JOB DESCRIPTION

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| **1.** | **JOB DETAILS** |  |
|  | Job Title: | Quality Manager |
|  | Line Manager | Consultant Clinical Safety Engineer |
|  | Directorate | Digital and Security (DaS) |
|  | DepartmentLocation: | National Clinical Informatics Service for Scotland (NCISS)Any NSS Location |
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| **2.** | **JOB PURPOSE** |
|  | To provide direction and leadership in relation to business effectiveness and improvement by ensuring Quality Management Systems within all DaS directorates are compliant with relevant ISO and IEC standards:* ISO 81001-1:2021
* ISO 14971:2019
* **ISO 13485:2016 (Specific Focus for QMS)**
* IEC 62304:2006+A1:2015

To ensure close and effective working relationships are developed and maintained with stakeholders internal and external to DaS.To lead the strategic direction and manage the implementation of business objectives through supporting service improvement that meet patient/client/customer needs.To provide leadership across DaS in total quality management approaches ensuring that the quality management system remains fit for purpose in relation to standards, compliance and registration requirements.To enable DaS to fulfil its health and safety statutory requirements and responsibilities through the implementation of effective safety management, organisation, safe working practises and health promotion.To provide leadership and support to the sustainability agenda ensuring DaS meets its corporate commitments in monitoring, reporting and improving environmental outcomes. |
| **3.** | **DIMENSIONS** |
|  | The post holder will lead the quality management function for DaS and will support improvement across all business areas in response to customer need.The post holder is responsible for ensuring all DaS business areas maintain ISO and UKAS standards and registration, and lead or oversee DaS and NSS improvement programmesThe postholder will enable DaS to fulfil its health and safety statutory requirements and responsibilities through the implementation of effective safety management, organisation, safe working practises and health promotion.The post holder and will be responsible for ensuring health and safety and environmental issues are monitored on behalf of the strategic business unit (SBU).The post holder will carry out line management duties*NB: The dimensions of this post have been extended as indicated and the wording has been refreshed in other statements* |

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| **4.** | **ORGANISATION CHART** |

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| **5.** | **ROLE OF THE DEPARTMENT** |
|  | The role of the DaS Strategic Business Unit (SBU) is to support the NHS Scotland national eHealth agenda through the effective delivery of digital products and specialist services that will enable clinical process and efficiency improvements across Scotland. This includes the delivery of digital services, systems, data, and contracts which enable cross-Board/ boundary integration, workflow, information sharing, cost efficiency realisation and collaboration.The DaS SBU has of the order of 400 staff, spread over sites across Scotland, where national level software application products are developed, maintained and supported. The DaS SBU is currently involved in over 50 projects and programmes in support of Digital Health and Care across NHS Scotland.The vision of the organisation is * to operate as a centre of excellence for digital, security, data and technology in Scotland, DaS aims
* to work collaboratively with our public sector partners to identify and deliver trusted and secure digital solutions to help us all achieve the ambitions for health and social care in Scotland.

The DaS SBU works in partnership with a wide range of organisations – NSS, NHS Scotland NHS Boards, Hospitals, Primary Care Practitioners, Community Health Partnerships, Local Authorities, Scottish Government Directorates, academic institutions, Other UK eHealth agencies, and major IM&T product and service providers operating in the Scottish public sector.The National Clinical Informatics Service for Scotland (NCISS) is a clinical sub-unit of DaS. Clinical informatics is a developing multidisciplinary clinical specialty and Clinical Informaticians must not only have a good working knowledge of their professional field of practice, but also have good knowledge of both how the healthcare system within NHS Scotland functions, and how Technology operates within this environment.The Quality Management Service will be responsible for standing up and maintaining a Quality Management System (QMS) for DaS, with a specific focus on Software as a Medical Device (SaMD) in addition to all other relevant areas requiring QMS use. |

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| **6.** | **KEY RESULT AREAS** |
| 1. Develop and implement a continuous improvement strategy for DaS informed by international standards and improvement models, working with staff at all levels within the organisation, ensuring that the benefits of the model are delivered to the staff, SBU 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 SBU Quality, Assurance, Health and Safety and Environmental activities are aligned to NHS NSS priorities so that the long term benefits are realised and ensure these processes are correctly initiated, implemented, co-ordinated, managed and controlled, so that existing registration and accreditation to the relevant ISO and IEC standards maintained.
4. As the SBU lead for Quality and Compliance, provide professional expertise, advice and guidance to all SBU staff in relation to Quality, Compliance, Health and Safety and environmental issues.
5. The postholder is responsible for developing SBU quality policy and procedures drawing from a wide range of sources such as legislation; EFQM documentation; international standards; internet research and current best practice.
6. Responsible for ensuring that the quality management system remains fit for purpose and meets the requirements of the relevant ISO and IEC 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.
7. 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.
8. 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 expectation. Use trend information to inform service improvement as part of continuous improvement.
9. Responsible for overseeing the management of SBU Health and Safety activities. This includes planning reporting, incident/accident investigations, risk assessments and health promotion and reviewing policies and procedures.
10. Lead implementation of environmental activities / certification, e.g. ISO14001.
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 medical physics quality assurance service for the Scottish Breast Screening Programme, Incident Reporting and Investigation, Sterilizer Validation Services and central contracting.
12. Lead the coordination and support of SBU improvement activities ensuring training opportunities are identified and made available to SBU staff in continuous improvement techniques and support effective team working.
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| 13. Work in partnership with colleagues in equivalent organisations within NHSS and NHS in England, Wales and Northern Ireland to develop national UK strategies, processes and measurements for benchmarking processes and activities. |
|  | *NB: changes highlighted in yellow* |

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| **7.** | **ASSIGNMENT AND REVIEW OF WORK AND DECISIONS AND JUDGEMENTS** |
| 1. The post holder will have the freedom to act on own initiative and schedule and prioritise their own workload within the strategic framework of the Directorate business plans. Resources will be allocated in accordance with the quality plan agreed by the Consultant Clinical Safety Engineer and improvement plans developed within the Directorates. Work will also be generated from the output from specific project and management meetings
2. Judgements will be based on knowledge and experience as well as interpretation of legislation, standards and customer requirements
3. Decisions will be based on the ability to balance management of resources, potentially conflicting priorities, the ability to think strategically and take account of staff governance, standards and NSS policies
4. Objectives will be set and reviewed through the appraisal process with the Consultant Clinical Safety Engineer.
5. The post holder will generate and review his/her own work to ensure satisfactory standards are achieved. A major role will be to promote the creation of ideas and initiatives designed to improve services, provide a safer work environment, reduce costs or increase productivity. Implementation will be by the post holder after agreement with the Consultant Clinical Safety Engineer and NCISS senior management team.
6. The post holder will continuously review quality of work within own areas of responsibility and across the workstreams as to the relevance of content, challenging poor quality work and poor performance where necessary
7. The post holder is required to show highly developed analytical skills involving matters such as problem identification, task definition, structuring of solutions or determining performance. The information is generated from areas such as supplier quality assurance appraisals, internal quality assurance audits, disciplinary investigations, customer issues, risk analyses, accident investigations, environmental issues 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.
8. Regularly undertakes research on topics such as:
	* customers’ perception of the service delivery of individual sections;
	* surveys of staff attitude, opinion and perception;
	* on site evaluation of suppliers’ processes.

This includes the formulation of questionnaires, the content of which are tailored to specific processes and customers. Analytical and statistical skills are required in order to provide meaningful information that forms the basis for identifying opportunities for improvement, formulating action plans and setting up outcome monitoring.*NB: additional statements highlighted in yellow to reflect line management duties and new reporting structure as the level of specialism required to fulfil the role.* |

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| **8.** | **COMMUNICATIONS AND WORKING RELATIONSHIPS** |
| **Internal**1. 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; accident investigations; customer surveys. This requires developed interpersonal skills to secure meaningful results through good communications e.g. people skills, listening, empathy and motivation.
2. Presenting often highly complex or highly 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.
3. Liaise, lead and promote quality, improvement and compliance across the SBU through leading and planning development and improvement programmes and communicating through face to face meetings, e-mails, publishing articles, participation in working groups; making presentations and training staff at all levels.
4. Liaise and work in partnership with NSS quality improvement team to implement agreed improvement reviews and improvement programmes requiring highly developed interaction and communication skills to achieve objectives
5. Influencing, persuading and questioning techniques are employed whilst undertaking internal audits and during continuous improvement activities.
6. Promote and deliver training to SBU staff about continuous improvement and quality management, quality standards and systems.

**External**1. Manages the relationships with BSI, UKAS, external auditors and specialist QA consultancy companies regarding the maintenance of the relevant ISO and IEC registrations and accreditations together with maintaining the process of continuous quality improvement. BSI audits are typically 3 days per year and UKAS audits are typically 2 days per year.
2. Communicates with customers and suppliers regarding complaints, satisfaction measurement and opinion surveys to ensure satisfactory complaint resolution and to establish perceptions. Managing customer expectations and complainants require effective interviewing and questioning skills.
3. Participates and collaborates with other NHS Bodies and outside agencies regarding Quality Improvement and Assurance to share best practice and maintain knowledge base.
4. Actively participates with other NSS staff to implement national or NSS initiatives ensuring that Divisional staff are consulted and their interests taken into consideration.
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| **9.** | **MOST CHALLENGING PART OF THE JOB** |
| a) | DaS adopts a process of continuous quality improvement to ensure it delivers services that will support the highest possible quality of patient care in Scotland.The postholder must motivate, develop and guide SBU staff to achieve this objective by* Creating a change in culture that will deliver full commitment to Health and Safety, environmental issues, continuous improvement and quality assurance activities in a changing environment.
* 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 SBU teams to meet organisational and improvement objectives
* Managing conflicting priorities to produce results that will improve SBU service delivery to customers.
* Managing teams by persuading people to work together to arrive at balanced, practical and realistic decisions.
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| **10.** | **SYSTEMS** |
|  | 1. The post holder is responsible for ensuring that records of all calculations, analyses and outcomes relating to SBU processes are maintained in accordance with the requirements of the relevant ISO and IEC standards.
2. Use of Quality Management System software that maintains information, records, change requests, document control and equipment calibration.
3. Microsoft Office suite that includes Outlook, Word, Excel, PowerPoint, Project and PI database.
4. NSS systems, electronic and paper based
5. Web based applications
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| **11.** | **PHYSICAL, MENTAL, EMOTIONAL EFFORT** |
| **Physical Effort**The position requires nominal effort such as using VDU, sitting at desk, attending meetings and other associated office tasks. May have a requirement for light effort for short periods e.g. standing, walking or carrying light loads. |
| **Mental Effort**Work is conducted in an open plan office. As a consequence, frequent interruptions are experienced because of conversations, telephone calls and normal day to day activities of other staffFrequent requirement for concentration within an unpredictable work pattern.Long periods of concentration are required for activities such as: analysing information from legislation or standards; investigations into disciplinary or process problems; writing reports about all aspects of DaS quality activities; researching and producing raw data; writing process procedures; processing raw data statistically; auditing processes; preparing for meeting; producing project plans for continuous improvement; responding to documents from a variety of sources such as the 'Summaries of reports of investigations of complaints about NHSScotland' published by the Scottish Public Services Ombudsman.Responding to questions from BSI or UKAS auditors during assessment audits when justification has to be made about our interpretation of standards.Interruptions to concentration can occur either in person or by telephone to provide advice or answer queries.Regularly design and undertake research on topics such as:* customers’ perception of the service delivery of individual sections;
* surveys of staff attitude, opinion and perception;
* on-site evaluation of suppliers’ processes.

This includes the formulation of questionnaires, the analysis of results, identifying opportunities for improvement, formulating action and monitoring results.**Emotional Effort**Exposure to dealing with adversarial behaviour from external auditors, staff and customers. This can occur because of differences of opinion during or as a result of health and safety and environmental work, continuous improvement activities, internal auditing, accident investigations, workplace inspections, implementing recommendations, during audits from external bodies and from the complaints processes. |

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| **12.** | **ENVIRONMENTAL/WORKING CONDITIONS AND MACHINERY AND EQUIPMENT** |
|  | 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 |

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| **13.** | **KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB** |
| Highly developed specialist knowledge of quality assurance, health and safety, environmental issues that is reinforced by theory and experience is required.The post holder will have a degree or equivalent in a relevant subject, be a member of an appropriate recognised professional body and have a comprehensive knowledge, experience and expertise of quality assurance, health and safety. This will be supplemented by further training, attendance at specialised courses and continual professional development.The post holder will have significant experience within the quality assurance profession and have experience in the application of techniques and systems to recognised British or International standards such as ISO13485 (Quality management systems, EFQM Excellence Model and Total Quality Management.The post holder will also have experience in an environment where there is a high level of interaction with a diverse range of stakeholders. This also includes advising NCISS senior management team, through Consultant Clinical Safety Engineer, and other managers on relevant matters relating to their areas of influence.The post holder must have initiative, have the ability to prioritise work, meet deadlines and to be able to demonstrate diplomacy and sensitivity when dealing with staff at all levels within the SBUThe ability to manage staff and assign and review work to meet the business objectives of the SBUThe post holder will be required to show initiative, demonstrate excellent leadership, tact and diplomacy.It is essential that the post holder possesses a high level of listening, facilitation, personal, numeric, written communication skills and oral communication.A good knowledge of information technology, software applications are required together with standard keyboard skills. A driving licence is an essential requirement.Provides and receives complex, sensitive information from internal or external sources such as reports, accident investigations, customer surveys. This requires developed interpersonal skills to secure meaningful results through good communications e.g. people skills, listening, empathy and motivation. |

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| **14.** | **JOB DESCRIPTION AGREEMENT** |  |
|  | Job Holder’s Signature: | Date: |
|  | Senior Officer/Head of Department: |  |
|  | Signature: | Date: |
|  | Title |  |