

1. JOB IDENTIFICATION

Job Title: Quality Manager, Diagnostic Services, NHS D & G

Department(s): Laboratories and Radiology

Job Holder Reference: AHP002LAB.24

No of Job Holders: 1

2. JOB PURPOSE

To be responsible for leading the design, implementation and management of a Quality Management System (QMS), within the Acute and Diagnostics Directorate, ensuring the delivery of a service fit for purpose that represents the patients best interests and provides a highly specialised quality service within the Acute and Diagnostics Directorate over multiple sites. The QM will manage the system with the objective that the Diagnostics Services become progressively more effective in delivering a high quality service and in meeting both regulatory and accreditation requirements.

To be a key member of the Diagnostic Services Senior Staff team ensuring that the quality agenda is delivered throughout the Directorate.

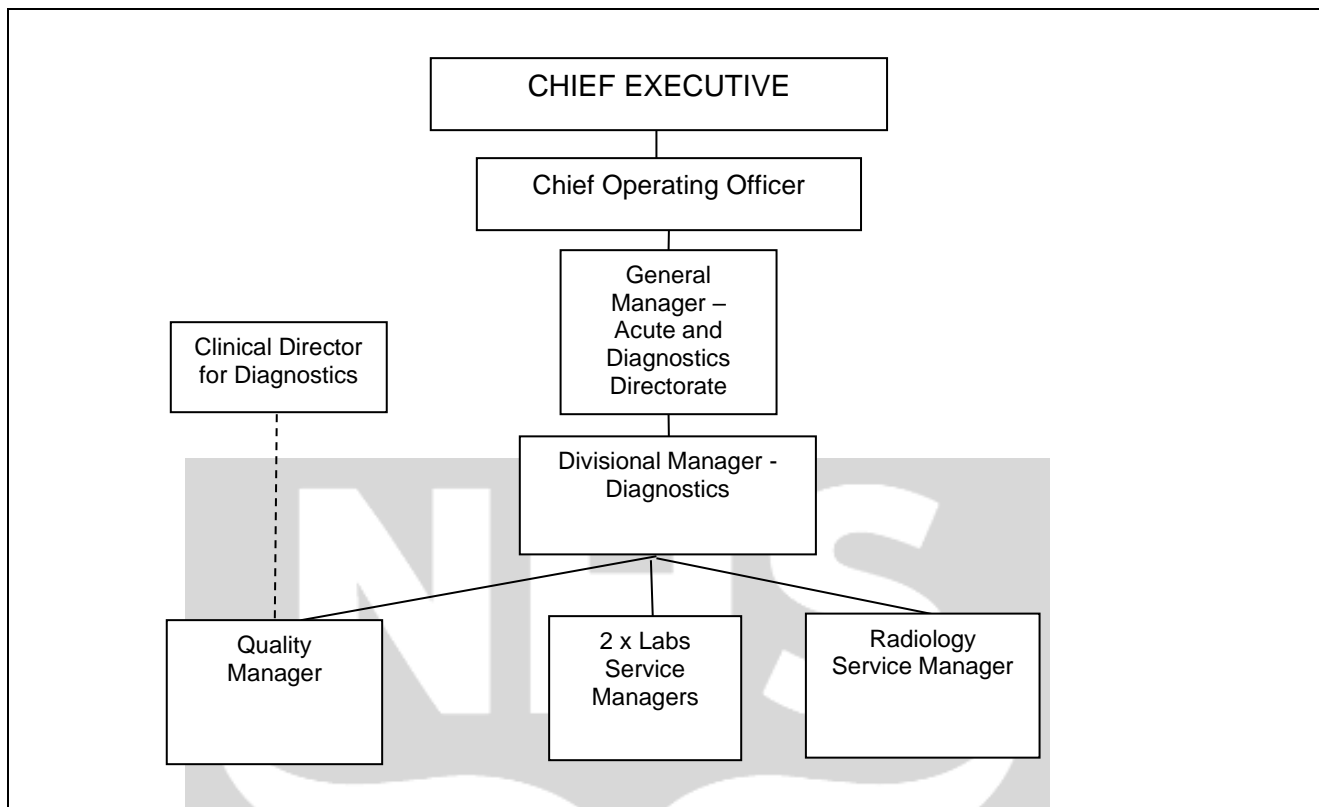
To represent Diagnostic Services at the NHS D&G organisational level and nationally where appropriate on matters relating to quality management.

3. ORGANISATIONAL POSITION

Accountable to:

Divisional Manager – Diagnostics with professional links to the Clinical Director for Diagnostics.

**NHS DUMFRIES AND GALLOWAY
DIAGNOSTICS DIRECTORATE**



4. SCOPE & RANGE

The Acute and Diagnostics Directorate provides a full and comprehensive range of diagnostic services for the population of Dumfries and Galloway, including hospital based users in Primary Care and General Practice

The scope and range of involvement of the Quality manager for Diagnostics will include involvement at various levels within Histopathology, Cytopathology, Biochemistry, Haematology, Blood Transfusion, and Microbiology. The Quality Manager will also link with the Radiology Department leads for Health and Safety and IRMER and provide general support on quality management issues within the department as necessary.

The system requires the Quality Manager to closely examine activities and procedures throughout the Acute and Diagnostics Directorate to ensure a high level of quality assurance by achieving high standards set by external accreditations bodies such as United Kingdom Accreditation Service (UKAS), NEQAS and MHRA.

Provide specialist training in all matters of quality, e.g.QA, QC, IQA, audit techniques, root cause analysis etc to Diagnostics Managers, Technical Managers, Specialists, Clinical Scientists and Medical Staff across all of Diagnostics.

Provide expert advice in the highly specialised service, on all quality matters to a range of people (internal and external to laboratories) such as quality managers, service and practice managers in Scotland and UK.

The Quality Manager is also expected to act as a convener of the Health and Safety Sub group of the Laboratory Services and to represent Diagnostics Services in related matters within NHS Dumfries and Galloway. The Quality Manager will take a lead role for the Diagnostics Services in

implementing 'Improving Safety and Reducing Harm' and will be a key member of the organisational working group.

The Quality Manager has defined authority for:

- Developing and managing the Quality Management System (QMS)
- Coordinating awareness of the needs and requirements of users
- Reporting on the functioning and effectiveness of the Quality Management system
- Reviewing departmental risk registers

The Quality Manager works autonomously, but will be responsible to the Divisional Manager for Diagnostics and will have a professional link to the Clinical Director for Diagnostics.

Develop audit systems and supply specialist training in this important area to technical managers and specialists in their proper use to achieve factual-based-evidence.

The Quality Manager will work with Clinical Governance and the Diagnostics service users to promote Diagnostics issues and ensure that effectiveness of service provision is maintained and continually developed.

Within this scope and range the post holder develops a programme to ensure the high quality of diagnostic service from validation of testing through avoidance of variation (standardisation), comparison through benchmarking to assessment of customer satisfaction by a range of defined quality tools.

5. MAIN DUTIES

- Responsible for formulating the Quality Policy, implementing and ensuring adherence.
 - Responsible for the design, implementation and management of the Q pulse electronic information system for document control and quality management. The post holder will be responsible for managing all training requirements with the system.
 - Write quality policies and procedures to comply with International Standards on which assessments are based e.g. Customer focus, Process review, Setting Plans & objectives, Evaluation and Continual improvement.
 - Minimise variation by playing a significant role in formulating national standard methods (in keeping with NHS Scotland's drive towards standardisation).
 - Achieve and maintain accreditation with the certificating bodies. Support other departments within Diagnostics to achieve standards set both internally and externally regarding the quality of service provision.
 - Regularly review plans and objectives throughout the year.
 - Responsible for formulating each Department's annual management review, collating annual reports and preparing the annual management report.
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- Quality representative on the Laboratory Divisional Group.
- Chair of the Laboratories Health and Safety Group and play a key leadership role in evolving this group into a Diagnostics Directorate Health and Safety Group.
- Responsible for representing Dumfries and Galloway Health Board at National and Regional Diagnostics Quality Management Meetings.
- To provide leadership direction and consistency in all matters of quality relating to diagnostic and laboratory services in Dumfries and Galloway.
- Provide guidance and specialist advice to other areas of the Health Board in relation to Quality issues.
- Seek to continually improve the service to the user by designing, issuing an annual user survey and acting on the findings. Meet with users on a regular basis to discuss the service and any issues that may have arisen from user surveys.
- To produce quality policies and objectives that have direct effect on the different departments within Diagnostics Services. These policies may also effect change in the wider organisation.
- System manage the Laboratory webpage ensuring that it is up to date, current and easily accessible to all service users.
- To undergo regular appraisal by the Diagnostics Divisional Manager where work performance is reviewed. New objectives and subsequent training, if necessary will be scheduled accordingly.

Education and Training

- Design and provide an education and training programme of quality principles and practice to provide help and advice for functional managers, clinical scientists and medical staff ensuring that the results of the quality awareness programme forms part of the development, training and education of all staff.
 - To provide training and education in internal audit for Diagnostic Managers, biomedical and clinical scientists and medical staff in Dumfries and Galloway.
 - To provide specialist training to managers and staff in the use of Q Pulse software programme.
 - Provide specialist training in quality and document control to the Diagnostics Staff and other departments within the organisation.
 - Coach staff in a positive behavioural approach which is key to quality.
 - Maintain records of training in quality delivery.
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- Provide specialist training in the software associated with the web-page in particular training staff in how to make changes to the page.
- Provide advice and support regarding quality issues to other departments within the organisation eg. CSSD, Pharmacy, NNU, Community Hospitals and Transport
- Provide advice and support regarding quality issues to external organisations eg contractor, courier/taxi companies.
- Provide advice and support on CPD programmes.
- Design, develop and deliver CPD training programmes involving quality to all diagnostic facilities.
- Help coordinate mandatory training for all Diagnostic facilities.

Clinical Governance

- To be familiar with the relevant statutory and accreditation requirements, clinical governance, risk management and audit policies of the organisation and integrate them into standard practice within Diagnostics.
 - To arrange, plan and conduct a programme of scheduled and unscheduled audits of the laboratories both in DGRI and Galloway Community Hospital to monitor compliance with standards.
 - To perform or supervise internal audits and ensure that corrective actions are effected, preventive actions are discharged and to monitor the effectiveness of any actions taken.
 - To identify areas where there is the potential for quality improvement that benefits service delivery
 - To liaise with the organisation's risk manager and participate in the Patient Safety Initiative to continually seek to improve clinical effectiveness and reduce risk of harm to patients.
 - To investigate complaints and incidents throughout Diagnostics, carry out root cause analysis and ensure that effective immediate corrective and preventive actions are taken and to monitor the effectiveness of any actions taken.
 - To follow up on external assessments, develop action plans and verify the completion of the corrective actions as required by the reports of the assessors.
 - To monitor the requirements of laboratory users and to ensure these requirements are reflected within the quality objectives.
 - The post holder will manage organisational quality indicators in conjunction with clinical governance ensuring that ongoing status is known and outstanding activities or improvements required are followed up
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- The post holder is responsible for ensuring key performance indicators in the laboratories area identified and monitored for any trends or themes. This may involve reviewing and implementing change after discussion with the General Manager for Diagnostics, Clinical Director for Diagnostics, Departmental Speciality Team Leads and Departmental Service Managers.
- The post holder will be responsible for meeting with Diagnostic departmental Managers/Heads to continually monitor compliance with any accreditation partner standards advising on any corrective or preventative action required.

Risk Management

- To advise the Divisional Manager (Diagnostics) and Clinical Director for Diagnostics of any concerns regarding failings in the quality management system that could lead to or result in adverse patient incidents.
- Develop awareness of 'risk' among staff
- Ensure each department within Diagnostics has effective risk management and health and safety procedures in place that reflect NHS Board, regulatory and accreditation requirements.

Monitoring and Control

- To identify areas where there is the potential for improvement of quality that will benefit the service provided by the Directorate.
 - Prepare the quality management information system for external audit
 - To provide information for the annual management review (data analysis of incident reporting)
 - To provide regular written and verbal reports for the management group on the functioning and effectiveness of the quality management system
 - Review and evaluate internal quality control, internal quality assurance and National External Quality Assurance schemes (NEQAS) within Laboratory services.
 - To maintain records of referral laboratories and review their performance in EQA and their ability to meet their published turnaround times within laboratory services.
 - Maintain confidentiality with audit report findings from various sites.
 - Work within the requirements of GDPR, the "Data Protection Act 1998" and be Caldicott compliant.
 - Participate in Quality in Scotland audits
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- Liaise with suppliers and maintain records of Diagnostics supplier's accreditation status.

Health and Safety

- Chair the Laboratory H&S meetings. The post holder is responsible for coordinating Health and Safety issues within the laboratories and in some circumstances the wider organisation.
- Responsible for collating and managing the risk register for all Diagnostic facilities.

Responsible for and coordinating security issues within Diagnostics.

- Refer H&S issues through the appropriate routes for action.
 - Communicate with HSE & SEPA for advice on H&S and environmental issues.
 - Ensure waste management policies are strictly adhered to.
 - Ensure there is a system of on-going safety training highlighting risks in each area.
 - Comply with statutory requirements and organisational H&S policies.
 - To ensure that records are kept up to date and to comply with local and national policies for the safe, secure and confidential processing and storage of patient and other laboratory information.
 - To use the Diagnostics Information Systems according to the authorised protocols.
 - To check the validity and reliability of analytical processes, maintaining and monitoring satisfactory performance by internal quality control and external quality assessment and to take corrective action as necessary.
 - To continually improve service provision by contributing to the development of standard operating procedures.
 - Responsibility for ensuring the laboratories fully participates in the national laboratory benchmarking scheme.
 - Responsibility for ensuring that the laboratory Web page remains current and up to date. This requires specialist knowledge in the background software.
 - Supervise a programme of internal audits across Diagnostics against defined quality performance measures and ensure that effective follow up actions are taken.
 - Follow up external inspections and verify the completion of corrective action as required by the reports of the inspectors.
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- Other tasks that arise from time to time relevant to delivering the objectives of the Diagnostic Services Quality Manager.

6. SYSTEMS AND EQUIPMENT

- Manages and administrates the Q pulse electronic management software system.
- Manages and administrates the laboratory web page ensuring information remains current. The post holder is responsible for all developmental work and is required to produce reports of work carried out. Analyse reports and advise and manage changes to improve service.
- Is proficient in the use of the hospital and Diagnostics IT systems to report test results, access patient information and conduct audits
- Is highly competent in the use of business systems including Microsoft Office 365.

7. DECISIONS AND JUDGEMENTS

- Independently decides on the design and proper functioning of the Quality Management Information System to satisfy accreditation partner standards, taking due consideration of timeframe to prepare an effective fit-for-purpose service that stands inspection by external assessment. In most cases the post holder will establish the way in which these may be interpreted and therefore introduce change, advising Managers and Quality Leads in each diagnostic facility.
 - Considers the frequency of process audits to be effective and meaningful whilst taking care not to overwhelm the service and possibly alienate staff.
 - Competent in interpreting highly complex data and making valid judgements on the basis of the data e.g. non-compliances (failure to meet a standard) uncovered during internal audit, anomalous test results etc and how they are imparted to relevant personnel with helpful assistance on resolution. In most cases the post holder will establish the way in which these may be interpreted and therefore introduce change.
 - Uses judgement in referring critical clinical or operational events to the relevant departmental manager, Divisionals Manager (Diagnostics) or Clinical Director depending on the nature of the event.
 - May be required to escalate problems to a higher level eg General Manager/Clinical Director level if quality of service is thought to be at risk.
 - Refers adverse patient incidents directly to the Divisional Manager/Departmental Managers following judgement in assessing incident category, root cause analysis, likelihood of recurrence and preventive action.
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- Reach clear conclusions based on an understanding of underlying issues, dealing with urgent or priority situations effectively e.g. system failure that directly impinges on patient care. In most cases the post holder will establish the way in which these may be interpreted and therefore introduce change.
- Reviews and escalates outstanding non compliances raised from scheduled programme of internal audit within Diagnostics which involves review of all processes which affect the patient's diagnostic report.
- Formulate quality plans and objectives for the following year, based in the first instance, on the previous year's performance with critical fact-based analysis.
- Continually seeks to improve performance
- Perform Risk and COSHH and general health and safety assessments where required

8. COMMUNICATIONS AND RELATIONSHIPS

The postholder is a key member of the Diagnostics Services Senior Staff meetings.

The postholder is also expected to develop positive relationships with the other senior managers and clinicians throughout NHS Dumfries and Galloway eg General Managers, Speciality Team Leads, Head of Service.

- Communicates by PowerPoint presentations in formal tutorial settings (>20 people) to consultants and other medical staff, senior nursing staff, administrative staff and quality managers within the organisation and in other hospitals on various matters of quality service delivery.
- Communicates to user groups (>30 people) who are generally unknown to the post holder regarding quality issues of the service. This involves a formal meeting and information is presented using various forms eg power point presentation, visit to individual laboratories etc. The users may have mixed interests or have contentious issues to be discussed, these may include pre analytical issues such as sample ID, transport, phlebotomy and general service provision.
- Required to be responsible and pivotal in resolving above issues through the appropriate channels eg Changes to work practises, procedures, processes, retraining or further discussion forums.
- Communicates with General Practitioners, practice managers and hospital clinicians and follows up on issues raised to ensure that the needs and requirements of users are met. Organises and manages user group meetings on a regular basis where the quality of service is discussed and any concerns raised are investigated.
- May have direct patient contact while conducting internal audits at clinics etc
- Required to construct and update policies and procedures relating to quality management and contribute to other management policies and effect their dissemination between the Diagnostics Services and service users. These policies will directly affect service/policy change in other departments of the Diagnostic service delivery.

- Required to investigate service complaints or problems originating from patients, quality managers, practice managers, nursing or medical staff with tact and diplomacy.

Participates in departmental meetings e.g. Governance Audit Meetings, Departmental Management Meetings and Health and Safety Meetings, Senior Staff Meetings and meetings involving staff at all levels. The postholder will be involved in departmental policy and service related changes.

- Participates in individual departmental annual management reviews and organisational performance reviews where significant input will be expected in relation to quality, clinical governance and health and safety. The post holder will be instrumental in the design of quality indicators and annual audit schedules for the departments.

- Required to negotiate with equipment suppliers in resolving quality issues e.g. validation, accuracy, sensitivity, specificity and reproducibility.

Negotiates with contractor's suitable dates to audit their facilities & services

- Liaising with external accreditation partners eg CPA and their assessors and MHRA and their assessors
- Managing and coordinating all aspects of planned and unplanned visits from external accreditation partners eg UKAS and MHRA assessors from arranging of visit to satisfactory and timely closure of non-conformities found. This involves leading activity and working on a daily basis with external agencies over prolonged periods of time.

9. PHYSICAL DEMANDS OF THE JOB

Physical Skills

- Keyboard skills inputting data using Q-Pulse and Microsoft office software. Frequent VD operations
- There is a high degree of sitting in the same position while using VDU.
- May be an element of light lifting.

Mental Demands

- 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 this accounts for approximately 60% of the working day
- Performing lengthy audits often over a whole day demands intense thinking with cross-reference to ISO standards.
- 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.

Emotional Demands

- Is responsible for imparting unwelcome news to staff as required.
- Deals with incidents/errors and complaints from staff, patients and service users, which require a subjective factual based approach and good diplomacy skills.

Working Conditions

- Anti social hours which arise from travel between sites in Stranraer and Dumfries as well as attending national meetings.
- Frequent 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 test analysis; many of which are potentially hazardous or carcinogenic.

10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB

- Using emotional quotient (EQ) skills of tact, diplomacy and understanding when working with difficult individuals in order to get the best out of them and defuse/resolve contentious issues by engaging in productive/persuasive dialogue.
- Negotiating with and influencing the behaviour of staff and managers within the organisation to achieve quality objectives. Behaviour being the key to quality
- Expressing ideas lucidly, presenting arguments logically in an easy to follow and well presented manner often in a formal setting to >30 personnel.
- The ability to cope with demanding situations and tight deadlines
- Always maintaining a positive approach (in a blame free culture, errors are seen as learning opportunities)
- Maintaining a professional attitude, including a degree of empathy towards service users when solving contentious issues such as major non-compliances, which can have an impact on service demands.
- Introducing change within the laboratories in a controlled, timely and traceable manner based on changes in Standards, legislation or more efficient working methodologies.

Maintaining a philosophy of "CAN DO"

11. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB

- BSc Honours Degree in a relevant discipline with a formal management qualification and additional specialist knowledge in quality management attained through the post graduate qualification in quality management.
 - Management experience and knowledge appropriate to the post is required and should include specialist knowledge of management issues in the NHS, organisational skills, legislation, counselling, attendance management, disciplinary procedure, etc. This may be represented by a formal management qualification.
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- Quality Management post graduate qualification or working towards one is required
- Membership with the Institute of Quality Assurance (IQA) is desirable
- Attendance at IQA meetings is advantageous and represents CPD in the quality arena
- Excellent communication and presentation skills is essential
- Post holder must be energetic, highly motivated and committed to quality
- Detailed knowledge of various standards ISO 9000, ISO 15189, MHRA, DOH and IRMER quality principles and targets etc is expected
- Trained in the use of Q-Pulse quality management software programme as the Administrator of the Q-Pulse system and demonstrate continuing and up to date knowledge by attending training.
- Specialised scientific/technical knowledge is required by the post holder to perform their duties effectively and to advise others in the application of quality principles
- Practical knowledge of Risk Assessment including COSHH (Control of Substances Hazardous to Health) and Health and Safety holder of IOSH certificate.
- Provide quality leadership in the department with good planning, organisational and interpersonal skills to enable the post holder to build and maintain positive working relationships with a range of senior clinicians and senior managers across the organisation.
- Demonstrate high level of competence in problem solving and prioritising workloads.

12. 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:

Head of Department Signature:

Date:

PERSON SPECIFICATION

**Job Title: Quality Manager
Diagnostic Services – Laboratories and Radiology**

<u>ESSENTIAL</u>	<u>DESIRABLE</u>
<p><u>QUALIFICATIONS</u></p> <p>BSc honours degree that meets the requirements of HCPC or Equivalent experience in Quality Management</p>	<p>Recognised quality/training/management qualification</p>
<p><u>SKILLS</u></p> <p>Good IT skills, presentation and manipulation of data required.</p> <p>Ability to prioritise and organise workload</p> <p>Good communication skills and fluency in spoken English</p> <p>Able to maintain patient, staff and commercial confidentiality</p> <p>High level of competence in problem solving</p>	
<p><u>EXPERIENCE</u></p> <p>Management experience and Knowledge appropriate to the post</p> <p>Evidence of continuing professional development including quality improvement and training</p>	<p>Laboratory Management</p>
<p><u>KNOWLEDGE</u></p> <p>Demonstrate an advanced theoretical and practical knowledge and understanding of accreditation and regulatory systems, including standards of accreditation, regulatory and professional agencies/bodies, relevant to Hospital Laboratories.</p> <p>Practical knowledge of Risk assessments including COSHH and Health & Safety</p>	<p>Knowledge of Medical laboratories: ISO15189</p>

<p>Comprehensive knowledge of the Institute of Biomedical sciences</p> <p>Knowledge of the proficiency standards of the HCPC and their application in the workplace</p>	
<p><u>PERSONAL CHARACTERISTICS</u></p> <p>Pleasant disposition and able to work as part of a team</p> <p>Ability to work under pressure and to tight deadlines</p> <p>Autonomous working and ability to work on own initiative</p> <p>Good interpersonal skills</p> <p>Flexible and adaptable</p>	

