



CANDIDATE INFORMATION BOOKLET

Open competition for appointment to the position of:

**Clinical Evaluator
Medical Devices Division**

**National Standards Authority of Ireland
Closing Date:
03/05/2019**

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/>**



Job Description

JOB TITLE:	Clinical Evaluator
DIVISION:	Certification
DEPARTMENT:	Medical devices
UPDATED:	April 2019
REPORTS TO:	Head of Medical Devices
GRADE:	PSO
REFERENCE	15-19

Job Overview

A European notified body for medical devices wishes to recruit a Clinical Evaluator for the approval of medical devices and in-vitro diagnostic devices. The Clinical Evaluator reports directly to the Chief Clinical Evaluator in NSAI.

Key Tasks and Responsibilities

- Responsible for the clinical assessment of technical documentation.
- Scientifically challenge and evaluate technical documentation pertaining to: pre-clinical data, clinical data, clinical trial data, post market evaluation data, instructions for use, risk management documentation for medical devices seeking CE mark certification for new application, substantial changes applications and recertification applications in accordance with established procedures, directives, regulations, common specification, standards and guidance documents.
- Where necessary identify and assign clinical device files to appropriately qualified external clinical experts in consultation with the chief clinical evaluator. Advise the external expert of the implications and limitations of their review.
- Appropriately train external experts in the relevant requirements of the directive, regulations, common specification, standards and guidance documents.
- Scientifically challenge and evaluate clinical reviews carried out by external clinical experts to ensure device safety and performance have been demonstrated.
- Ascertain comparability and consistency of the assessment of clinical evaluations conducted by external experts.
- Be able to make an assessment of the manufacturers clinical evaluation and a clinical judgement of the opinion provided by the external clinical expert.
- Liaise with external clinical experts to ensure project timelines are maintained.
- Ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.



- Schedule, acknowledge, process and track product applications and submissions in keeping with procedures and lead times.
- Cooperate with other members of the Medical Device team to satisfy EU requirements in relation to the body's notified body status.
- Provide support as requested in relation to the management and control of all medical device activities.
- Assessment of vigilance and safety reports associated with medical devices and associated issues.
- Representing NSAI at national and international meetings and conferences as required.
- Providing clinical support during the medical device audits by competent authorities and the European Commission.

Qualifications and Experience

Essential

- A medical practitioner registered with the Irish Medical Council or equivalent thereof.
- Four years post graduate experience in the field of medicine with direct work experience in patient care.

Technical Competencies

- Experience in clinical research or related experience in conducting or assessing pre-clinical or clinical trials.
- Comprehensive technical knowledge of the European Directives, European regulations and relevant MEDDEV guidance documents, standards and common specifications in relation to Medical Devices and related technologies desirable.

Core Competencies

- Strong project management, communication, interpersonal and team-building skills.
- Exceptional writing and presentation skills.
- Excellent planning, organisational and administrative skills.
- Ability to work on own initiative and as part of a team.

Key Competencies for Clinical Evaluator

Leadership and Strategic Direction

Demonstrate the ability to:

- Develop and implement top level strategies and policies for the Department and contribute to the strategy development for the Organisation.
- Build and sustain high levels of individual and team performance, addressing any performance issues as they arise.
- Clearly define objectives and goals and encourage others to take ownership and responsibility for tasks.
- Develop capability of others through the effective management of the PMDS System and provide feedback, coaching & opportunities for training and skills development.

Judgement & Decision Making

- Research's issues thoroughly and makes clear, timely and well-grounded decisions.
- Consulting with internal and external experts as required to gather all relevant information needed to evaluate an issue.
- Understands complex issues quickly and considers the wider implications of decisions on a range of stakeholders.
- Takes a firm position on issues s/he considers important.

Management & Delivery of Results

- Takes responsibility for challenging tasks and delivers on time and to a high standard.
- Plans and prioritises work in terms of importance, timescales and other resource constraints, re-prioritising based on changing circumstances.
- Ensures quality and efficient customer service is central to the work of the division.
- Effectively manage the annual budget for the Division with emphasis on accurate forecasting and planning for the year.
- Looks critically at issues to see how improvements can be made.
- Is open to new ideas, initiatives and creative solutions to problems.
- Ensures controls and performance measures are in place to deliver efficient and high value services.
- Effectively manages multiple projects and delegates responsibilities to ensure effective resource allocation.

Interpersonal & Communication Skills

- Presents information in a confident, logical and convincing 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 their area of responsibility.
- 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's objectives and targets of self and the team and how they fit into the work of the Certification Division.
- Has a breadth and depth of knowledge of Department and Governmental issues and is sensitive to wider political and organisational priorities.
- Is considered an expert by stakeholders in own field/ area.
- Is focused on self-development, seeking feedback and opportunities for growth to help carry out the specific requirements of the role.

Application and Selection Process**How to Apply**

Please submit the 2 documents as set out below to human.resources@nsai.ie by COB **Friday, 3rd May 2019**.

- 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.

We request that **the two documents are submitted in a single word document or PDF** where possible.

Please note that omission of any or part of the 2 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.

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 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 is available in an alternative format. You can make a request for documents/information in an alternative format by emailing human.resources@nsai.ie or in writing to the following address: HR Department, NSAI, 4th 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 3rd May 2019. Applications received after the specified deadline cannot be accepted.

If you do not receive an acknowledgement of receipt of your application within 2 working days of applying, please email human.resources@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 focussed, interview;
- A second-round interview;
- 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 short-listing 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.

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

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

References

NSAI would appreciate it if you would start considering names of people who you feel would be suitable referees (1 - 2 names and contact details). The referees listed do not have to include your current employer but should be in a position to provide a work reference for you. Please be assured that NSAI will only collect the details and contact your referees should you come under consideration at interview stage.



The admission of a person to a competition, or invitation to attend interview, or a successful result letter, is not to be taken as implying that NSAI is satisfied that such a person fulfils the requirements or is not disqualified by law from holding the position.

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 the panel on the results of this selection process.

Deeming of candidature to be withdrawn

Candidates who do not attend for interview or other test 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: €77,835 (Point 1), €81,826 (Point 2), €85,822 (Point 3), €89,352 (Point 4), €92,862 (Point 5), €96,396 (Point 6), €99,375 (Point 7), €102,463(LSI 1) *, €105,553 (LSI 2) * per annum.

PSO Non-Contributory scale: €74,070 (Point 1), €77,862 (Point 2), €81,660 (Point 3), €85,013 (Point 4), €88,347 (Point 5), €91,705 (Point 6), €94,534 (Point 7), €97,468(LSI 1) * €100,402 (LSI 1) * per annum (only applicable for relevant category of Civil/Public Servants).

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

Starting Salary

Candidates should note that entry will be at the minimum 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. Salary implications for existing Civil/Public servants should be queried with HR Unit, NSAI. All appointments are made in accordance with Dept. of Finance and Public Expenditure and Reform guidelines.

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 in order to adapt to changing business needs.

Annual Leave

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

Hours of Attendance

Working hours are from 9:00 a.m. to 5:15 pm on Monday to Thursday and 09.00 to 16.45 on Friday, with 45 minutes lunch break unless otherwise stated. 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 permanent basis. The appointee must serve a probationary period, which normally lasts for 12 months. Should the appointee's service be satisfactory as regards 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 is currently based at 1 Swift Square, Northwood, Santry, Dublin 9.



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.

Pension Related Deduction

This appointment is subject to the pension-related deduction in accordance with the Financial Emergency Measures in the Public Interest Act 2009.

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, Cover Letter. 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/transferrable 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 ☐ 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.