

**JOB DESCRIPTION**

1. **JOB DETAILS**

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| Job Title | Quality Specialist |
| Line Manager | Quality Manager |
| Directorate  Department | National Procurement / National Specialist and Screening Services / NHS Scotland Assure  Quality |
| Location | Any NSS Location |

1. **JOB PURPOSE**

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| **The Quality Specialist is responsible for supporting the Quality Manager in leading and determining the strategic direction in relation to business effectiveness and improvement by influencing policy and strategy for the development and implementation of business excellence in processes to improve service provision to the benefit of NHSS, Customers, Patients, Stakeholders and Staff.**  **Ensuring that business processes and activities within National Procurement (NP), National Specialist and Screening Services (NSD) and NHS Scotland Assure (NHSSA) Directorates are fully compliant with relevant ISO and IEC standards and contribute to the development of SBU strategy and delivery of KPIs. Relevant ISO and IEC standards include:**   * **ISO 13485:2016 (Specific Focus for QMS)** * ISO 14971:2019 * ISO 9001:2015 * ISO 17025:2017   **To ensure close and effective working relationships are developed and maintained with stakeholders internal and externals to our Directorates.**  **Supporting the Quality Manager in leading the strategic direction and management of the implementation of business objectives through maintaining and improving services, ensuring quality standards are achieved, processes are monitored and measured, undertaking internal audits, process measurements and continuous improvement activities to meet/exceed the needs of customers, clients and patients.**  **To provide leadership across NP, NSD and NHSSA in total quality management approaches, ensuring that the quality management system remains fit for purpose in relation to standards, compliance and registration requirements.**  **This role is key to the delivery of strategic outcomes in relation to improvement, it is also critical in the development of the Directorates as centres of expertise.** |

1. **DIMENSIONS**

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| * The post holder will be recognised as a deputy for the Quality Manager in Quality and will provide support and management of improvement across all business areas in response to customer needs * The post holder will manage external third party suppliers and internal solution providers/support teams across the Directorates, NSS as required for ensuring all our business areas maintain compliance with the relevant ISO standards stated above. * The post holder will support the Quality Manager or oversee activities relating to NSS improvement programmes. * The post holder is responsible for ensuring quality issues are monitored and timely corrective action implemented on behalf of the Directorates. * The post holder has specific responsibility to lead and deliver the ISO 13485 processes including complaints, product recall/alerts and the effective implementation and ongoing management of our Quality Management System. |

1. **ORGANISATION CHART**

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1. **ROLE OF THE DEPARTMENT**

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| The role of the National Procurement (NP), National Specialist and Screening Services (NSD) and NHS Scotland Assure (NHSSA) Directorates is to provide a complete range of specialist services and expert advise to a range of stakeholders including Health Boards, Scottish Government and the wider public sector. For further information on our service provision go to: www.nss.nhs.scot and click the links for the following services:   * Antimicrobial Resistance and Healthcare Associated infection * Health facilities * NHS Scotland Assure * Procurement and logistics * Specialist healthcare   The Quality team is tasked with co-ordinating support services to the three Directorates and engaging with other Directorates within NSS. We are responsible for leading, managing and directing the implementation of improvement across PCF, providing assurance that standards of service delivery are met and improvement supported and reported as required. We support the Directorates to achieve health, safety and wellbeing and sustainability objectives, best practice identified and implemented.  The Directorates have circa 700 staff, spread over sites across Scotland.  The Quality Management Service will be responsible for standing up and maintaining a Quality Management System (QMS) for the Directorates, this role having a specific focus on Manufacturing of Medical Devices in addition to all other relevant areas requiring QMS support. |
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1. **KEY RESULT AREAS**

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1. Responsible for supporting and deputising for the Quality Manager to develop and implement quality and continuous improvement systems; working with staff at all levels within the organisation, ensuring that the benefits of the model are delivered to the staff, Directorates and stakeholders.
2. Align improvement activity to the Institute of Healthcare improvement model to raise standards of practice and meet organisational improvement objectives.
3. Ensure that Directorate Quality Management activities are aligned to NHSS and NSS priorities so that the long-term benefits are realised and ensure these processes are correctly initiated, implemented, co-ordinated, managed and controlled to ensure ongoing compliance and registration to all relevant ISO standards. Incorporate new business activities into the relevant ISO certifications and achieve business excellence
4. Provide professional expertise, advice and guidance to all staff within NP, NSD and NHSSA in relation to Quality Management. Manage quality and performance of key suppliers in conjunction with other business leads, establishing supplier strategies and continuous improvement plans.
5. Responsible for ensuring that the quality management system remains fit for purpose and meets the requirements of the relevant ISO standards. This includes overseeing the implementation and performance of all aspects of the quality management system to ensure compliance and identify and support continuous improvement in business practices
6. Responsible for supporting the development and review of NSS and Directorate policies, procedures and plans in relation to quality.
7. Contribute as a lead representing Quality through engagement with other Directorate leads in groups /organisations, such as MHRA, to identify and implement process improvement
8. Provide leadership, support, coaching and development to the Directorates and other employees supporting the Quality agenda, eg timely effective implementation of corrective action, sharing best practice, supporting continuous improvement.
9. Responsible for overseeing the complaints and product recall processes to ensure that complaints and issues are resolved in a timely manner and meet patients’ /customers/ stakeholders’ expectations. Use trend information to inform service improvement as part of continuous improvement.
10. Work in partnership with Directors, NSS and 3rd party auditors to ensure that external audit activity is appropriately targeted in high risk business areas and audit findings agreed and acted upon.
11. The post holder is responsible for ensuring that systems and processes that directly affect patient care are effective, maintained and improved. These processes include product safety and information alerts, coordinating the recall of products from NHS Scotland Health Boards, working closely with external suppliers, NHS Boards and clinical groups such as the MHRA.
12. Lead the coordination and support of improvement activities ensuring training opportunities are identified and made available to staff in continuous improvement techniques and support effective team working
13. Undertake research and measurement of Directorate activities in relation to Quality using literature review, internet search, or questionnaires to identify areas for improvement or new international standard registrations in the organisation
14. The post holder is responsible for developing procedures drawing from a wide range of sources such as legislation; EFQM documentation; international standards; internet research and current best practice.
15. Responsible for providing training across NP, NSD and NHSSA at all levels in:

Continuous improvement techniques

Effective complaint handling

Effective management of product and service issues

Use of the Quality Management System

1. **ASSIGNMENT AND REVIEW OF WORK**

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| 1. The post holder is subject to managerial direction and to formal review with objectives agreed annually, and reviewed quarterly, with the Quality Manager. 2. The post holder will have the freedom to act on own initiative and schedule and prioritise their workload within the strategic framework of the Directorate business plans. 3. Judgements will be based on knowledge and experiences as well as the interpretation of customer requirements, legislation and standards. A range of options are available when judging the best course of action in relation to the requirement of International (ISO) standards. International standards are written to express what is required, the information has to be interpreted and adapted to suit individual situations and processes. The post holder will apply the most appropriate methods to meet the requirements. 4. The post holder is required to show highly developed analytical skills to identify the root cause of complex issues involving matters such as problem identification, task definition, structuring of solutions or determining performance. This will involve the post holder making informed decisions and judgements based on information from several sources such as audits, complaints, corrective action, customer issues, supplier and product issues, process issues, risk analyses, and continuous improvement activities. This also involves making complex and creative judgements that have often to be made in situations of ambiguity, such as the interpretation of legislation and standards. 5. The post holder is fully accountable for leading and driving progress within the identified areas of responsibility and within the parameters of established national and local priorities, policies and procedures. A high degree of autonomous working and innovation will be required of the post holder which will in turn require him/her to fully develop the capabilities of the department. The post holder will be an important, core member of the team and must demonstrate considerable initiative. 6. The post holder will continuously review quality of work within own area of responsibility and across the work streams as to the relevance of content, challenging poor quality work and poor performance where necessary. The post holder will brief the Quality Manager regularly on progress against delivery of any objectives contained in the Business Plan. 7. Initiatives and action to improve services, increase customer satisfaction and more effective ways of working will be formulated and implemented by the post holder 8. The post holder is responsible for producing the internal audit plan, focusing on areas of risk, previous historical performance and new service provision. 9. Responsible for planning the process to review the Quality Management System to ensure its continuing suitability and effectiveness. 10. The post holder regularly undertakes research on topics such as:  Customers perception of the service delivery of the DirectoratesSurveys of staff attitude, opinion and perception Evaluation of suppliers’ processes in support of delivery of services to the Directorates.  This includes the formulation of questionnaires, the content of which are tailored to specific  processes and customers. Analytical and statistical skills are required to provide meaningful  information that forms the basis for identifying opportunities for improvement, formulating action  plans and setting up outcome monitoring. |

1. **COMMUNICATIONS AND WORKING RELATIONSHIPS**

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| **Internal**   1. The post holder will provide quarterly status reports to the Quality Manager. 2. The post holder will liaise regularly with Directors, Department/Service Heads, Internal Project Groups, Partnership representatives and NSS leads to develop, to deliver continuous improvement. 3. The post holder will provide regular internal reporting requirements on quality related issues requiring action can be complex and confidential and comes from internal or external sources such as: consultation papers draft policies; audit reports; customer surveys. This requires developed interpersonal skills to secure meaningful results through developing highly effective working relationships; good communications e.g. people skills, listening, empathy and motivation. 4. The post holder will present often complex or contentious information to senior management regarding audit findings within business areas. Performance issues may arise from this requiring sensitive reporting and handling in potentially hostile, antagonistic or highly emotive situations. 5. The post holder will liaise, lead and promote quality, improvement and compliance across the Directorates through leading and planning development and improvement programmes and communicating through face to face meetings, e-mails, publishing articles, participation in working groups; design and deliver awareness sessions, QMS workshops and training staff at all levels. 6. The post holder will liaise and work in partnership with NSS quality improvement team to undertake business reviews, implement agreed improvement reviews and improvement programmes requiring highly developed interaction and communication skills to achieve objectives 7. The post holder will influence, persuade, negotiate and use questioning techniques whilst undertaking internal audits and during continuous improvement activities. 8. The post holder will promote and deliver training to SBU staff about continuous improvement, quality management, quality standards and systems. 9. The post holder will lead in the effective management of customer complaints, product alerts and recalls contributing to patient safety   **External**   1. The post holder must build and manage highly effective relationships with United Kingdom Accreditation Services, BSI Management Systems, Registration Bodies and NSS senior staffs to ensure management systems are maintained and improved. 2. The post holder will manage conflict that occurs during audits conducted by external accreditation and certification bodies in the interpretation of the meaning or application of the requirements of the international standards. 3. The post holder will manage conflict that occurs during internal audits where differences of opinions are expressed and a considered judgement must be made. 4. The post holder will manage the relationships with external auditors and specialist QA consultancy companies regarding the maintenance of relevant ISO registrations maintaining the process of continuous quality improvement. 5. The post holder will support the Quality Manager with the relationship with UKAS regarding the maintenance of all relevant ISO registrations and accreditations. External audits are typically 8 days per year. 6. The post holder will consult with customers and suppliers in relation to queries, complaints to ensure satisfactory resolution, managing expectations which requires effective interviewing and questioning skills. 7. Participates and collaborates with other NHS Bodies and outside agencies regarding Quality Improvement and Assurance to share best practice and maintain knowledge base. 8. Actively participates with other NSS staff to implement national or NSS initiatives ensuring that Directorate staff are consulted and their interests taken into consideration. 9. The post holder will represent NP, NSD and NHSSA at meetings such as NHS Equipment Coordinators, Clinical & Quality Group, to ensure adoption and enhancement of services, adopting best practice and compliance with NSS requirements. 10. Communications will be verbal, written and electronic with all external interface to stakeholders   Excellent communications skills are required since a major purpose of communication is to persuade others and to negotiate the development and implementation of change. The post holder is expected to have strong presentation skills and to be able to express views/perspectives convincingly and coherently, verbally and in writing. |

1. **MOST CHALLENGING PARTS OF THE JOB**

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| NP, NSD and NHSSA adopts a process of continuous quality improvement to ensure it delivers services that will support the highest possible quality of patient care in Scotland. As an expert in the aforementioned relevant ISO standards the post holder:   * Must motivate, develop and guide Directorate staff to achieve this objective by creating a change in culture that will deliver full commitment to continuous improvement and quality activities in a changing environment. * Provide guidance and give opinions to the Directorates Senior Management Teams * Challenging existing ways of doing things and breaking down barriers while staying close and sensitive to stakeholder and staff needs during a period of significant change. * Ability to be flexible and multi-task and react to constant demands, prioritising tasks appropriately. * Managing, influencing and solving areas of conflict and with confidence, sound judgement and professional acumen to ensure the continued smooth running of the organisation * Handling sensitive and confidential information that is complex and communicating effectively to achieve outcomes * Working in partnership with NSS and Directorate teams to meet organisational and improvement objectives * Managing conflicting priorities within the Quality team to produce results that will improve service delivery to customers. * Managing and influencing teams by persuading people to work together to arrive at balanced, practical and realistic decisions. * Is responsible for providing training in own discipline:   + Provide formal quality induction training to new starts   + Training, coaching and mentoring and supporting the audit service.   + Practical training and support on quality improvement tools such as PDSA, process mapping, Pareto analysis * Is responsible for supporting local management, reporting and resolving any clinical governance issues. * Can be flexible and multi-task and react to constant demands, prioritising tasks appropriately |

1. **SYSTEMS**

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| The post holder is responsible for ensuring that records of all calculations, analyses and outcomes relating to processes are maintained in accordance with the requirements of all relevant ISO standards.  This requires knowledge of   * Quality Management Systems * Q-Pulse * Microsoft Office Suite: Word, Excel, PowerPoint, Visio, Outlook * NSS systems –Crown, Eess, e-KSF, Risk Register, CCM, Business Objects * Management and governance over the Q-Pulse system that maintains information, records, change requests, document control and equipment calibration. |

1. **PHYSICAL, MENTAL, EMOTIONAL EFFORT**

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| **PHYSICAL**  The job is office based; however, regular travel is required between Edinburgh, Glasgow and Canderside and occasional travel across Scotland to attend meetings, training sessions, conduct internal audits, and second party audits. Frequency and duration is dependent on business needs.  Delivery of workshops / training and awareness sessions which may result in standing for long periods of time, presenting or supporting group work.  The position also requires nominal effort such as using VDU, sitting at desk and other associated office tasks or carrying of light loads such as laptop case, training materials.  **MENTAL**  Work is conducted in an open plan office. High levels of concentration are required for all aspects of the role- this includes planning, facilitation, data analysis, report writing, legislation or standard reviews, auditing, chairing meetings, meeting deadlines, work prioritisation, unpredictable work patterns. Changing from one activity to another is common, as are frequent interruptions – inevitable due to the many aspects of the business activity.  Responding to questions from external auditors during assessment audits when justification has to be made about our interpretation of standards.  Responding to questions from NHS Boards, suppliers and customers on product quality and safety issues which may impact patient safety. This type of effort is required at all times every day, on an ongoing basis.  **EMOTIONAL**  Exposure to dealing with adversarial behaviour from external auditors, staff and customers. This can occur because of differences of opinion during or because of quality, continuous improvement activities, incident investigations, conducting audits, participating in audits from external bodies and the complaints, recalls and alerts processes.    Improvement work often results in implementing change, resulting in a resistant sometime hostile environment. It can also be stressful trying to influence colleagues to prioritise Quality requirements when they have other demanding priorities in relation to the service delivery.  Due to nature of the role there may be instances of reporting staff performance issues which have a negative impact on the effectiveness of the QMS need to be addressed |

1. **ENVIRONMENTAL/WORKING CONDITIONS & MACHINERY AND EQUIPMENT**

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| **External Working Conditions**   |  | | --- | | Frequent use of a VDU and other office equipment and observes personal duty of care in relation to IT equipment and office resources used in course of work |   **Internal Working Conditions**  The post holder works within an open plan office. There may be moderate but frequently intrusive noise from conversations, office traffic, IT equipment and telephones etc.  A daily requirement for sitting/inputting at a laptop for a significant part of the working day. **Machinery and Equipment** Everyday use: laptops, desktops, printers, photocopiers, telephones, mobile  Regular use: projectors - communications sessions / presentations |
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1. **KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB**

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| **Qualifications**   * Degree or equivalent in a related subject be a member of an appropriate recognised professional body or at least 5 years equivalent experience in a Quality Management role.   **Experience**   * Proven expert and specialist in a Quality environment * Significant experience implementing a quality management system and driving continuous improvement * Highly developed comprehensive and specialist knowledge of quality management, quality assurance, quality improvement. This will be supplemented by further training, attendance at specialised courses and continual professional development. * In-depth knowledge of quality improvement tools and techniques and their application * Significant experience within the quality management profession and have experience in the application of techniques and systems to recognised British or International standards such as ISO 13485 (Quality management systems), EFQM Excellence Model and Total Quality Management. * Experience in an environment where there is a high level of interaction with a diverse range of stakeholders. This also includes advising senior management team and other managers across the Directorates on relevant matters relating to their areas of influence. * Must demonstrate leadership skills, initiative, and ability to prioritise work, meet deadlines, and demonstrate diplomacy and sensitivity when dealing with staff at all levels within the SBU. A high level of listening, facilitation, personal, numeric written and oral communication skills are essential. * Must have the ability to coordinate, mentor and coach staff to meet the business objectives of the SBU. * The post holder provides and receives complex, sensitive information from internal and external sources such as reports, incident investigations, and customer surveys. This requires developed interpersonal skills to secure meaningful results through good communication eg people skills, listening, empathy and motivation.     **Competencies**   * **Leadership**: Communicates a vision and provides visible and supportive direction and guidance that empowers, enables, motivates and develops colleagues to achieve the organisation’s goals. * **Strategic Thinking**: The ability to implement strategy, planning and project/change management to deliver continuous improvement. * **Improving Quality:** Focuses on continually improving outcomes for customers, patients and other stakeholders, the ability to prioritise work and meet deadlines. * **Achieving Results:** Supports the development and implements KPIs and Objectives and business plans, reviewing own team and service performance against these. The ability to support and mentor staff, review work to meet the business objectives of the Directorates * **Political Sensitivity**: Fostering and building effective alliances underpinned by a strong ethos of partnership working with a broad range of stakeholders to enable effective working. Provides and receives complex, sensitive information from internal or external sources such as reports, incident investigations * **Working in Partnership**: Builds effective relationships with staff, customers and other stakeholders, demonstrating tact, diplomacy empathy and good listening skills. * **Improving Performance through Team-Working**: Works effectively as a team member and influences colleagues with tenacity to deliver shared goals. * **Caring for Staff**: Employs a healthy, safe and dynamic working environment in which staff wellbeing is promoted and individuals are supported and motivated in their roles and demonstrate diplomacy and sensitivity when dealing with staff at all levels within the SBU. * **Communicating effectively**: Communicates clearly and consistently and ensures that staff, customers and other stakeholders influence quality initiatives. Possesses a high level of listening, facilitation, personal, numeric, written communication skills and oral communication. * **Promotes a Learning Organisation**; Views learning as integral to service planning and delivery and develops organisational learning plans to maximise staff potential.   **Demonstrates through behaviours and actions an absolute commitment to the NSS Values:-**   * **Customer Focus** – *recognising everyone as a customer and putting customers first* * **Respect and Care** – *demonstrating that we value the views of others and showing mutual respect for each others’ differences and diversity* * **Openness** – *sharing timely and consistent information* *regularly and ensuring honesty and transparency in our communications* * **Integrity** – *ensuring our decisions, actions and behaviours are based on ethical* *principles and values and that we take responsibility for them* * **Committed to Each Other** *– listening to our staff/customers and treating each other consistently and supportively thereby building trust* * **Excel and Improve** *– embracing change and striving for continuous improvement aligned to customer need; seeking out best practice, sharing ideas and learning from our mistakes.*   A driving licence is an essential requirement. |

1. **JOB DESCRIPTION AGREEMENT**

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|  | Job Holder’s Signature: | Date: |
|  | Senior Officer/Head of Department: |  |
|  | Signature: | Date: |
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