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| 1. **JOB IDENTIFICATION**   **Job Title:** Graduate Innovation Fellowship in health Technology (GIFT) – Biomedical Design Engineer  **Responsible to:** Head of Mechanical Engineering, Medical Devices Unit  **Department:** Department of Clinical Physics & Bioengineering  **Directorate:** Diagnostics |
| **2. JOB PURPOSE** |
| Working under the direction of the Head of Mechanical Engineering within the Medical Devices Unit (MDU), the post holder will develop their engineering skills and expertise in a structured and supportive environment providing engineering input across a variety of projects. |
| **3. ROLE OF DEPARTMENT** |
| The Department of Clinical Physics and Bioengineering (DCPB) is based in Glasgow, Scotland, and serves the scientific and technical needs of NHS Greater Glasgow and Clyde. The department is one of the largest of its kind in Europe. Its influence covers a large area of the west of Scotland. DCPB is organised around the five services of radiotherapy, imaging, clinical engineering, medical equipment management and core services.  This job is based in the Medical Devices Unit (MDU). The MDU sits within the DCPB clinical engineering service but also provides some core services. It is a multi-disciplinary unit composed of scientists; software, electronic and mechanical engineers; and technical staff. MDU staff support innovation projects from inception to completion, including project planning, design, manufacture, verification, validation and adoption of new medical devices and test equipment to improve patient diagnosis, treatment and care. MDU staff also provide equipment repair, maintenance and calibration services. |
| **4. ORGANISATIONAL POSITION** |
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| **5. SCOPE AND RANGE** |
| The post holder will support the objectives of the Medical Devices Unit (MDU) through design, development, test and manufacture of novel devices and equipment for patient diagnosis, treatment and care. Medical devices will be designed and manufactured under the MDU’s certified Quality Management System.  Work is project-based; the post holder may be involved in several projects within the MDU.  The post holder is required to carry out duties that require knowledge of relevant legislation. Training in such legislation will be provided while in post.  This post is currently based at the Medical Devices Unit at West Glasgow Ambulatory Care Hospital, but these duties may be expected elsewhere in Glasgow & Clyde. Occasional travel to other locations within central-belt of Scotland may be required. |
| **6. MAIN TASKS, DUTIES AND RESPONSIBILITIES** |
| 1. Establish and document user needs and requirements. 2. Design, development and analysis of mechanical components and assemblies across a range of projects for new or modified/adapted medical devices where commercial options do not exist or are not viable. 3. Undertake verification and validation of new or modified devices before they are introduced into clinical service through engineering analysis and prototype testing. 4. Support manufacture and production acceptance testing of devices for patient use. 5. Provides biomedical engineering expertise to clinical colleagues. 6. Comply with relevant Quality Management Systems, maintaining records for all activities undertaken. 7. Generate documentation conforming to the ISO13485 medical device quality standard. 8. Contribute to risk assessments relating to the device use. 9. Ensure that work is performed safely with regard to Health and Safety legislation and local rules. In some situations this will require the choice and use of appropriate personal protective equipment. 10. Report incidents using the GG&C incident reporting process. 11. Ensure that all work follows departmental procedures and work instructions. 12. Ensure that work is completed to acceptable time scales, often under pressure if a patient or clinician is waiting for the equipment. 13. Ensure care of in-house equipment during use, reporting any equipment faults or limitations to section managers. Ensure that good housekeeping skills are observed to ensure a clean and safe workplace. 14. When working directly or indirectly with patients, customised, or patient connected equipment; perform all procedures safely to ensure the patient is not placed at undue risk of injury, and with due regard to the patient’s medical condition. 15. Represent the section in a positive and professional manner when working with, patients and other clinical, scientific, technical, and support staff. 16. Maintain confidential information when working on research and test projects. 17. Practice competencies that demonstrate insight, understanding and mutual respect of patients, their families, carers and work colleagues. The post holder is expected at all times to be an exemplar of person centred care, embracing their Code of Conduct to a high standard as part of an integrated health professional team. |
| **7a. EQUIPMENT AND MACHINERY** |
| * Digital manufacturing equipment such as 3D printers and laser cutters. * Tools and systems necessary for inspection and test including precision metrology equipment. * Hand tools. * Consumables such as adhesives, lubricants and solvents. |
| **7b. SYSTEMS** |
| Design, development and test and administrative tools including:   * Computer applications (frequent): email, internet, Microsoft Office software, 2D and/or 3D CAD software (SolidWorks), CAM software, equipment databases, quality management software (eQMS), incident reporting software, Health and Safety management systems. |
| **8. DECISIONS AND JUDGEMENTS** |
| The post holder is responsible for the prioritisation and management of his/her own workload and to achieve their own learning outcomes.  He/she must meet expected results using their own initiative and following general principles and applicable regulations, standards, guidelines and departmental operating procedures and work instructions.  The post-holder is required to work both independently and as part of a team and is accountable for professional actions whilst working independently.  The post holder is expected to prioritise their actions and make the decisions and judgements required to:   * Ensure that work is being completed to specification. * Contribute to decisions on the best provision of tools, materials, and consumables, based on cost and delivery. * Use initiative, experience and expertise in situations that require analysis and immediate problem solving, seeking advice where specialist interpretation is required. |
| **9. COMMUNICATIONS AND RELATIONSHIPS** |
| The post holder must be able to work as part of a team, with a close working relationship between the physics/engineering, technical, nursing, medical and administrative staff. The post holder must be able to communicate effectively with all members of the team. The post holder will be expected to provide complex technical equipment related information and advice to staff, colleagues and suppliers.  The post holder must be able to discuss work required with the request originator to ensure understanding and assist MDU Managers in gaining agreement for the proposed work.  Encourage and maintain good relationships with other staff in all departments and particularly those which deal with the MDU.  Participate and contribute to regular staff meetings  Demonstrate appropriate sensitivity with regard to the individual’s illness when communicating with patients. (infrequent)  Present the results of his/her own work to fellow engineers, scientists and clinicians at scientific meetings (UK and potentially internationally) and through scientific publications. |
| **10. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB** |
| **PHYSICAL & MENTAL**   * Working in confined or restricted spaces when working on some equipment. * Using a desk top PC for prolonged periods. Working with CAD systems or database work requires some of the working day to be spent sitting in a restricted position. * Requirement to work with delicate instruments and mechanisms. This requires concentrated effort, visual acuity, hand-eye co-ordination and dexterity.   **EMOTIONAL**   * The work can generate high levels of stress since incorrect actions or decisions can have serious consequence. * There may occasionally be some emotional distress when working on equipment for disabled or critical patients especially children, where there is direct or indirect contact.   **ENVIRONMENTAL**   * When working in nuclear medicine, radiography or radiotherapy areas, there is a possibility of exposure to radiation and there may be a requirement to wear an exposure badge for monitoring. |
| **11. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB** |
| The post holder is contributing to solutions to complex problems can be implemented using reasonable resources within a reasonable time scale and can improve the provision of healthcare.  The post holder should be capable of innovative thought to develop solutions to problems not yet encountered.  He/she will be required to analyse, interpret and compare a wide range of complex and potentially conflicting options for creating new, or modifying existing devices for healthcare use. In such developments, the post holder must have due regards for “best practice”, legislative/regulatory requirements and quality control to ensure that errors are not introduced into clinical practice.  To improve continually on the expected performance standards set out in the Department operational procedures whilst responding to demand-led situations and dealing with them in an assured and tactful way to achieve a positive outcome. |
| **12, KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB** |
| **Qualifications**  A Bachelor’s degree or higher qualification in Biomedical Engineering/Medical Devices Engineering/Mechanical Engineering/Product Design Engineering or other relevant subject is essential.  **Scientific and Technical knowledge and Experience**  The post holder must have demonstrable knowledge and experience of:   * Design, development of mechanical parts and assemblies. * Engineering design databases: Ability to create 3D models using CAD tools including integration of anatomical and engineered features. * Documenting user needs and technical specifications. * Verification of design inputs through engineering analysis and prototype testing including application of analysis tools to model engineering systems, e.g. FEA. * Materials: ability to identify materials, and be conversant with their physical properties * Methods for idea generation and creative problem solving. * Systematic literature review methods * Basic human biology and anatomy   Knowledge and experience in the following areas would also be preferable:   * Design, development and test of devices within a quality management framework. * Engineering design databases: Ability to create 2D drawings which conform to ISO standards and conventions. * Design for manufacture principles. * Digital manufacturing methods: Experience of 3D printers, laser cutters and other computer aided manufacturing systems. * Fastening methods: Familiar with mechanical fastening techniques and use of adhesives. * Workshop practice: Safe, accurate and economical use of hand tools and precision inspection instruments. * Knowledge of the design, construction and operation of various types of medical equipment with a mechanical function. * Regulations and standards appropriate to medical device design (including UK or EU Medical Device Regulations, ISO 13485 and ISO 14971) |