

# NHS FORTH VALLEY

# JOB DESCRIPTION

Quality & Training Manager, Laboratories

**1. JOB DETAILS**

**Job Title: Laboratories Quality & Training Manager**

**Responsible to**)**: Head of Acute Services- Diagnostics**

**Department(s): Microbiology, Pathology, Clinical Chemistry, Haematology/ Transfusion Clinical Laboratories and PoCT service.**

**Job Reference: BN-LABS-22-06**

**2. JOB PURPOSE**

The single post holder is responsible and accountable for the design, development, implementation, and maintenance of the Laboratories Quality Management System (QMS) and compliance with the Laboratories Training, Education & Competency Framework. Responsible for the provision of effective and high quality diagnostic services across distinct scientific specialties; Biochemistry, Haematology and Blood Transfusion, Microbiology, Pathology and PoCT (unaccredited)

**3. KEY DUTIES**

**There is a responsibility to:**

The Clinical Laboratories in Forth Valley Royal Hospital comprises departments of Biochemistry, Haematology (including Blood Transfusion), Microbiology (including Virology) and Pathology (including Cytology, histology, Infertility and Mortuary Services) and PoCT service which spans the Acute Service. The Quality and Training Manager is lead specialist for the Pan Laboratories Quality Management System (s) and Education and Training. As such, this individual’s responsible for Quality (UKAS ISO;15189 standards), compliance and competency aspects of the service to ensure compliance with mandatory regulatory agencies and compliance with Institute of Biomedical Science and Association of Clinical Biochemists Educational requirements.

The post holder works in partnership with the Department Managers, with the Head of Service as line manager for appraisal & HR aspects. In the role of Quality & Training Manager there may be situations where a conflict of interest could occur; in this dimension the reporting relationship will be directly to the Head of Clinical Governance.

The post holder will have responsibility across discreet departments, for achieving mandatory regulation for organisations which include:

Medicine and Health Products Regulatory Authority (MHRA)

United Kingdom Accreditation Service (UKAS)

Human Tissue Act (HTA)

Human Fertilisation and Embryonic Authority (HFEA) - as applicable.

A comprehensive, analytical, interpretive and clinical advisory laboratory based service is provided to: • Hospital In-patient, Out-patient and Day Care Units. • General Practitioners in Primary Care and Community Health Services and Hospitals. Prison Service, • Public Health Medicine. • Occupational Health • Procurators Fiscal

In addition the services collaborate in a range of research and development and clinical audit projects with clinicians and other Healthcare professionals.

A staff of >150 provide services to the Forth Valley population. Approximately 50% of the investigations are carried out for hospital based patients and 50% for General Practitioners.

Population screening programmes for example Sexual Health Screening, and other investigations linked to programmes of health improvement across the county.

All acute aspects of the service operate 24 hours each day 365 days per year. The service is provided by various professionals including Biomedical Scientists, Clinical Scientists, HCSW’s and Medical staff

The post holder will be expected to develop and implement policies and procedures relevant to all areas of work in accordance with Departmental, Unit, Hospital and regulatory requirements. Policies/procedures could affect areas out with the department.

The post holder will be involved in quality aspects of LIMS (Laboratory Information Management System) system changes, configurations, upgrades, evaluation work and decision making, ensuring compliance of any changes and documentation with ISO;15189 UKAS Accreditation Standards.

There is responsibility for continued development and management of a highly complex and effective multi-service Quality Management and Competency framework system for Laboratory Medicine This must be in accordance with Divisional policies and statutory accreditation standards.

Key duties include;

* May deputise for Department manager in ensuring Quality and Governance standards are maintained within departments e.g. via meetings and audit visits.
* Is lead point of contact for UKAS assessment visits
* Ensures compliance with Quality Management Policies to ISO;15189 standards
* Responsibility for training and Education Policies to Institute of Biomedical Science Educational framework
* Regulation to meet Health & Care Professions Council Standards of Proficiency and Conduct
* Liaison with internal and external organisations e.g. NES Healthcare Science and Higher Education Institutes.

Responsible for;

Design and implement user surveys (Acute site and community) and report responses to the Laboratory Management Team.

To construct and directly supervise a programme for all departments within the laboratories of internal and external audits against defined quality performance measurements, ensuring effective and immediate follow up actions are taken in compliance with UKAS standards.

Plan and oversee the scheduled audit programme for each laboratory discipline, including Good Manufacturing Practice audit, as well as overseeing completion of corrective actions and ensuring actions are signed off as effective.

Ensure that Diagnostic sample target Turnaround Times are monitored, achieved and maintained for the organisation.

Responsible for collating overarching annual reports for various mandatory regulatory agencies, such as MHRA and UKAS

To maintain and update the Laboratory Quality Policy and Quality Manual(s)

To liaise with Laboratory Managers and Quality Officers in all disciplines, to ensure all elements of the Quality Policies and Quality objectives are implemented and audited.

Responsibility to develop, establish, and maintain the Pan Laboratories Quality Group; including responsibility for chairing group meetings and development of a pan Laboratories Quality Plan to promote standardisation of polices and process across all Laboratory Departments

Ensure Training and Competency Assessment Compliance and directly supervise Training Officers in roll out

Chair Pan- Laboratories Quality Meetings and Educational and Training Group meetings

Attend Laboratories Clinical Governance Group and be the conduit to Head of Clinical Governance. Post holder is the Risk Coordinator for the Laboratories.

Attend and report for laboratories to the Ambulatory, Diagnostics and Theatres Clinical Governance group

Responsibility for Laboratories Risk Management

Adherence to NHSFV policies and current data protection legislation.

POCT Committee member

Ensure the Handbook(s) for all Laboratory Users is current and available electronically for the organisation and GP intranets

Organise and conduct clinical waste audits with relevant departments

Ensure there is a system of on-going safety training highlighting risks in each area, and ensure Health & Safety compliance of appropriate areas.

In collaboration with the Laboratory team, achieve and maintain accreditation to ISO;15189 standards with the certificating body, UKAS.

* **Patient Client Care**

**There is a responsibility to:**

The lead role in ensuring compliance with ISO;15189 Quality and Competency standards for all laboratory disciplines. The post holder must ensure integrity and quality of all laboratory results, which directly impact patient care and patient safety.

Ensure compliance with needs of all service users, and external regulatory agencies, which can directly impact patient care eg MHRA.

There will be frequent contact with service users e.g. response to complaints and adverse events, ensuring full investigations and root cause analysis are carried out, and reviews of protocols and standard operating procedures in response to incidents..

Responsibility for annual surveys of users, and actions from these.

Overarching responsibility for Quality Control Processes e.g. laboratory analysers generating patient results are implemented to ISO;15189 standards, with appropriate programme of audit in place.

* **Policy and Service**

**There is a responsibility to:**

The post holder is required to make an analysis, assessment and judgement of a number of conflicting legislation, guidelines, policies, processes and systems into the laboratories Quality Management System and Staff Training & Competency Programmes

Working with Department Managers, the post holder will contribute to and coordinate the Management Reviews for all departments (a requirement of ISO;15189 standards), an essential aspect of the accreditation guidelines with subsequent publication of reports for each discipline and to the Head of Service.

To ensure change control is applied to service developments across the disciplines.

Ensure, with the departmental training leads, that IBMS training accreditation is gained and maintained for pre and postgraduate training compliance, up to doctorate level.

To ensure any new and / or updated standards produced by UKAS, including the Competency standards within, are interpreted critically and implemented appropriately within the service, with responsibility for developing required documentation.

Establishes, implements and maintains the Quality Management System to ensure compliance with Good Manufacturing Practice (GMP) for Transfusion service.

As Lead for Risk Management for laboratories, establishes, implements and maintains the Risk Management System to ensure compliance with Legislative requirements.

Develop and implement quality indicators and systems that will support and deliver cost effectiveness and flexibility to meet patients’ needs.

Responsible for establishing and maintaining effective communication systems within, and between all departments to ensure that all staff are aware of changes and developments in Quality and Training and Competency standards.

* **Finance and Physical Assets**

Responsible for the budget associated with a range of United Kingdom Accreditation Services (UKAS) services to a value of £50,000.

Involved in recommendation, procurement and validation of equipment compliant with these processes, up to a value of £200,000 per item.

**There is a responsibility to:**

Monitor best use of UKAS budgets, ensuring departments are of required standard for assessment, eg extension to scope and pan-laboratories quality & training initiatives will be investigated, where applicable, to reduce assessment costs. Responsible for the budget for the Quality Management System to a value of £50,000

Manages Training budget for the laboratories ensuring equity of access

Contribute to the development and implementation of demand management within the service which will contribute to the reduction of inappropriate analysis and thereby contributing to the ongoing Cost Improvement Plan initiatives within the service.

* **Staff Management/Supervision, Human Resources, Leadership and/or Training**

Plan, co-ordinate and review a programme of staff education and development including performance and training.

Responsible for training Quality and Training co-ordinator teams in each of the departments, a major responsibility of the post..

This involves the development, organisation and delivery of training and competency assessment programmes, Specialist professional qualifications e.g. IBMS portfolio levels, Certificates of Expert Practice and Associate of Clinical Biochemists Educational requirements.

Orientation and induction of new staff as required (e.g. in the Quality Management System), and for qualified staff to ensure relevant training and competency compliance is maintained

Establish, develop, and maintain the Pan Laboratories Quality Group, and Education and Training Committee; including implementation of regular meetings which the post holder will chair, development of pan Laboratories Quality, and Education and Training Plans to provide an equitable and standardised approach to quality management, and education and training across all Laboratory Departments and for all Laboratory staff groups.

Lead on IBMS accreditation of departments to deliver Certificate of Competence and Specialist Portfolio training.

Establish policies and procedures where required in accordance with Hospital and regulatory requirements. Monitor compliance within areas of responsibility taking action to improve or maintain performance as required, advising other senior laboratory staff on the above.

Identify to Laboratory Managers and Head of Service, any areas of concern e.g. staff, equipment, regulatory compliance or work related issues.

Assist other senior staff in development of operational policies and in the assessment of new procedures, which may affect other service users’ e.g. new pieces of equipment and test repertoire.

Involved in planning new systems e.g. new pieces of equipment to ensure timely testing and reporting of clinical samples allowing Forth Valley wide improvement of patient care and patient safety.

Develops plans to ensure compliance with MHRA/ISO;15189 legislation which may require modification due to constantly changing guidelines and will impact staff due changes to processes, change control compliance etc .

Responsible for the teaching /delivery of specialist training in all aspects of quality management and training including competency standards.

Responsible for establishing and maintaining effective communication systems within, and between all departments to ensure that all staff are aware of changes and developments.

Responsible for delivering quality management and administrative standards, policies and procedures in accordance with hospital and regulatory requirements.

Liaise with users of the service, via User Surveys and other methods, to ensure that it meets their needs.

Attends Clinical Laboratory Management Group to advise on implementation of changes to policies and procedures, which may affect staff, and to enhance overall service delivery.

Trains laboratory Quality Officers on appropriate corrective or preventative actions to resolve problems.

Contributes to the development of hospital and NHS FV policies through involvement on Multi-Disciplinary Committees e.g. Emergency Planning Committee.

Support Trainee Clinical Scientist training programmes as required within departments.

Working with Department Managers, and under the QMS, ensures staff meet mandatory compliance regulation i.e. Health & Care Professions Council mandatory Continuous Professional Development.

Function as liaison between the department(s) and other hospital departments, other medical institutions, reference laboratories and vendors.

Contribute to the development of Hospital and NHS Forth Valley policies through involvement on multi-disciplinary committees.

Be the laboratories lead and representative at Organisational Risk Management at Risk management .

Responsibility, with lab managers, for programme of appropriate Contingency meetings.

Participates in recruitment exercises , particularly for Quality and Training personnel in each department

The POCT Manager will liaise with the Laboratories Quality and Training Manager in oversight of equipment monitoring, QC monitoring, audit and training and all aspects of compliance and competency of the POCT service with respect to ISO;15189 standards.

Support and develop educational visits to the laboratory for school pupils, nursing staff students, trainee clinical scientists and junior medical staff.

Coordinate delivery of Integrated Biomedical Science students Training Programmes, Pan-laboratories.

Liaise with HEI’s and external regulatory and audit of training eg IBMS and NES Healthcare Science

Coordinate Delivery of training to users of the laboratory services (e.g. Nursing Staff, Junior Doctors, and Trainees at prearranged study days.

* **Information Resources**

**There is a responsibility to:**

Record personally generated information relating to patients / clients on a regular basis, test results, case reports, financial, personal and / or research data.

Ensure the accurate recording of information and record keeping in line with Regulatory requirements and Professional Body guidelines.

Ensure the confidentiality of departmental records in line with Forth Valley Data Protection policy.

Uses Laboratory Information Systems and proprietary software to facilitate laboratory management functions: Compiles reports based on information

Develop and use i-Passport software package as the main tool for quality and laboratory management functions e.g. for producing, reviewing, storing documents and recording all staff training, customer complaints, equipment details and results of audit activity. The post holder will be the specialist for the i-Passport software system with accountability for its management and control.

Uses the Labor**a**tory Information Management System (LIMS) to extract required information.

Be proficient in the use of MS Office software for the production of documents, tables, charts, spreadsheets, surveys and presentations

Ensure that information is dealt with in an appropriate, sensitive and confidential manner at all times.

Use IT equipment including local and national systems to read, analyse and record patient / client information within the scope of local and national policies and procedures.

Responsible for the electronic quality and competency management system, i-passport, to ensure it meets the needs of the staff and service.

Use of PC’s and associated software applications, e.g. Microsoft Office 365 applications e.g. Microsoft forms

Will contribute to LIMS system evaluations, upgrades and ensure ISO;15189 compliance with change control.

Use of projectors for Powerpoint presentations.

Use of MS Teams functionality to conduct business.

* **Research and Development**

**There is a responsibility to:**

Recommend, guide, evaluate and implement new equipment, analytical methods, laboratory procedures and organisational changes as necessary in consultation with Department managers and Clinical Lead for the service.

Report on Clinical and Scientific audit and be point of contact for FV Clinical Trials Work.

Prepares reports for internal and National Audit Committees.

Be aware of any audit and research in progress with in the area and contribute to these as appropriate.

**Skills**

* **Physical**

May require multi tasking and prioritisation of work

Manual handling is required transporting documents and notebook computing equipment between the NHSFV departments and while conducting audits in te laboratories..

Sitting at VDU in the same positionfor long periods, e.g. compiling reports, and authorising documents

Standing for long periods of time during laboratory audits/ teaching/ training.

* **Communication**

**There is a requirement to:**

Provide and receive complex or sensitive information. This information will come from or be given to:

Other laboratory colleagues

Medical and nursing staff

Higher Management Colleagues including Clinical Governance

The communication could be verbal, written or electronic. Present action plans, analyses including trends analysis of monthly/ quarterly/ annual Quality reports ie incidents, complaints, risk assessments, Health & Safety monitoring, audit and training programmes.

# Internal

Liaise with multidisciplinary teams and Support Services on service needs and requirements;

## Medical Staff

* Laboratory services
* Liaising with colleagues within Laboratory services and Boards
* Higher Management/ Head of Service
* Liaison with other Units:
* National groups

As Quality and Training Manager for the Laboratories to present reports and updates on Quality Management, or Education and Training issues to internal and user groups eg Scottish Quality Managers Discussion Group and IBMS in Scotland Group..

Dealing with UKAS inspection Teams and Training Verifications.

As Risk Co-ordinator for the Laboratories to liaise with other Units and Services in relation to Incidents and Risks associated with or identified with areas out with Laboratory Medicine.

* Member of NHS FV POCT Committee

## External

Hospitals/ eg Reference Laboratories out with the Acute site

External Regulatory Authorities e.g. UKAS & MHRA.

General Practitioners:

As Quality Manager for the Laboratories to present reports and updates on Quality Management issues to external user groups i.e. Primary Care Study Days, Practice Managers, Community Diagnostics User Group.

To liaise with GPs on laboratory related audits and Quality Improvements .

To develop, analyse, and report to GPs on User questionnaire responses and lead on actions from said user surveys.

National Laboratory Information System (LIMS) Programme Board

### With Professional bodies

To obtain appropriate statutory information and to ensure that staff have the appropriate documentation.

HEI Employer Liaison Group representative

NES Healthcare Science

Scottish Quality Managers Group

IBMS in Scotland Training Group

Health Education Institutions

Other:

Liaise with research groups to organise appropriate specimen handling and analysis of study samples.

Communicates highly complex information to Management Groups, Clinical Groups and BMS staff meetings, presenting with action plans, analysis, including trend analysis of monthly/quarterly Quality reports i.e. Incidents, complaints, Risk assessments, Health and safety monitoring reviews.

Presents reports, audits, and related papers at local and national level as required.

Responsible for training of groups of professional staff in Quality and Risk management topics.

Records and monitors the appropriate action planning of responses to Laboratory associated complaints and discusses and presents details and action plans to Management and local discipline/site groups.

Provides updates and regular reports on Quality and Training performance and issues to the Head of Service. Provides reports and updates for the relevant Clinical staff (Clinical leads etc.,) as required.

Prepares business cases for presentation to higher level groups

Communication may involve persuasion and negotiation if policy change impacts on the service or patient care

Deals directly

* with complaints both to and from Laboratories.

Demonstrate the behaviours expected of all staff and recognise how these can influence others, relationships, the environment and culture and adapt these to meet the needs of any given situation.

Ensure that all communications are carried out in a manner that is respectful and considerate and does not discriminate on the grounds of age, disability, faith, religion or belief, gender, gender reassignment, marriage and civil partnerships, race or sexual orientation, by ensuring that all conversations and discussions are conducted to the highest standards of honesty, integrity, impartiality and objectivity.

* **Analytical and Judgements**

Resonsibility to establish, develop and manage a highly complex and effective Multi-service Quality Management system, including standards of staff competency, and quality , for Laboratory Medicine, in accordance with Divisional policies and statutory accreditation standards,

This requires understanding of scientific complexity across all laboratory disciplines e.g. in analyser verification and validation.

Works autonomously within Regulatory and Professional guidelines to deliver this service.

Contributes to the construction of Standard Operating Procedures, which govern work practices, and establishes their integration and implementation within the department.

Will contribute to LIMS system evaluations, upgrades and ISO;15189 compliance .

Responsible for approving User Requirement Specifications for ne equipment, up to a value individually of £200,000

Responsible for approving validation/ verification protocols and reports for same.

Responsible for ensuring satisfactory operation and compliance of all temperature monitoring equipment, thermal mapping and service across all temperature controlled equipment across all laboratory departments.

May undertake complex and unfamiliar work, across scientific disciplines.

Short and long term planning and operational requirements as new ISO/GMP standards are introduced and the Quality and Risk management systems are developed.

Responds to requests for information from Head of Service, Department Managers and Clinical Lead, other senior staff and clinical users.

Advises the Organisation on all aspects of Clinical Laboratory Quality Management and Competency Systems

Responsibility through audit for monitoring internal and external quality assurance for Laboratories to ensure accuracy and precision of patient test results, therefore ensuring patient safety.

Responsible for Root Cause Analysis of incidents and decision making on actions required.

Completes a structured review with the direct line manger to review performance against agreed objectives and agree PDP.

There will be regular informal discussions and reviews of work with the Line Manager and formally on an annual basis as part of the Personal Development Planning Review process when expectations and objectives will be discussed and agreed.

There is a requirement to take ownership of personal development and taking part in ongoing training and those deemed mandatory by the organisation.

## Equipment

Responsible for identification and purchase of calibrated equipment which meets UKAS standards.

Responsible for the satisfactory operation and maintenance of all temperature equipment including temperature monitoring, thermal mapping and service across all temperature controlled equipment across all departments.

Responsible for approving validation / verification protocols for new equipment.

Responsible for approving User Requirement Specifications for new equipment eg as part of Managed Service Contracts.

**There is a requirement to:**

Recognise and adhere to the scope of the job whilst using initiative and referring appropriately to the Registered Professional/Line Manager.

* **Planning and Organising**

**There is a requirement to:**

Individual in post will have autonomy to plan and organise own workload to meet given timescales. Thee will be both short and long term planning operation management of requirements.

Quality – meets demands of UKAS 4 yearly cycle.(with annual surveillance visits), which may have competing dates and timescales between departments

Training- meet IBMS portfolio timescales and integrated degree placement timescales., again there may be competing timescales between trainees and departments.

Time management of parallel projects and prioritisation of workload is essential and may change with external influences eg UKAS inspection given dates.

Coordinates the workload of Quality & Training Officers across departments and allocated resource.

Plans, with Dept Managers, schedules of Validation works on new analysers to deliver best cot effectiveness and improvements in patient care

Demand Optimisation initiatives , to deliver best quality improvements and cost effectiveness

**Effort and Environment**

* **Physical**

Keyboard skills inputting data using i-Passport and Microsoft office software.

May require multi tasking and prioritisation of work

Manual handling is required transporting documents and notebook computing equipment between the NHSFV departments.

Sitting at VDU in the same positionfor long periods, e.g. compiling reports, and authorising documents

Standing for long periods of time during laboratory audits.

* **Mental**

**There is a requirement to:**

Frequent (daily) periods of prolonged concentration required during the entry, screening and in depth analysis of large quantities of scientific and numerical data e.g. analysing test results and compiling reports and audit data.

Requirement for diverse, sustained and intense mental effort due to frequent interruptions, many necessitating an immediate change in direction of thought process.

Performing lengthy audits often over a whole day demands intense thinking with cross-reference to ISO standards.

In depth training of staff in audit process and performing competency assessments

Pressure of service delivery and maintenance of standards.

Involved in maintaining a service in the presence of possible adverse events including equipment failure staff shortages or when quality control results show unacceptable drift outside acceptable parameters.

Interpretation of complex legal requirements (eg Blood Safety & Quality regulations, Health and Safety at Work Act) and ensuring all laboratory disciplines are compliant.

* **Emotional**

**There is a requirement to:**

Deals with incidents/errors and complaints from staff, patients and service users, which require a subjective factual based approach and good diplomacy skills.

Diplomacy and support when dealing with staff training and trainee support, particularly trainees in difficulty.

* **Working Conditions**

**There is a requirement to:**

Frequent (daily) unavoidable exposure to open samples of blood and other biological body fluids of known or potentially infective material eg during audit / competency audit activities in the laboratory.

Frequent (daily) exposure to unpleasant smells such as faeces samples, anaerobic bacteria and smells generated from sterilisation of all laboratory waste prior to disposal.

Controlled exposure to reagents, chemicals, solvents, during audit process.

May occasionally be exposed to spills of hazardous chemicals; spills, leakage and breakage of specimen containers and culture bottles that may contain highly infectious material or chemical waste.

**4. FREEDOM TO ACT WITHIN THE JOB**

Decisions & Judgements

Predominately self-directing and works autonomously within professional guidelines and timescales to deliver ISO;15189 Accreditation for all departments and training to professional IBMS framework..

Work comes from the following sources:

* + Self generated
  + Laboratory Management Team
  + Clinical managers / Clinical Leads
  + Outcomes of multidisciplinary meetings
  + Clinical staff
  + Clinical Governance

The post holder must possess considerable time management, prioritisation skills and judgement to manage conflicting pressures from staff groups required in service delivery.

Author of Standard Operating Procedures, which govern work practices, and establishes their integration and implementation within the departments.

Short and long term planning and operational requirements as new ISO/GMP standards are introduced and the Quality and Risk management systems are developed. Freedom to decide planning schedules in line with conflicting demands and priorities is key to this multidisciplinary role.

Completes a structured review with the Head of service to review performance against agreed objectives and agree PDP. Freedom to raise and act on areas of non compliance to maintain regulatory body requirements. Autonomy to escalate areas of non-compliance e.g. to Governance committees.

Ownership of own personal development and taking part in ongoing training and those deemed mandatory by the organisation.

Prepares Business Cases for presentation to higher level groups. Communication may involve persuasion/ negotiation if policy change may impact on the service or patient care.

**5. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB**

Mandatory Registration with the Health & Care Professions Council

Mandatory Masters Level qualification Or equivalent qualification i.e. Fellowship of the Institute of Biomedical Science (IBMS) / IBMS Higher Specialist Diploma.

Evidence of continuing professional development for example a portfolio of highly developed specialist knowledge, including management, leadership and service development.

**6. DEPARTMENT ORGANISATION CHART**

Head of Service for Diagnostics

**THIS POST**

**Laboratories Quality and Training Manager**

Head of Clinical Governance

Point of Care Service

Haematology/ Transfusion Department

Clinical Chemistry Department

Pathology Department

Microbiology Department