security standards such as ISO 27001.
  Experience of software development methodologies