



**National Clinical Lead (Advisor) for Medical Devices
Job Specification**

Job Title, Grade Code	National Clinical Lead for Medical Devices This appointment will be on the basis of grade-to-grade reassignment/secondment and current remuneration will apply.
Remuneration	The successful candidate will retain all current terms and conditions (including remuneration and annual leave) on reassignment/secondment into the role. The standard working week associated with this post is 0.5 WTE per week, Monday to Friday. (Specific working days to be agreed on appointment). Clinical Practice will be facilitated.
Campaign Reference	NCL.20264
Closing Date	Tuesday 5th of May 2026 at 12 noon
Proposed Interview Date (s)	Skills-match interviews will take place after the shortlisting process is completed. Please note: this may be at short notice.
Taking up Appointment	The successful candidate will be expected to take up post as soon as possible after the completion of the selection process but no later than two months after the post has been offered.
Location of Post	Office of the National Clinical Lead for Medical Devices, Office of the Chief Clinical Officer is in Dr. Steevens' Hospital Dublin 8, the Brunel Building, Heuston South Quarter, Dublin 8.
Informal Enquiries	For Informal Enquiries, please refer to: Email: Dr Colm Henry, Chief Clinical Officer email CCO@hse.ie or Sharon Hayden General Manager Sharon.hayden@hse.ie or 0879389564
Reporting Relationship	The National Clinical Lead clinically reports to the Chief Clinical Officer or delegated clinical lead and work closely with National Clinical Head of Medical Devices.
Key Working Relationships	The Clinical Lead will work closely with (but are not limited) <ul style="list-style-type: none"> • National Medical Device committee • National Clinical Director, Integrated Care and team • HSE National Directors, National Clinical Advisor and Group Leads, Hospital CEOs, REOs, Clinical Directors, Consultants, Regional Clinical Directors, GPs, Directors of Nursing, HSCPs, Clinical Engineering, HSE National Services, Department of Health, postgraduate training bodies and professional representative groups

	<ul style="list-style-type: none"> • National Clinical Programme Leads: the appropriate Programme Managers & HSCP Leads, Nurse Leads as well as Management within designated NCAGL office • The post holder will work to build relationships across hospital and community with all key stakeholders • External stakeholders include, DOH Medicines and Medical Devices Regulation Unit, Health Protection and Regulation Authority (HPRA), HIQA and the State Claims Agency (SCA).
Scope of post	<p>Medical Devices provide considerable healthcare benefits to the population both in the assessment and diagnosis of disease and in the management of disease progression. However, they have been subject to controls that are arranged primarily about manufactory standards and functionality with limited requirements for the demonstration of clinical benefit or long-term use analysis. As such, significant clinical problems have frequently only become apparent in post marketing analysis by which time many patients have been harmed and considerable costs incurred for clinical mitigation and litigation e.g. silicone breast implants, metal on metal hip implants, mesh for prolapse repair. In addition, medical devices are proliferation, getting more complex, can be digitally or AI enabled and vulnerable to malfunction, cyberattack as well as more mundane but nonetheless disabling complications such as infection, inflammation, autoimmune activation, tissue erosion and wear and tear.</p> <p>The management of medical devices requires a full life cycle approach with pre-use assessment for clinical benefit and cost-benefit analysis, proper utilisation, storage and decontamination and planning for replacement. Device use needs to be monitored for compliance with MDR/IVDR and complications with non-conformance and/ or problems with device/ diagnostics reported to the HPRA and compliance with the Incident Management Framework and Patient Safety legislation ensured.</p>
Purpose of the Post	<p>To provide clinical governance, leadership and guidance to effect the development and implementation of best practice clinical care in the safe and effective clinical application of medical devices in compliance with the Medical Devices Regulation (MDR) (EU) 2017/745 within the Public Health Sector.</p> <p>To co-chair the HSE National Medical Device Management Committee which aims to support, advance and maintain compliance with the Medical Devices Regulation.</p>
Principal Duties and Responsibilities	<p>The NCLMD will be required to Co -chair the National Medical Device Management Committee with responsibilities to include:</p> <ul style="list-style-type: none"> • Provision of clinical support and leadership in collaboration with the National Clinical Head of Medical Devices (NCHMD) in the development and maintenance of policy and guidance documents together with the associated tools to support and maintain compliance with the Medical Devices Regulation (MDR) (EU) 2017/745. • Provision of clinical support and leadership in the development of National Guidelines for research and innovation in Medical Devices, including the assessment of proposed research protocols or innovation protocols as part of their submission for research and ethics approval. • Provision clinical support to the NCHMD for HTAs

- Working with the competent authority for medical devices, the Health Products Regulatory Authority (HPRA) in collaboration with the NCHMD, to support the education of healthcare professionals on MDR requirements
- Supporting the HPRA in the management of high risk/impact manufacturer Field Safety Notices (FSN's), Post Marketing Surveillance, and leading on National Serious Incident Management issues
- Reviewing in collaboration with the NCHMD and feeding back to Regional Medical Device Management Committees on quality improvement plans as generated by self-assessments to progress compliance with the regulations and other activities.
- Work with the National Programmes to ensure compliance with the MDR) (EU) 2017/745 and (IVDR) (EU) 2017/746 along with the role out of new services or service development.
- Work with National and International registries and audit in support of patient safety. Providing clinical input into registry formation and a national suite of Key Performance Indicators (KPIs) and the subsequent monitoring and actioning as required.
- Work with the State Claims Agency in collaboration with the NCHMD to mitigate identified risks.
- Provide clinical input into the medical device risk register.
- Provide clinical input into advice on medical device related issues to the HSE Senior Leadership Team.
- Provide in collaboration with the NCHMD assurance to the SLT on compliance with MDR, and on serious incident management and compliance with Patient Safety Legislation
- Provide clinical support in the role out of the National Trace and Trace system for Medical Devices

Other

- Make information available with respect to PQs or Reps for Government and so forth as required.
- Adhere to the HSE Communications protocol for any interaction with the press or media and in relation to any public relations events or queries and Government Agencies.
- Adhere to the HSE National Financial Regulations for any expenditure or costs associated with the programme of work.
- Comply with Freedom of Information and Data Protection legislation

	<ul style="list-style-type: none"> • Comply with the Ethics in Public Office and the Controls Assurance Statement process as required. . • Demonstrate pro-active commitment to all communications with internal and external stakeholders <p>The above Job Specification is not intended to be a comprehensive list of all duties involved and consequently, the post holder may be required to perform other duties as appropriate to the post which may be assigned to them from time to time and to contribute to the development of the post while in office.</p>
<p>Eligibility Criteria</p> <p>Qualifications and/ or experience</p>	<p>All staff of the HSE, other statutory health agencies, the Department of Health and bodies which provide services on the behalf of the HSE under Section 38 of the Health Act 2004 employed as a registered Medical Practitioner currently employed at Consultant or Clinical Director level with sufficient experience as a Consultant in an Acute or Community setting who are working within a substantive specialty are eligible to apply.</p> <p>Applicants must be registered with the Medical Council of Ireland on the specialist division of the register.</p> <p style="text-align: center;"><u>OR</u></p> <p>Applicants must be registered with a Medical Council of a different country and have the necessary clinical and healthcare experience to fulfil the duties of this role.</p> <p>1. Professional Qualifications Registration as a specialist in the Specialist Division of the Register of Medical Practitioners maintained by the Medical Council in Ireland in a substantive</p> <p style="text-align: center;">AND</p> <p>2. Applicants must demonstrate all of the criteria listed below:</p> <ul style="list-style-type: none"> • Have a minimum of 10 years' experience as a substantive Consultant. • Have experience in a substantive leadership role as a Consultant providing significant senior clinical input into planning and operational decision making. • Possess relevant experience of leading extensive operational, planning and management functions within public health service sector, which must have included Acute Hospital Service delivery. <p>Health A candidate for and any person holding the post must be fully competent and capable of undertaking the duties attached to the post, and be in a state of health that such as would indicate a reasonable prospect of ability to render regular and efficient service.</p> <p>Character A candidate for and any person holding the post must be of good character.</p>
<p>Other requirements specific to the post</p>	<p>Access to appropriate transport to fulfil the requirements of the role as the post will involve travel.</p> <p>Flexibility in relation to working hours is also required to meet any urgent needs that may arise.</p>
<p>Skills, competencies and / or knowledge</p>	<p>Candidates must demonstrate the following:</p> <p>Professional Knowledge & Clinical Expertise:</p> <p><i>Demonstrates:</i></p>

	<ul style="list-style-type: none"> • Substantial professional knowledge and clinical expertise within the area of specialist care <p>Leadership, and Direction:</p> <p><i>Demonstrates:</i></p> <ul style="list-style-type: none"> • Credibility and ability to command respect as a recognised clinical leader within the clinical community, with a good understanding of the HSE Corporate and National Service Plans, DoH policies, Sláintecare and related requirements of clinical leaders. • An understanding of Health Informatics, data metrics, KPIs, Outcome Frameworks (such as HSPA) and Standards setting. • Experience in providing significant senior clinician input to operational decision-making. • A track record as an effective leader who has developed effective teams and driven and delivered sustainable change programmes to transform clinical services. • A capacity to operate successfully in a challenging environment. • A commitment to and focus on quality and promoting high standards to improve patient outcomes, by consistently putting service users and clinicians at the heart of decision-making and involving patients and the public in their work. <p>Results focused with critical analysis and decision making:</p> <p><i>Demonstrates:</i></p> <ul style="list-style-type: none"> • Strong personal emphasis on achieving high standards of excellence and willingness to take personal responsibility to initiate activities and drive objectives through to a conclusion. • Ability to rapidly assimilate and analyse complex information, make timely decisions and take ownership of those decisions and their implications. • Capacity to anticipate problems and to recognise when to involve other parties at the appropriate time and level. • Uses evidence to make improvements and seeks out innovations. • Adequately identifies, manages and reports on risk within area of responsibility <p>Working with and through others</p> <p><i>Demonstrates:</i></p> <ul style="list-style-type: none"> • An ability to influence and negotiate effectively in furthering the objectives of the role. • An ability to build excellent collaborative networks and a track record of building and maintaining key internal and external relationships in furtherance of organisational goals. • Highly developed communication skills, which include an ability to convey clinical priorities and complex messages to colleagues, various stakeholders, media and interest groups.
Campaign Specific Selection Process	A ranking and or shortlisting exercise may be carried out on the basis of information supplied in your application form. The criteria for ranking and or shortlisting are based on the requirements of the post as outlined in the eligibility criteria and skills, competencies

<p>Ranking/Shortlisting / Interview</p>	<p>and/or knowledge section of this job specification. Therefore it is very important that you think about your experience in light of those requirements.</p> <p><u>Failure to include information regarding these requirements may result in you not being called forward to the next stage of the selection process.</u></p> <p>Those successful at the ranking stage of this process (where applied) will be placed on an order of merit and will be called to interview in 'bands' depending on the service needs of the organisation.</p> <p>The HSE is an equal opportunities employer.</p>
<p>Code of Practice</p>	<p>The Health Service Executive will run this campaign in compliance with the Code of Practice prepared by the Commission for Public Service Appointments (CPSA).</p> <p>The CPSA is responsible for establishing the principles that should be followed when making an appointment. These are set out in the CPSA Code of Practice. The Code outlines the standards that should be adhered to at each stage of the selection process and sets out the review and appeal mechanisms open to candidates should they be unhappy with a selection process.</p> <p>The CPSA Code of Practice can be accessed via https://www.cpsa.ie/.</p>
<p>The reform programme outlined for the Health Services may impact on this role and as structures change the Job Specification may be reviewed.</p> <p>This Job Specification is a guide to the general range of duties assigned to the post holder. It is intended to be neither definitive nor restrictive and is subject to periodic review with the employee concerned.</p>	