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| NSAI would like to invite applications for the following position | |
| Job title: | European Operations Manager |
| Division: | Medical devices |
| Updated: | January 2019 |
| Reports to: | Head of Medical Devices |
| Grade: | PSO |
| No. of direct reports: | 11 |
| FTE: | Full time |
| Status: | Permanent |
| REFERENCE | 22-18 |

**Job Overview**

As a Notified Body under the Active Implantable, In Vitro Diagnostic and Medical Devices Directives, NSAI provides particular expertise in the CE Marking of medical devices and invitro diagnostic test. Working with a worldwide client base, NSAI has issued EC quality system certificates covering over 300 product families and in excess of 11,000 individual catalogue items.

NSAI is looking to recruit for the position of European Operations Manager who will be responsible for managing a team of medical device and in vitro diagnostic product technical file reviewers and auditors.

**Key Tasks and Responsibilities**

* Manage the resources of the European Medical Device division, including responsibility for staff, systems, budget, operational plans and procedures.
* Plan and manage audits and product technical file reviews in conjunction with client service representatives as well as resources from other regions.
* Assess competency of staff, develop and manage training programmes for auditors and product technical file reviewers.
* Perform and manage witness audits of the auditors.
* Liaise with auditors and product technical file reviewers in relation to site issues, standards, product and regulatory issues. Provide input into technical review of audit packages and product technical file review.
* Provide auditors with real time support whilst they are on site. Engage with auditors post audit and ensure responses to non-conformances and expenses are addressed in a timely manner.
* Manage the product technical file review team, liaise with them in relation to issues regarding the technical file review. Ensure reviews occur within a timely manner.
* Chair technical review meetings for certification, substantial change and recertification approvals of product technical files.
* Responsible for maintenance and development of all associated Quality System Documentation and effective execution of all activities assigned to the Operations Manager. Organise internal audits and review the non-conformances associated with this.
* Functions as the deputy Management Representative for all management system activities. Responsible for external accreditation audits and the investigation, corrective action and effective close out of any non-conformances which arise. Keep the CAPA system up to date.
* Responsible for communications with associated accreditation bodies including external audit preparation, corrective actions, invoicing and any other associated requirements. Review and implement accreditation updates /bulletins.
* Liaise with clients in relation to quotations, contracts, audit and product planning and site issues if they arise. Attend periodic meetings with key clients.
* Act as Chair of the vigilance review committee and makes ultimate determination if certificates are in danger.
* Maintain and manage client feedback and complaint system in accordance with procedures.
* Plan and oversee unannounced and for cause audits in conjunction with the unannounced audit co-ordinator, US operations Manager and Director of medical devices.
* Attend meetings and conferences promoting NSAI at national and international level. Co-operate and work with the Business Development and Marketing functions within NSAI, in order to maximise the marketing potential of the NSAI’s Medical Device operations and the maintenance of Client Relations.
* Prepare net revenue reports, performance reports and business plans. Take an active role in management review activities for medical devices to ensure targets and budgets are met.
* 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.

**Qualifications and Experience**

**Essential**

* Successful completion of a university degree, technical college degree or equivalent qualification in relevant studies such as: medicine, pharmacy, engineering or other relevant sciences.
* A qualified lead auditor with extensive experience in ISO 13485, ISO 9001, ISO 17021, MDSAP, MDD, IVDD.
* Extensive knowledge of the MDSAP scheme.
* Comprehensive understanding of the relevant harmonised standards, common specifications, guidance documents, medical device directive, active implantable device directive, in vitro diagnostic device directive, medical device regulation, in vitro diagnostic device regulation.
* At least four years’ experience in the field of healthcare products or related activities such as manufacturing, quality assurance, regulatory affairs, or regulatory auditing.
* Knowledge of medical device quality management system auditing, evidence of knowledge and experience of quality management system standards.
* Knowledge and experience of risk management and related device standards and guidance documents.
* Knowledge and experience of the conformity assessment procedures in the aforementioned directives and regulations.
* Extensive management experience.
* Ability to draw up records and reports.

**Core Competencies**

* Strong project management, communication, interpersonal and team-building skills.
* Exceptional writing and presentation skills.
* Excellent planning, organisational and administrative skills.

**Application Process**

**Please submit CV and cover letter to** [**Human.resources@nsai.ie**](mailto:Human.resources@nsai.ie) **including ref no. 22-18 no later than noon Friday st February 2019.**

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

Please note in accordance with DPER guidelines, all new entrants to the public service are appointed on the first point of scale, €77,835.

**Salary Scale**

**PSO Contributory Salary 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) p.a.

**PSO Non-Contributory Salary 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 2) p.a. (Only applicable for relevant category of Civil/Public Servants)

Please note in accordance with DPER 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 & Expenditure guidelines.

\*increment point is applicable after 3 years’ service on the previous point on scale.

**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>