SNBTSG261



**NHS NATIONAL SERVICES SCOTLAND**

# JOB DESCRIPTION

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| **1. JOB DETAILS** | |
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| Job Holder |  |
| Job Title | (BMS2) Quality Officer |
| Immediate Senior Officer | (BMS3) Quality Manager |
| Division | SNBTS |
| Location | Jack Copland Centre, Edinburgh |
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| **2. JOB PURPOSE** | |
| As a key member of the Quality Assurance team, fulfils a supervisory role and provides a primary advisory function in the delivery of quality support to the Centre, satellite SNBTS sites (e.g. NAT(PCR) testing, Clinical Services, Clinical Apheresis depts.) and the SNBTS region.  The post holder has delegated responsibility for supervising departmental staff in the operational provision of, and for contributing to the development, delivery and maintenance of the Centre’s quality system to provide:   * Assurance of efficient performance of laboratory procedures always in compliance with regulatory and accreditation requirements * Assurance of timely and effective reporting of quality monitoring and service delivery performance data to other operational areas within Centre; and thus facilitating and affirming quality in the manufacture and provision of efficacious blood components, products and quality clinical services for patients * Day to day influence on working practices in the Centre and SNBTS region, by promoting the concepts of GMP and GLP, by investigation and action taken in response of adverse events and by contributing to the delivery of Quality Awareness training to Centre staff from all disciplines.   The scope of the work undertaken is wide ranging; due to quality support to all operational areas within the centre, to regional SNBTS collection teams and to transfusion professionals within the region. Consequently, in addition to professional expertise in Blood Transfusion, the post requires wide and on-going knowledge and experience of the organisation to discharge effectively a supervisory and advisory role in the provision of the Centre’s Quality Management System. | |

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| **3. DIMENSIONS** |
| The Quality Department retains staff in each of the five Regional Centres, Head Office and the SCRM. Additionally, the SNBTS Maintenance and Validation Services/Engineering team is part of the Quality Department.   * This post is required under current regulation or guidelines and work output may be the subject of regulatory inspection and assessment. * Postholder has some responsibility for the management of Quality department (as delegated by the Quality Manager), and will help manage the team budgets to ensure effective, efficient and accountable use of resources.            Postholder may manage department or area staff (n= 2-3 staff), however the post requires the postholder to persuade and influence staff within the Quality Department and other departments within SNBTS.   * Postholder is a delegated authorised signatory (within defined budget limits) for ordering materials, consumables, and re-agents, to ensure suffcient stockholding to maintain and complete on -going workload. Day-day ordering of consumables -£400-£500 daily. |
| **4. ORGANISATION CHART**  Quality Assurance Manager  Quality Manager  Quality Officer / BMS2  Quality Officer / BMS2 |
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| **5. ROLE OF THE DEPARTMENT** |
| SNBTS’s primary function is to provide blood components and clinical transfusion services to > 50 major hospitals. In addition, there is an increasing involvement in the provision of tissues and stem cells for patients in Scotland. The Service employs >1000 staff and its efficient operation makes a crucial contribution to patient care in Scotland.    The Quality Department provides quality management systems support and advice and quality performance monitoring functions to all areas within the Service and, increasingly, provides advice on Quality Management Systems to peripheral blood banks and hospitals within NHS Scotland. A key area of activity is in ensuring that SNBTS remains up to date with all regulatory developments which could affect our activities. Specific activities within the Department include the following:           Development and maintenance of a functional quality management system (QMS) which meets the needs of appropriate regulatory and accreditation bodies *e.g.* MHRA, HTA, UKAS. Elements of these are delivered centrally and others are delivered locally within all centres (five regional, Head Office and Scottish Centre for Regenerative Medicine (SCRM) sites).         Ensures ongoing compliance with current regulatory standards to achieve continued approval by licensing and accreditation bodies.        Provides the focus within the Service for effective communication, investigation and management of quality related problems, to raise standards and promote the concepts of continuous improvement and customer satisfaction.        Disseminates and promotes quality ethos to all SNBTS staff and throughout the country at the SNBTS / ‘customer’ hospital interface. |
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| **6. KEY RESULT AREAS** |
| * 1. Delegated co-ordination of the throughput of samples from blood components, and supervision of the performance of quality monitoring testing and analyses in accordance with the BSQR & Guidelines for Blood Transfusion Services in the U.K and in compliance with GMP. Review trend analysis data of assay controls for any adverse trends, which might affect the accuracy, reliability and/or reproducibility of results.   Identify out of specification blood components and consider and initiate appropriate actions to prevent the release of substandard product for patient care.  6.2 Supervise the entry of quality monitoring data into the Quality data-base utilising NWA Quality Analyst software; reviewing and authorising quality-monitoring reports, and performing trend analysis on data to identify and highlight any adverse trends. Prepare and review component quality monitoring data from Centre for onward reporting to Quality Department; thus providing the basis for the preparation of local and national quality reports.  6.3 Record, examine and perform trending of defects in relation to blood collection bags, Apheresis kits, or technical issues. Prepare and review data, which will form the basis for local and National reports. Liaise with manufacturers in product fault reporting, and in the subsequent reconciliation of fault liability.  Where potential for other blood component or production deficiencies, either due to defective manufacture or technical failure, is identified, assess and ensure appropriate corrective actions are implemented; highlighting any trends or defects of potentially major consequence to the Quality Officer for further consideration.  6.4 Supervise the review of temperature monitoring data of blood and blood component deliveries. Investigate and report any out of specification deliveries identified in accordance with regulatory guidelines for Blood and in compliance with GMP.  6.5 Perform and supervise the temperature mapping of critical storage areas for blood components and blood products and review the reports. Identify any non-conforming storage areas and participate in the investigation of any deviation from specification.  6.6 Supervise the performance of a wide range of environmental monitoring procedures in all areas within the centre. Review the monitoring data, identify and assist in the investigation of any out of specification conditions.  6.7 Monitor the operational performance of the Centre’s system for temperature control and monitoring of critical storage areas. Co-ordinate calibration of temperature probes and alarm challenges to ensure compliance with GMP; liaising where necessary with departmental staff, MVS and/or system suppliers in relation to any problems identified.  6.8 Delegated responsibility for review of QC inspection checks and release (manual & electronic) of incoming product. Review the investigation and inspection reports of post - release reports of non-conforming product.  6.9 Co-ordinate the appropriate response to notifications of routine recalls of non–conforming blood components, products or consumables. Participate and assist as delegated in the co-ordination and reconciliation of non-routine or extensive product/component recalls; liaising as necessary with other SNBTS Centres and hospital blood banks.  6.10 Identify, gather and document relevant information required in reporting of quality incidents; with responsibility as delegated for incident investigation and advising on appropriate corrective and preventative measures.  6.11 Lead in the performance, and reporting of local internal/self inspection audits, and participate in the compilation of audit checklists and planning of audits. Participate in the SNBTS Audit Programme, which ensures systematic review of practice and regulatory compliance within all SNBTS sites.  6.12 Participate in performing equipment calibrations. Review reports; identifying and removing from use any equipment, which does not meet specification, within Quality Department  Responsibility as delegated for planning, writing protocols, execution and reporting of change control and validation exercises on new processes and/or equipment.  6.13 Contribute to the development, preparation and critical review of procedural documentation. Initiate and supervise the continuous review of working methods and SOPs; identifying any problem areas and making suggestions for improvement.  6.14 Participate in the recruitment process for BMS1, trainee and MTO grades within the Quality department and participate in their development, motivation and performance review.  6.15 Participate in the training of BMS 1 and Trainee grades during secondment from other SNBTS departments, and as visitors from other organisations. Participate in the delivery of Quality Awareness/GMP training to all regional staff, and involvement in the delivery of Quality training as part of the SNBTS Induction Programme.  6.16 Complete and authorise stores requisitions for operational supplies. Raise on-line requisitions for non- stores items on authorisation from the Quality Manager. Supervise the monitoring of stocks of operational supplies.  6.17 Participate in multi-disciplinary project teams dealing with the development of novel blood components or services, in the implementation of blood safety initiatives or related to quality issues identified.  6.18 Regular use of a wide range of software packages. These are applied to a variety of quality functions: data entry, trend analysis and report preparation in Quality Analyst; QPulse for the management of incidents, equipment calibration and maintenance; Comark evolution software for the retrieval of temperature monitoring data; MS Word for the preparation of written reports; Excel in report generation; Power point for preparation and delivery of presentations; email system etc.  6.19 Ensure that all maintenance, calibration and validation of equipment and instrumentation is completed and documented on schedule to ensure the highest level of performance and output is achieved, within the Quality Department. 6.20 Will take part in, and assist in the preparation of reports on evaluations/trials/projects involving new tests, manufacturing processes, blood packs and/or equipment as required. |

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| **7. ASSIGNMENT AND REVIEW OF WORK** |
| Output from the postholder will be self generated or delegated by the Quality Manager and/or Quality Assurance Manager, mainly in response to departmental targets and quality problems encountered within the Centre  and the regional hospitals it serves.  The operational objectives for the postholder are agreed and set annually with the Quality Manager, and thereafter formally reviewed at six months with informal discussion and review as required.  The postholder participates in local and National quality initiatives and projects as delegated by the Quality Officer and in the development of novel blood components/products or patient services. The postholder will be accountable to the Quality Manager for his/her contribution to their progress.  Dealing with quality problems and responses to requests for quality support and advice requires judgmental and investigative skill and, although guidance will be readily available, active participation in the decision making process and the ability to act independently and responsibly is expected.  In relation to analysis and judgement, the postholder is required to participate in investigations and discussions related to product non conformance and potential product quarantine/ discard or production halt situations by sourcing as delegated and collating investigative and quality test data. Participation in the analysis of root cause and the consequential development of strategies for preventative action are also involved. All of these functions require aptitude for logical investigation and skill in evidence-based decision making.  The postholder will plan and organise work to deliver laboratory work commitments accurately and on time; despite unpredictable demands made by developing quality issues.  Postholder is required to deputise for the Quality Manager in his/her absence. |
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| **8. COMMUNICATIONS AND WORKING RELATIONSHIPS** |
| Communication and effective individual people skills are key to the success of the department in promoting quality ethos within the centre and to transfusion practice in the region. The post holder must communicate widely with personnel at all levels within the SNBTS, and with Blood Transfusion & Haematology professional staff in regional hospitals; receiving and providing complex and sensitive information.  Provides highly specialist advice/training to less experienced staff and other professions including clinicians in a specialist area & hospital blood banks.  Key communications will include: Internal  * Quality Assurance Manager * Quality Manager * Associate Director of Quality and Regulatory Compliance * Laboratory Staff * Section heads/managers * Blood Collection teams and nursing staff. * Clinical & Donor Medics * NSS IT   Participation in operational and business departmental meetings, planning meetings and in interdepartmental operational meetings. External  * Professional personnel in local hospitals and peripheral blood banks. * Personnel in customer and supplier organisations. * Personnel within the Quality Department in the other SNBTS Transfusion Centres. * Suppliers in respect to technical specifications, defects and performance monitoring. |
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| **9. MOST CHALLENGING PART OF THE JOB** |
| * High levels of concentration * Meeting tight deadlines * The ability to think creatively and develop innovative approaches to solving specific problems as well as a degree of self-confidence and effective communication with both peers and managers whilst maintaining regulatory compliance. * Prioritising workload in response to unexpected QMS issues, own workload & that for other staff. * Working with constant interruptions to workflow either by telephone or in person & dealing with different demands on times & different priorities. |
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| **10. Systems** |
| * Quality data-base utilising NWA Quality Analyst software * QPulse * Evolution (Comark) * Email * LIMS, Proteus, eProgesa, Traceline, TissueTrace * MSOffice * Pecos * Temperature Monitoring System |
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| **11. WORKING ENVIRONMENT AND EFFORT** |
| **Physical Effort** |
| The post holder will be required to exert moderate physical effort e.g. lifting and moving cases of blood components/products and/or equipment. |
| Mental Effort |
| The post will require significant mental and on occasions emotional effort, in terms of the following:   * High levels of concentration and attention to detail inherent in work. * Great flexibility and organisational skills in responding to both short term “crises” and long term planned workload. * Need to meet tight deadlines to deal with immediate and unpredictable quality problems. * Effectively promoting the SNBTS Quality ethos in the concepts of continuous improvement, customer satisfaction and quality awareness within the Centre and to its extensive and varied staff groups by personal contact and training will require considerable communication and interpersonal skills. * The post may also involve extended hours on occasions in follow up to quality problems encountered. |
| **Emotional Effort** |
| * May be exposed to potentially stressful situations due to work pressures both personally and, in acting a supervisory role, with other members of the QA laboratory. * Dealing with staffing issues, as required, as a line manager. * Liaising with other Centres and hospital blood banks often require tact and good judgement in communicating information that may be of a sensitive nature. |
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| **12. ENVIRONMENTAL / WORKING CONDITIONS & MACHINERY AND EQUIPMENT** |
| Some adverse working conditions will be encountered by post holder:   * Occasional exposures through direct contact with potentially infectious blood and blood components. * Occasional exposure to adverse conditions of cold rooms and ‘walk-in’ freezers. * Prolonged use of visual display screens * Decontamination of equipment either routinely or prior to service or repair |
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| **13. QUALIFICATIONS AND/OR EXPERIENCE SPECIFIED FOR THE POST** |
| The post holder will have the following essential qualifications:   * An Honours Degree in Biomedical Science or equivalent acceptable to the health professions council. A Post Graduate qualification at MSc level (or equivalent demonstrable experience). HCPC registration in a relevant profession (e.g. Biomedical Scientist) or equivalent professional society registration/membership, (e.g. Royal Society of Chemistry). Demonstrates evidence of continuous professional development * Demonstrable post qualification experience in a relevant environment with some supervisory experience being desirable. * Demonstrable experience at BMS level 1 or equivalent. * A wide ranging operational knowledge of Transfusion Science practice required to provide the ‘first line’ advisory function in quality support to Centre. * They must maintain and further develop specialist knowledge across a wide range of work procedures and practices; underpinned by appropriate theoretical knowledge. * An understanding of GMP, regulatory and accreditation systems and quality management. The continued development of knowledge of Quality Management Systems and skill in its communication will be required to successfully perform the duties of the post. * Good communication (both verbal and written) and interpersonal skills. * Good organisational and planning skills. * Computer literate. |

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| **14. JOB DESCRIPTION AGREEMENT** | | | | | |
| A separate job description will need to be signed off by each jobholder to whom the job description applies. | | | | | |
| Job Holder’s Signature |  | | Date |  |  |
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| Head of Department |  | |  |  |  |
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| Signature |  | | Date |  |  |
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| Title |  | |  | | |
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| HR Department will check job description format and content and then send the job description to the AfC Team | | | | | |
| HR Representative’s Signature |  | |  | | |
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| Date Job Description Agreed: | |  |  | | |
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