



## NSAI WOULD LIKE TO INVITE APPLICATIONS FOR THE FOLLOWING POSITION

<b>JOB TITLE:</b>	Certification and Inspection Officer for medical devices
<b>DIVISION:</b>	Certification
<b>DEPARTMENT:</b>	Medical devices
<b>UPDATED:</b>	07/9/2018
<b>REPORTS TO:</b>	European Operations Manager
<b>GRADE:</b>	SSO
<b>NO. OF DIRECT REPORTS:</b>	0
<b>FTE:</b>	Full time
<b>STATUS:</b>	5-year Fixed Term Contract
<b>REFERENCE</b>	13-18

### **Job Overview**

NSAI is looking to recruit a certification and inspections officer for medical devices. The role will include performing regulatory and non regulatory audits, as well as reviewing technical file dossiers submitted by manufacturers for CE mark approval of medical devices. The division will be approximately 70% auditing and 30% product technical file review but this is subject to change.

### **Key Tasks and Responsibilities**

- Conduct Registration, Surveillance and Recertification activities at client facilities to assess their conformity to the related management system standard.
- Conduct the above audits and prepare the associated pre and post audit documentation in accordance with all NSAI procedures.
- Conduct Internal Audits of independent areas of NSAI's Quality Management System.
- Perform technical reviews of product Technical Documentation to determine compliance with applicable standards and regulations, and to ensure safety and performance.
- Communicate with assigned clients and NSAI staff to ensure efficient audit planning and timely resolution of questions and non-conformities.
- Stay abreast of technology and regulatory trends affecting certification.
- Promote the Certification/Inspection service through the dissemination of information by correspondence, lectures and publications or otherwise as the opportunity arises.
- Respond to technical enquiries and responsible for timely communication and support to clients, administrative staff and Medical Device team members.
- Maintain strict confidentiality of matters relating to client work at all times.
- Undertake travel to evaluate applications for Certification and Registration Schemes operated by NSAI.
- Perform any other duties as may be required by the European operations manager.

## **Qualifications and Experience**

### **Essential**

- Successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, pharmacy, engineering or other relevant sciences;
- Four years professional experience in the field of healthcare products or related activities, such as 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.
- Two years experience in the area of quality management

## **Technical Competencies**

### **Essential**

- Knowledge of device legislation, harmonised standards, guidance documents
- Knowledge of risk management and related device standards and guidance documents
- Knowledge of the Medical Device Regulation
- Knowledge of the conformity assessment procedure
- Knowledge of quality management systems and related standards and guidance documents
- Ability to draw up records and reports
- Training or qualification as QMS Auditor or QMS Lead Auditor under ISO 13485, with preference given to Notified Body experience and/or CMDCAS certification.
- Strong understanding of international regulatory requirements for medical devices, with particular emphasis on European requirements and MDSAP.
- Understanding and working knowledge of International Standards for medical devices, such as ISO, EN, IEC, ASTM, ANSI and/or AAMI.
- Ability to analyse data and write clear, concise summary reports.

### **Desirable**

- Industrial experience in one or a combination of these areas
  - Cardiovascular
  - Orthopaedics
  - Ophthalmology
  - Dental technology

## **Core Competencies**

- Good interpersonal skills, with the ability to relate to people at all levels within and outside the NSAI.
- Ability to work on own initiative and to work as a team member
- Presentation skills as necessary.

## **Application Process**

**Please submit your CV and Cover letter to [Human.resources@nsai.ie](mailto:Human.resources@nsai.ie) no later than 15th October 2018.**

***NSAI is an equal opportunities employer***



### **Salary Scale**

Level SSO Contributory Salary scale: €59,632 (Point 1), €62,416 (Point 2), €65,200 (Point 3), €66,951 (Point 4), €69,658 (Point 5), €72,367 (Point 6), €75,074 (Point 7), €77,769 (point 8), €80,487 (point 9), 82,948 (LSI 1, moving onto this after 3 years on point 9) & €85,786 (LSI 2, moving onto this after 3 years on LSI 1) p.a.

Level SSO Non-Contributory Salary scale: €56,737 (Point 1), €59,384 (Point 2), €62,027 (Point 3), €64,672 (Point 4), €66,300 (Point 5), €68,875 (Point 6), €71,446 (Point 7), €74,007 (point 8), €76,589 (point 9), €78,927 (LSI 1, moving onto this after 3 years on point 9) & €81,624 (LSI 2, moving onto this after 3 years on point LSI 1) p.a. (only applicable for relevant category of Civil/Public Servants)

Please note in accordance with departmental guidelines, all new entrants to the public service are appointed on the first point of scale. 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.

### **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>