



## CANDIDATE INFORMATION BOOKLET

Open competition for appointment to the position of:

**EU Medical Devices Operations Manager  
Medical Devices Division – PSO Grade**

**National Standards Authority of Ireland Closing Date:  
13<sup>th</sup> May 2024**

PLEASE READ CAREFULLY

GDPR Privacy Statement is appended to the back of the booklet

National Standards Authority of Ireland is committed to a policy of equal opportunity

**Contact: NSAI Human Resources Department on 01 8073839 or at  
1 Swift Square, Northwood, Santry, Dublin 9, Ireland  
Telephone Number: (353) 1 8073839  
URL: <https://www.nsai.ie/>**

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## JOB DESCRIPTION

<b>JOB TITLE:</b>	EU Medical Devices Operations Manager
<b>DIVISION:</b>	Medical Devices
<b>UPDATED:</b>	April 2024
<b>REPORTS TO:</b>	Director of Medical Devices
<b>GRADE:</b>	Principal Scientific Officer (PSO)
<b>TENURE:</b>	5 year Fixed Term Contract
<b>LOCATION</b>	Santry, Dublin 9 or Galway (Hybrid working available)
<b>REFERENCE</b>	14-24 & 15-24

### Job Overview

NSAI is looking to recruit for the position of EU Medical Devices Operations Manager/ Head of Notified Body who will be responsible for managing a team of medical device and/or in vitro diagnostic product technical file reviewers and auditors.

NSAI is a Notified Body designated under the following Regulations and Directives:

- Medical Devices Directive 93/42/EEC,
- Active Implantable Medical Devices Directive 90/385/EEC,
- In Vitro Diagnostic Medical Devices Directive 98/79/EC,
- Medical Devices Regulation 2017/745,
- In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

And is accredited to the following management system certification services:

- Medical Device Single Audit Program (MDSAP) recognised auditing organisation
- ISO 13485 Certification Body
- ISO 9001 Certification Body

### Key Tasks and Responsibilities

- The Head of Notified Body will have overall responsibility for all conformity assessment activities in relation to IVDR devices.
- This person will be responsible for or final reviews and decision-making on certification.
- Responsible for making the decisions on issuing, suspending, restricting, re-instating or withdrawing of certificates and for defining the period of certification. This person should base their decision on the final review report and supporting documentation according to Section 4.8 of Annex VII.
- Establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities.
- Manage the resources of the European Medical Device division, including responsibility for staff, budget (including financial reports for the CEO and Executive Management Team), operational plans and procedures
- Chair technical review, vigilance review and significant change committee meetings.
- Responsible for ultimate determination of certificates on all Medical Device EU



Annex IX, XII Certificates and IVDR Medical Device EU Annex IX Certificates.

- Manage a team of Quality Management Systems (QMS) Auditors and Product Reviewers.
- Selection, verification of competency and authorization of the personnel to carry out conformity assessment activities within the organisation.
- Conduct the verification of the performance of the personnel and the definition and the verification of their initial and ongoing training.
- Liaise with Clients, Auditors and Product Reviewers in relation to site issues, standards, product and regulatory issues.
- Member of the corrective and preventive action (CAPA) team.
- Assign competency and authorise product reviewers & QMS auditors based on IVDR/IVDD/ ISO 13485.
- Ensure ongoing monitoring and mentoring of the team in conjunction with the Training and Education Officer.
- Assist HR in the recruitment process for new staff in the Medical Devices Division.
- Member of the Customer relationship management (CRM) implementation team.
- Work in conjunction with the US Medical Devices Operations Manager, Medical Device Single Audit Program (MDSAP) program manager and Chief Clinical Evaluator.
- Assist with client quotations, contract reviews and onboarding new clients for conformity assessment activities.
- Act as a Competent Authority liaison.
- Work closely with the management team to expand NSAI's services internationally and participate and contribute in the development of supporting business and operational strategies.
- Participate as a member of the NSAI Leadership Management Team (LMT).
- Other relevant/appropriate duties as requested by NSAI management.

## **Qualifications and Experience**

### **Essential**

- Successful completion of a university or a technical college degree or equivalent qualification in relevant studies such as medicine, pharmacy, engineering or other relevant sciences.
- Adequate experience in conformity assessments on medical devices under the IVDR or previously applicable law that should have been acquired by working in a Notified Body
- Four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research, of which two years shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed.
- Minimum 2 years' experience working in a Notified Body as a site auditor and/or product reviewer.
- Knowledge of device legislation and relevant guidance documents
- Appropriate knowledge and experience of budgeting (to include financial management and forecasting skills to evaluate business performance against budget/revenue)
- Appropriate knowledge and experience of risk management and related device standards and guidance documents.
- Appropriate knowledge and experience of the conformity assessment procedures in



the areas of IVDR.

- A broad base of knowledge of device technologies, including sufficient experience of conformity assessment of devices being reviewed for certification, the device industry and the design and manufacture of devices.
- Knowledge of the notified body's quality management system, related procedures and the required qualifications for personnel involved.
- The ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

#### **Desirable**

- Appropriate knowledge and experience of the conformity assessment procedures laid down in the following: IVDR/IVDD
- A qualified lead auditor with extensive experience in ISO 13485, ISO 9001, ISO 17021, MDSAP, IVDD, IVDR.
- Professional experience leading and managing teams in a relevant complex and specialised environment.
- Demonstrable experience of leading high-performing teams and a proven ability to develop, coach and mentor staff.
- Experience of a range of IT systems and an excellent working knowledge of file management and quality systems. .

#### **Core Competencies**

- Strong project management, financial, communication, interpersonal and teambuilding skills.
- Exceptional written and presentation skills.
- Excellent planning, organisational and administrative skills.

This job specification is intended as a guide to the general range of duties for this post. It is intended to be neither definitive nor restrictive and will be subject to periodic review with the post holder.

## Key Competencies for EMDOM

<b>Leadership and Strategic Direction</b>
<ul style="list-style-type: none"> <li>• Actively contributes to the development of the strategies and policies of the Department/ Organisation.</li> <li>• Brings a focus and drive to building and sustaining high levels of performance, addressing any performance issues as they arise.</li> <li>• Leads and maximises the contribution of the team as a whole.</li> <li>• Considers the effectiveness of outcomes in terms wider than own immediate area.</li> <li>• Clearly defines objectives/ goals and delegates effectively, encouraging ownership and responsibility for tasks.</li> <li>• Develops the capability of others through the effective management of the Performance Management and Development System (PMDS) and provides feedback, coaching &amp; opportunities for training and skills development.</li> <li>• Identifies and takes opportunities to exploit new and innovative service delivery channels to include planning, developing, training and launching new standards in line with industry demand.</li> <li>• Proactively manages the ongoing response to Brexit and other economic and societal developments as they apply to industry needs, in a constantly changing regulatory and business environment.</li> </ul>
<b>Judgement &amp; Decision Making</b>
<ul style="list-style-type: none"> <li>• Research issues thoroughly, consulting appropriately to gather all information needed to evaluate an issue.</li> <li>• Understands complex issues quickly, accurately absorbing and evaluating data (including numerical data)</li> <li>• Integrates diverse strands of information, identifying inter-relationships and linkages.</li> <li>• Makes clear, timely and well-grounded decisions on important issues.</li> <li>• Considers the wider implications of decisions on a range of stakeholders.</li> <li>• Takes a firm position on issues s/he considers important.</li> </ul>
<b>Management &amp; Delivery of Results</b>
<ul style="list-style-type: none"> <li>• Takes responsibility for challenging tasks and delivers on time to a high standard.</li> <li>• Plans and prioritises work in terms of importance, timescales and other resource constraints, re-prioritising in light of changing circumstances.</li> <li>• Ensures quality and efficient customer service is central to the work of the Division.</li> <li>• Effectively manages the annual budget for the Division with particular emphasis on the need for accurate forecasting and planning for the year.</li> <li>• Examines issues critically to see how results can be better achieved.</li> <li>• Is open to new ideas, initiatives and creative solutions to problems.</li> <li>• Ensures controls and performance measures are in place to deliver efficient and high value services.</li> <li>• Effectively manages multiple projects and resource allocation.</li> </ul>

**Interpersonal & Communication Skills**

- Presents information in a clear, articulate and impactful manner, verbally and in writing.
- Encourages open and constructive discussions around work issues.
- Promotes teamwork within the section, but also works effectively on projects across Departments/Sectors.
- Maintains poise and control when working to influence others.
- Instils a strong focus on Customer Service in his/her area.
- Develops and maintains a network of contacts to facilitate problem solving or information sharing.
- Engages effectively with a range of stakeholders, including members of the public, public service colleagues and the political system.

**Specialist Technical Knowledge, Expertise and Self Development**

- Has a clear understanding of the role, its objectives and targets and how they fit into the work of the organisation.
- Has an extensive knowledge of Departmental and Governmental issues and keeps up to date with wider political and organisational priorities.
- Is considered an expert by stakeholders in own field/area.
- Maintains a strong focus on self-development, seeking feedback and opportunities for growth to assist with delivery of the specific requirements of the role.
- Provides a lead role in NSAI's participation at national and international fora and liaises with other industry bodies to promote best practice in the application of standards to Irish and international industry.

## Application and Selection Process

### **How to Apply**

As part as of the application process you will be required to submit the following documentation:

- a) A comprehensive CV detailed as relevant to the position (no longer than 3 pages);
- b) A short cover letter/ personal statement (i.e. no more than 2 pages) outlining why you wish to be considered for the post and where you believe your skills and experience meet the requirements for the position;

Please note:

- CV and Cover letter must be submitted in a single word document or PDF.

**Please note** that omission of any or part of the 3 requested documents, as set out above, will render the application incomplete. Incomplete applications will not be considered for the next stage of the selection process.

**Please upload your application via <https://www.nsai.ie/about/work-with-us/>**

*If you do not receive an acknowledgement of receipt of your application within 2 working days of applying, please email [recruit@nsai.ie](mailto:recruit@nsai.ie)*

### **Requests for Reasonable Accommodations**

NSAI, in line with the Employment Equality Acts 1998-2015, will ensure that it does all that is reasonable to accommodate the needs of a person who has a disability and will ensure that its services are accessible across the range of disabilities.

If you require reasonable accommodations made, please indicate this during the application process by emailing [human.resources@nsai.ie](mailto:human.resources@nsai.ie) or by writing to the following address: HR Department, NSAI, 1 Swift Square, Northwood, Santry, Dublin 9 DO9 AOE4. Any requests for reasonable accommodation need to be accompanied by a medical/psychologist's report, the purpose of which is to provide NSAI with information necessary to make the decision on reasonable accommodation as promptly as possible. NSAI will consider each request on a case-by-case basis. All information provided will be treated as strictly confidential.

### **Requests for Documentation/Information in an Alternative Format**

All documents/information related to the application process are available in an alternative format. You can make a request for documents/information in an alternative format by emailing [human.resources@nsai.ie](mailto:human.resources@nsai.ie) or in writing to the following address: HR Department, NSAI, 4<sup>th</sup> Floor, 1 Swift Square, Northwood, Santry, Dublin 9 DO9 AOE4.

Please provide the following details when making a request:

- Name, address, contact details
- Details of document/information being requested
- The information format sought

All requests will be acknowledged within 3 working days of receipt and will be dealt with within 10 working days. Where a delay in providing the requested information occurs, NSAI will confirm the new date the person can expect to receive the information. If NSAI is unable to provide the requested information, the reason will be explained fully in writing to the person making the request.



### **Closing Date**

**The closing date and time for applications is 5pm on the 13<sup>th</sup> May 2024. Applications received after the specified deadline will not be accepted.**

*If you do not receive an acknowledgement of receipt of your application within 2 working days of applying, please email [recruit@nsai.ie](mailto:recruit@nsai.ie)*

### **Selection Methods**

NSAI will convene an expert board to carry out the competitive stages of the selection process to the highest standards of best practice. The approach employed may include:

- Shortlisting of candidates on the basis of the information contained in their application;
- A competitive, competency focused interview;
- A second-round interview (if applicable);
- Presentation/Work sample/role play/media exercise, and any other tests or exercises that may be deemed appropriate; and
- Reference and online checks.

### **Shortlisting**

Based on the number of applications received, the NSAI may in the first instance conduct a shortlisting exercise.

During any shortlisting exercise that may be employed, NSAI is guided by an interview board who examine the applications and assess them against pre-determined criteria based on the requirements of the position. It is therefore in your own interest to provide a detailed and accurate account of your qualifications/experience on your application.

Prior to recommending any candidate for appointment to this position NSAI will make all such enquiries that are deemed necessary to determine the suitability of that candidate. Until all stages of the recruitment process have been fully completed a final determination cannot be made nor can it be deemed or inferred that such a determination has been made.

### **Interviews**

The onus is on each applicant to ensure that she/he is in receipt of all communications from NSAI. Candidates should make themselves available on the date(s) specified by NSAI and should make sure that their contact details specified on their application are correct. NSAI will not be responsible for refunding any expenses incurred by candidates for attendance at interview.

### **Panel**

Should the person recommended for appointment decline, or having accepted it, relinquish it, NSAI may at its discretion, select and recommend another person for appointment from a panel established for this purpose. Candidates will be placed on the panel in order of merit. Any panel created will expire after a designated period from its establishment (usually six months). Placement on a panel is for the purpose of filling this appointment, candidates not appointed at the expiry of the panel will have no claim to this post thereafter.

### **Candidates' Rights– Review Procedures in relation to the Selection Process**

NSAI will consider requests for review in accordance with its Recruitment & Selection Policy.

### **NSAI Recruitment and Selection Review Process**

In relation to all NSAI recruitment campaigns, Human Resources (HR) take all necessary steps to ensure a fair, open and transparent appointment process that produces a quality





outcome and commands public confidence. HR also abides by the core recruitment principles of probity, equity and fairness, selection based on merit, and best practice, which are observed in all NSAI recruitment processes. All appointments made will also comply with relevant employment and equality legislation, and all candidates will be treated fairly, to a consistent standard and in a consistent manner.

**Stage One Review:** When a request for a review of a selection decision is received from a candidate every effort is made to resolve the matter at Stage One by e.g. providing feedback to the candidate. The Stage One Review process may be availed of within five working days of notification of the initial decision and should normally take place between the candidate and the person who communicated the decision.

HR will carry out the Stage One Review without delay and within a period of time that enables the candidate to avail of the Stage Two Review procedures within the specified

timelines should he/she so wish. Where a candidate remains dissatisfied following a Stage One Review, he/she may adopt the Stage Two procedures set out below. If the candidate wishes the matter to be dealt with by way of a Stage Two Review, he/she must notify HR within two working days of the notification of the outcome of the Stage One review. Recruitment and selection processes will not be suspended pending the outcome of a review.

**Stage Two Review:** The candidate must address his/her concerns in relation to the process in writing to the Head of HR, setting out those aspects of the action or decision in relation to his/her candidature that he/she wishes to have reviewed.

The candidate must support their request for review by outlining the facts they believe show the action/decision taken was wrong. A request for review may be refused if the candidate cannot support their request.

The case will be reviewed by a person other than any individual directly associated with the decision in question. The person(s) conducting the Stage Two Review will consider any written submissions made by the candidate, and all other relevant information, including any relevant e-mails, notes or memoranda held by HR in respect of the selection process. Where necessary, the reviewer may meet with the personnel involved in the selection process and/or the candidate for the purpose of eliciting further information. The outcome will generally be notified to the candidate within 10 working days of receipt of the complaint or request for review. Where the investigation does not allow a decision within this timeframe, the reviewer will keep the candidate informed of the status of the review. The decision of the Stage Two reviewer is final.

### **Deeming of candidature to be withdrawn**

Candidates who do not attend for interview or other selection processes when and where required by NSAI, or who do not, when requested, furnish such evidence as NSAI require in regard to any matter relevant to their candidature, will have no further claim to consideration.

## **Principal Conditions of Service**

### **Remuneration:**

PSO Contributory scale: €91,207 (Point 1), €96,042 (Point 2), €100,884 (Point 3), €105,162 (Point 4), €109,414 (Point 5), €113,694 (Point 6), €117,303 (Point 7), €121,045 (LSI 1\*), €124,788 (LSI 2\*) per annum.



PSO Non-Contributory scale: €86,646 (Point 1), €91,241 (Point 2), €95,840 (Point 3), €99,902 (Point 4), €103,944 (Point 5), €108,010 (Point 6), €111,438 (Point 7), €114,995 (LSI 1\*), €118,548 (LSI 2\*) per annum.

\*Please note this increment is applicable after 3 years' service on the previous point

All appointments are made in accordance with Department of Finance and Public Expenditure and Reform guidelines.

Salary implications for existing Civil/Public servants should be queried with HR Unit, NSAI.

### **Starting Salary**

Candidates should note that entry will be at the first point of the appropriate scale and will not be subject to negotiation. The rate of remuneration may be adjusted from time to time in line with Government pay policy.

### **Duties of the Post**

The duties and responsibilities set out in this job description are indicative of responsibilities related to this role. As with all posts, the nature of NSAI business is evolving and flexibility is required to adapt to changing business needs.

### **Annual Leave**

Annual Leave 30 working days and this leave is exclusive of Public Holidays.

### **Hours of Attendance**

Hours of attendance will be fixed from time to time but will amount to not less than 35 hours net Monday to Friday per week. No additional payment will be made for extra attendance as the rate of remuneration payable covers any exceptional extra attendance liability that may arise from time to time.

### **Tenure**

The appointment will be on a full-time, permanent basis. The appointee must serve a probationary period, which lasts for 12 months. Should the appointee's service be satisfactory with regards to health, conduct, and efficiency generally during the probationary period, the appointee, on completion of the period will be finally appointed. Should the appointee's services be unsatisfactory, the appointment may be terminated at any time during the period.

### **Location**

This position will be based at 1 Swift Square, Northwood, Santry, Dublin 9 with a hybrid working option available.

### **Confidentiality and Conflict of Interest**

Employees are prohibited from having any personal or financial interest in any industry that NSAI certifies from the date of appointment with the NSAI. Employees are prohibited from disclosing any information in relation to the business of any person obtained in his/her capacity as an officer of the NSAI.

### **Superannuation and Retirement**

The appointee will be offered public service pension terms and retirement age conditions in accordance with pension arrangements in NSAI depending on the status of the successful appointee:

a) In general, an individual who has no prior pensionable Public Service history in the 26 weeks prior to appointment will be a member of the Single Public Service Pension Scheme (Single Scheme) which commenced from 1 January 2013 [Section 10 of the Public Service Pensions (Single Scheme and Other Provisions) Act 2012 refers];



b) An individual who was a member of a “pre-existing public service pension scheme” as construed by the Public Service Pensions (Single Scheme and Other Provisions) Act 2012 and who does not qualify for membership of the Single Scheme will have standard public service pension terms reflecting new entrant or non-new entrant status for the purposes of the Public Service Superannuation (Miscellaneous Provisions) Act 2004.

### **Appointee’s status for superannuation purposes**

Appointees will be required to disclose their full public service history. Details of the appropriate superannuation provisions will be provided upon determination of appointee’s status. The following points should be noted:

#### **Pension Accrual**

A 40-year limit on total service that can be counted towards pension where a person has been a member of more than one existing public service pension scheme will apply. This 40-year limit, which is provided for in the Public Service Pensions (Single Scheme and other Provisions) Act 2012 came into effect on 28 July 2012. This may have implications for any appointee who has acquired pension rights in a previous public service employment.

#### **Pension Abatement**

The Public Service Pensions (Single Scheme and Other Provisions) Act 2012 extended pension abatement so that a retiree’s public service pension is liable to abatement on re-entering public service employment, even where the new employment is in a different area of the public service. However, if the appointee was previously employed in the Civil Service and awarded a pension under voluntary early retirement arrangements (other than the Incentivised Scheme of Early Retirement (ISER) or the Health Service Executive VER/VRS which render a person ineligible for the competition) the entitlement to payment of that pension will cease with effect from the date of reappointment.

#### **Ill-Health Retirement**

Please note that where an individual has retired from a Civil/Public Service body on the grounds of ill-health his/her pension from that employment may be subject to review in accordance with the rules of ill-health retirement within the pension scheme of that employment.

#### **Annual Superannuation Contribution (ASC)**

This appointment is subject to the ASC deduction as provided for under Part 4 of the Public Service Pay and Pensions Act 2017.

For further information in relation to public service superannuation issues please see the following website: <http://per.gov.ie/pensions>

## **GDPR Privacy Statement- Recruitment Process**

### **Purpose of Processing**

NSAI conducts a competency-based recruitment process to fill vacancies within the organisation. To complete this, interested individuals are asked to submit a CV, a cover letter and a completed key achievements form for assessment by the interview panel. For the successful candidate, some of the information provided will form the basis of the contract of employment (e.g. address).

### **Legal Basis for Processing**

- Necessary for performance of a contract or to enter into such a contract
- Compliance with legal obligation (Terms of Employment Information Act)

### **Recipients**

The following shall receive your information for reasons outlined below:



Recipient	Reason
HR (internal)	Storing application, acknowledging responses and corresponding with applicants.
HR (external Service provider)	If outsourced support is sought, NSAI's outsourced HR provider may receive applications to assist with elements of administration, or to manage the entire recruitment process.
Interview Panel	The Interview Panel will receive your applications to conduct shortlisting and assessing applicants.
Referees	Applicants are asked to provide references for people who can be contacted to validate work records and/or comment on suitability of the applicant for the NSAI position in question. These people shall be contacted, and the applicants name will need to be provided to receive the reference.
Company Doctor	NSAI will use your personal details to refer you to the company doctor if considered for appointment.

#### Details of Data Transfers Outside the EU

This does not apply to this process.

#### Automated Decision Making

This does not apply to this process.

#### Retention Period for Data

For unsuccessful candidates, applications and correspondence shall be retained for 2 years. For successful candidates, their application will be placed on their employee file and retained during their employment and for 7 years thereafter.

#### Your GDPR Rights in Relation to this Process

Right	Explanation
Access	You can request and receive access to the information requested in the process at any time.
Portability	You can request and receive a copy of this data, in electronic/transferable format, at any time.
Erasure	You can request the data held be erased. We have outlined the anticipated retention period above.
Rectification	You can request that any incorrect information, due to this information being updated or otherwise, be corrected.
Objection	You can object to this information being processed

If you have any questions or complaints about NSAI's use of your personal data, please contact NSAI's Data Protection Officer:

- By post: Data Protection Officer, National Standards Authority Ireland, 1 Swift Square, Northwood, Santry, Dublin 9 DO9 AOE4, or by phone: +353 1 8073800

You also have the right to lodge a complaint with the Data Protection Commission if you are not happy with the way we have used your information or addressed your rights. Details of how to lodge a complaint can be found on the Data Protection Commission's website.