#### Form JE 5



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| 1. JOB IDENTIFICATION |
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| Job Title: Lead Quality Manager |
| Responsible to:  | Clinical Laboratory ManagerDiagnostics LaboratoriesDiagnosticsAccess**1684(rev25)**1 |
| Department(s) |
| Directorate:  |
| Operating Division:  |
| Job Reference:  |
| No of Job Holders:  |

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| 2. JOB PURPOSE |
| This postholder is the specialist lead in Quality Management and has operational management of the Diagnostics Laboratories (Blood Sciences and Microbiology) Quality Management System and Quality Assurance in the Ninewells and Perth Royal Infirmary laboratories. In Blood Sciences and Microbiology, there is line management responsibility for quality officers as part of the Quality Management team. The Lead Quality Manager is part of the laboratory executive team where the decisions are made affecting the Quality Management system. As part of the Quality Management system a key responsibility is Clinical Governance, where the risks and adverse events are managed with attendance at the Quality and Performance Review meetings.The post holder has responsibility for the Quality Management Systems accreditation and regulation in all departments. They are responsible for co-ordination of the activities of the quality team and the design of the framework and controls which deliver the quality strategy for the integrated service and is acceptable and demonstrable to accreditation bodies. They will work with the Clinical Leads, managers and wider staff to develop and embed the culture of quality as an implicit ongoing priority which is delivered routinely within the daily working lives of all staff. The post holder will be expected to liaise with Quality Leads in other laboratories to enable a lean approach to delivery of Quality Management systems, accreditation with relevant bodies and to enable sharing of best practice.They will provide expert advice to the Clinical Director of Diagnostics, Clinical Leaders, Clinical Laboratory Manager and laboratory staff on compliance and improvement measures. They have specific responsibility for ensuring that the services meet all internal governance and external accreditation standards, advising senior staff of requirements arising from evolving quality standards. They provide professional management leadership for clinical staff, scientists and support staff over a wide range of Quality Assurance, document control, adverse event management, audit and training in Quality Management, supporting the Clinical Laboratory Manager in the delivery of a high quality, continuously improving, clinical laboratory service. The post holder will liaise closely with the management teams, providing expert advice and guidance on interpretation, implementation or amendments to the quality policy or laboratory processes identified by scientific/clinical development or audit.They have responsibility for day-to-day line management, personnel development of the Blood Sciences, Microbiology Quality teams. Management of the internal audit processes and ensuring compliance with ISO 9001/15189, regulation to MHRA/HSE, including the review and management of Service Level Agreements, and Research & Development programme documentation. |
| 3. ORGANISATIONAL POSITION |
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| 4. ROLE OF DEPARTMENT |
| NHS Tayside Diagnostics Laboratories provide a comprehensive analytical, interpretative and clinical advisory service to primary and secondary care across NHS Tayside, North Fife and South Grampian. The department also collaborates in a range of research and development and clinical audit projects within Tayside, nationally and in association with third sector organisations and diagnostic companies. There is a considerable commitment to teaching across a diverse range of students, healthcare professionals and professional institutes.The Department is accredited to ISO 15189 standard, accredited separately as Blood Sciences and Microbiology. NHS Tayside Blood Sciences department is a United Kingdom Accreditation Service (UKAS) accredited medical laboratory No. 8681; and Microbiology No. 8610. The annual workload of the Department is in excess of 7 million tests, with workload rising by approximately 3-5% per annum, with a continually expanding repertoire. The total annual budget is over £20 million comprising of approximately £12 million staffing and £9 million reagents, consumables, equipment and services. The Department operates its services 24 hours per day, 365 days per year. Blood Sciences comprises of the following departments: Biochemistry, Haematology, Immunology, Bowel Screening, Point of Care Testing and Phlebotomy. The Blood Sciences laboratories receive over 10000 samples per day with a workforce of over 140 members of staff.Blood Sciences provides a 24/7 high quality, analytical, interpretive, and advisory diagnostic service, across two sites, with the main laboratory facility being at Ninewells Hospital in Dundee and a multi-disciplinary laboratory at Perth Royal Infirmary (PRI). The department is also a specialist referral centre for a range of tests, hosts the Scottish Bowel Screening Service, and provides Clinical Consultancy for Immunology across number of Scottish Health Boards.The multidisciplinary laboratory at PRI includes Biochemistry, Haematology and Blood Transfusion, which is regulated by the Medicines and Health Regulatory Agency (MHRA).Microbiology comprises of Bacteriology and Virology in Ninewells Hospital, including a multi-disciplinary Molecular Microbiology Diagnostics suite, providing a comprehensive analytical, interpretative and clinical advisory service. The Microbiology laboratories receive over 250,000 specimens per annum and employ over 100 staff. The Department acts as a source of expertise on control and management of infection, sterilisation and decontamination, antibiotic use and health and safety**.** Microbiology also provides a logistics service for the transportation of samples, pharmacy vaccines and chemotherapy drug deliveries across Tayside.The development and delivery of molecular assays for a number of microbial targets provides opportunities for rapid diagnosis in clinically relevant timeframes and permits detection of existing, new and emerging organisms of Public Health importance. These molecular assays are a new and expanding part of the Microbiology service provision. |
| 5. KEY RESULT AREAS |
| The postholder is responsible for the development of the Quality Management systems for Diagnostics Laboratories (Blood Sciences & Microbiology.They will lead the Blood Sciences and Microbiology Quality Management team to achieve this, where appropriate, in collaboration with other Quality Managers in the Diagnostics Group. They will be required to take responsibility for their own work, within a matrix management structure. They will also provide leadership and direction on quality and improvement issues, working with senior management within the department as an advisor on quality issues developing a team approach and encouraging sharing of best practice.* To lead on the integration of the Quality Management systems of the substituent Blood Sciences, Microbiology, to enable the department to maintain UKAS accreditation, MHRA and HSE regulation and advise on best practice across the disciplines.
* Day to day line management for the Quality team in Blood Sciences and Microbiology departments. Developing the Quality teams to ensure continued ongoing competence.
* Assess and advise the Clinical Laboratory Manager and Clinical Leads on compliance and appropriate improvement for non-compliance with the standards for external accreditation and regulatory schemes, UKAS, MHRA and HSE.
* To work co-operatively with lead quality managers from other disciplines within NHS Tayside to identify and address the overhead associated with delivery of accreditation:
* Sharing of best practice.
* Developing common approaches to generic issues and challenges across the Diagnostics group and laboratory services in other Directorates.
* To enable development of approaches that embed the tasks required for delivery of the Quality Management System and maintenance of accreditation standards as accepted day to day activities of all staff groups.
* Contribute highly specialist managerial knowledge and experience to service planning, management and development discussions in department strategic and operational committees.
* Provide the focus within the department for effective communication, investigation and management in Quality Management and to raise quality standards and promote the concepts of continuous improvement and customer satisfaction to all staff.
* To ensure staff involved with the investigation of adverse events or near misses are appropriately trained to undertake the task. They will discuss and agree appropriate action points with the Laboratory Managers, oversee their implementation and review the action plan for completion.
* To be responsible for the investigation, in consultation with the Clinical Leads and Clinical Laboratory Manager of all complaints and ensure that effective remedial and follow up actions are taken.
* Assess and advise the Clinical Laboratory Manager and Clinical Leads on compliance and appropriate improvement for non-compliance with the standards for external accreditation and regulatory schemes, UKAS, MHRA and HSE.
* Liaise with users of the service in the organisation and execution of regular feedback surveys. To monitor and advise the management team of negative feedback and implement appropriate actions identified to improve service delivery.
* Participate in joint discussions with clinical staff regarding the evaluation of laboratory quality standards and monitoring indices to ensure they are fit for the intended clinical setting. Discuss and agree a form of reconciliation or update to techniques with the management team in the light of adverse trends or poor performance.
* Design and review a Quality Management training programme that is robust and fit for purpose.
* Propose and write Standard Operating Procedures and departmental policies that define, reflect and improve activities/cultures within the Laboratory. As required, participate actively in formulating and maintaining department policies, to ISO 15189 standards appropriate for accreditation.
* Ensure that mechanisms are put in place to ensure that the department’s standard operating procedures, policies, Quality Manuals, User Guides and Quality policies are regularly reviewed, and document controlled on Q Pulse. Adhere to policies and procedures relevant to all areas of work in accordance with Department, Group, Hospital and regulatory requirements.
* Act as administrator for the Q Pulse Quality Management software and advise on future applications or upgrades.
* To lead the quality teams in planning and organisation of the audit programme, monitor recording of all non-conformances, corrective actions, recording of audit and reporting outcomes to the Clinical Laboratory Manager. This involves a broad range of complex activities including development of Quality Objectives, planning development of QMS to meet ongoing ISO standard / UKAS accreditation as well Health and Safety Executive (HSE)and MHRA Regulatory changes, which require the formulation and adjustment of plans.
* To ensure the department’s continued participation in appropriate external quality assessment schemes. Monitor performance in internal and external quality control and assist managers to investigate poor performance and instigate remedial action.
* To appraise the Blood Sciences, Microbiology Executive Team, of new initiatives in the development and performance of the Quality Management systems.
* Provide independent monitoring of performance in internal and external quality control and assist section leads to investigate poor performance and instigate remedial action.
* Provide expert advice and support to Blood Sciences and Microbiology staff on Quality Management matters, this includes leading on LAER, interpretation on accreditation and regulatory matters.
* Appraise the Clinical Laboratory Manager and Clinical Leaders of new initiatives in the development and performance of the Quality Management systems. Liaise with the Clinical Laboratory Manager regarding the availability and allocation of resources to meet quality improvements. Working closely with the Clinical Laboratory manager to review financial statements, budgets and potential areas for savings targets.
* Approver in SSTS, confirming the Microbiology Logistics staff hours of work.
* Organising the invoicing for accreditation activities with UKAS.
* To keep up to date with national guidelines and current topics in quality to support expert knowledge and assist the Clinical Laboratory Manager in implementation of new developments.
* Produce reports of quality outcomes in Blood Sciences and Microbiology e.g. SBAR’s, User survey, turnaround times, quality reports, audits, adverse event reviews, and compile the annual reports for the Blood Sciences and Microbiology review meetings and the summary report for accreditation and regulatory bodies.
* To monitor performance indicators agreed by the Diagnostic Improvement Group, have a focus on system improvement and agree implementation with the Clinical Laboratory Manager within agreed timescales and alert the Clinical Laboratory Manager to delays.
* Contribute to the support of the Departments general management activities within the management team.
* To implement the requirements of the RCPath Key Performance Indicators, reporting on compliance at Blood Sciences and Microbiology meetings with escalations to the Diagnostics Improvement Group and Quality & Performance Review meeting.
* Collation of patient surveys and feedback to services.
* Conduct Quality Management induction and training programmes for the clinical and technical service.
* Participate in equipment procurement, leading on laboratory purchases where required, as well as providing expert advice for other managers procuring equipment in line with accreditation and regulatory requirements.
* Participate in disciplinary/grievance panels, investigations and outcomes.

**Training, Education and Development*** Maintain and develop the Quality Management Training in Blood Sciences and Microbiology departments.
* To develop and deliver in-house training and tutorial support to Clinical staff, Biomedical Scientists, trainees, Medical Laboratory Assistants, medical students and Specialist Trainees in Quality Management.
* To participate in review of training logbooks and personal portfolio’s to ensure they are kept up to date and signed off on a regular basis as competence and proficiency is achieved in Quality Management.
* To undertake and establish evidence of continuing professional development and proficiency in order to maintain mandatory HCPC registration, which will be formally reviewed at Personal Development Review meetings.

**Personnel*** Responsible for the line management of the Quality Management team in Diagnostics Labs (Blood Sciences & Microbiology).
* Participate in the recruitment and selection process involving the selection, short-listing and interviewing of Managers, Scientists, Trainees and support staff candidates.
* Participate in Personal Development Review and conduct PDR interviews with scientist and support staff. Liaise with the senior laboratory staff in the appraisal process and contribute to the provision of suitable objectives for staff.
* Ensure that all new staff receives appropriate Quality Management induction.
* Manage personnel using eESS for attendance, maternity, sickness absence and return to work interviews.
* Participate in the initial stages of complaints from staff, supports grievance and disciplinary investigations in accordance with NHS Tayside or One for Scotland policies.
* Regularly update management and Quality Management knowledge to ensure continual ongoing competence.
* Assess and advise the managers in laboratory procurement project teams on the Quality Assurance aspects in the evaluation of new analysers and reagents.
* Assess and advise the managers on the impact on Quality Assurance in the validation of changes to process in the laboratory.

**Health and Safety*** Comply with and ensure compliance within the section to National, Tayside and department Health and Safety policies, procedures, rules and regulations, e.g. NHS Tayside and Department Health and Safety policies, Control of Substances Hazardous to Health, risk assessment and manual handling.
* Maintain competence in the safe handling of spillages of biohazardous material and broken sample containers.
* Liaise with H&S groups within the laboratories to maintain a safe working environment for all staff
* To be fully aware of the dangerous pathogens advisory groups classification of pathogens, the rules and regulations for containment and the safe handling of high risk samples.

To support NHS Tayside values of quality, teamwork, care and compassion, dignity and respect, and openness, honesty and responsibility through the application of appropriate behaviors and attitudes.**Responsibility for Records Management and retention**All records created in the course of the business of NHS Tayside are corporate records and are public records under the terms of the Public Records (Scotland) Act 2011. This includes email messages and other electronic records. It is your responsibility to ensure that you keep appropriate records of your work in NHS Tayside and manage those records in keeping with the NHS Tayside Records Management Policy and with any guidance produced by NHS Tayside specific to your employment. |
| 6a. EQUIPMENT AND MACHINERY |
| * Temperature monitoring systems
* Laboratory analysers and equipment
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| **6b. SYSTEMS** |
| * Networked laboratory computer system
* Independent software e.g. Q Pulse
* NHST Business Systems
* E-mail and various word processing packages
* SunQuest Integrated Clinical Environment (ICE) requesting/reporting system
* Quality Assurance systems
* Video conferencing software
* Mobile devices as part of the executive team
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| 7. ASSIGNMENT AND REVIEW OF WORK |
| The Quality Manager will report directly to the Clinical Laboratory Manager. |
| **8. DECISIONS AND JUDGEMENTS** |
| * Operates within department procedure and policies and own scope of practice.
* Decides upon the priority and organisation of own work in co-ordination with other team members, deadlines and meetings as allocated by Clinical Laboratory Manager. Enjoys considerable autonomy and may refer or discuss complex situations with the Service Managers.
* Identifies resources required to support existing and new quality improvements.
* Uses own judgement to support the Clinical Laboratory Manager in identifying action points to resolve non-compliance and poor performance.
* Makes judgements on whether the departments continue to meet accreditation and regulatory standards and key performance indicators (KPIs) in self inspections and initiates action plans as appropriate.
* Assesses staff as competent to carry out Quality Management duties within the laboratories.
* May be required to deputise and make decisions on behalf of Clinical Laboratory Manager.
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| 9. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB |
| * Negotiating with and influencing the behaviour of staff and managers within the organisation to achieve a Quality Management culture through quality objectives and training.
* The ability to cope with demanding situations and tight deadlines.
* Supporting staff to maintain high quality service provision to ISO 15189 (Laboratory) and s, MHRA and HSE regulatory compliance.
* Maintaining advanced, specialist expertise in an environment characterised by rapid change and development.
* Investigating highly sensitive adverse events using root cause analysis to identify the sources of error and to put in place corrective action and preventative measures. Empathy, tact and reassurance are required while discussing incidents with staff involved to establish the root cause without apportioning blame.
* Maintaining a positive working culture.
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| **10. COMMUNICATIONS AND RELATIONSHIPS** |
| The postholder is accountable to the Clinical Laboratory Manager. The post holder can take unresolved issues of quality directly to the Associate Medical Director and Clinical Care Group Manager should this be required.* Within the line management structure, they will be responsible for the Quality Management team’s activities.
* Organise and Chair departmental quality meetings.
* Provides the culture within the department for effective communication, investigation and management in relation to Quality Management, to raise quality standards and to promote the concepts of continuous improvement and customer satisfaction which requires negotiation skills.
* Meet regularly with the management teams to discuss quality management aspects of service planning, management and development.
* Within the laboratory, they will communicate with managers, scientists, support staff, medical staff, clerical staff and others to discuss Quality Management issues matters:
	+ Development of Quality Management and improvement strategy
	+ Quality Assurance reports and action plans related to audit, quality control and incident review.
	+ changes to policy/procedures in a timely manner
	+ new issues in Quality Assurance
	+ service redesign and improvement
* As well as accreditation related issues, issues relating to GCP, GCLP, ISO standards and regulatory requirements.
* Meet with the Training Officer(s) to discuss training requirements for students and trainees.
* Meet regularly with the Clinical Leads and Clinical Laboratory Manager to discuss quality reports, governance and accreditation and regulatory issues.
* Out with the laboratories and Diagnostics Group, they will liaise with staff from accreditation and regulatory bodies: UKAS, MHRA, HSE, and discuss accreditation standards and national regulation.
	+ liaise with staff from accreditation and regulatory bodies: UKAS, MHRA, HSE, SNBTS and discuss accreditation standards and national regulation.
	+ liaise with staff from EQAS agencies in respect of quality performance, and standards.
	+ manage and chair meetings regularly with Quality Managers in other disciplines to ensure consistency of approach throughout Diagnostics, to share examples of best practice and to identify opportunities for common approaches to delivery of Quality Management and accreditation.
	+ represent the Department as the laboratory expert at external quality meetings.
* Communicate with NHS Tayside Executives on laboratory matters, directly or through the clinical governance meeting structure. Presenting laboratory data to the executives for scrutiny and ongoing justification for the performance of the departments.
* Deputise, when required, for the Clinical Laboratory Manager at appropriate meetings and in projects.
* The Quality Manager will contribute to effective communication within the department through attendance at management meetings.
* Contribute to Department decision making and problem solving.
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| **11. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB** |
| **Physical:*** Sitting for extended periods of time at a personal computer for up to 3 hours per session daily. (50% time)
* Accurate hand-eye co-ordination in PC/keyboard skills.
* Long periods of presenting training material
* Chairing meetings and investigations i.e. LAER

**Mental/Emotional:*** Frequent periods of sustained concentration when compiling complex reports in multiple departments
* Continuous awareness of the risks involved in the handling of specimens and maintaining safe laboratory practice across two hospital sites.
* Occasional need to impart unwelcome news to staff and to deal professionally with the adverse reaction.
* Work patterns can be unpredictable and subject to interruption.
* Pressure of service delivery and maintenance of standards.
* Requirement to deal with human resource issues including counselling, staff grievance and disciplinary matters.
* Requirement to use subjective factual-based approach and good diplomacy skills when dealing with incidents/errors and complaints.

**Environmental**:* Occasional exposure to actually and potentially infectious patient specimens.
* Occasional exposure to a variety of hazardous chemicals with poison, corrosive and flammable risks.
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| 12. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB |
| * Registered with the Health and Care Professions Council (HCPC) as a Clinical or Biomedical Scientist in a relevant discipline.
* BSc (Hons) in Biomedical Science or equivalent in a relevant science subject.
* Institute of Biomedical Science IBMS post graduate Specialist Skills Diploma or equivalent.
* MSc and/or FIBMS or equivalent academic achievement ratified by a relevant professional body.
* Evidence of continuing professional development and proficiency in accordance with HCPC guidelines.
* Extensive experience as a practitioner in UKAS accredited clinical laboratories.
* Knowledge and experience of Quality Management systems, Lean management and investigation tools.
* Evidence of training i.e. in audit, quality control, risk management and adverse incident reporting.
* Training and experience in the use of IT applications to compile documents, databases and spreadsheets.

**Induction Standards & Code of Conduct** Your performance must comply with the national “Mandatory Induction Standards for Healthcare.  |
| **13. JOB DESCRIPTION AGREEMENT** |
| A separate job description will need to be signed off by each job holder to whom the job description applies.Job Holder’s Signature:Head of Department Signature: **(I confirm this Job Description accurately reflects the duties and** **responsibilities of the postholder and does not impact upon any other** **postholders role)**  | Date:Date: |