



**OPPORTUNITY**

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gets real.



**Reference: 0416-25**

**Grade: 09**

**Salary: £46,735 to £55,755 per annum, depending on experience**

**Contract Type: Fixed Term till April 2028**

**Basis: Full Time (36.5 Hours)**

## Job description

### Job Purpose:

Aston University is seeking a specialist in In Vitro Diagnostic Regulatory (IVDR) expert to act as a key staff member for the expanded Midlands SPARK Innovation Accelerator.

The postholder will support translational and preclinical development projects led by academics, clinicians, and companies across 15 Midlands universities, ensuring regulatory strategies for diagnostic technologies are robust, investor-ready, and compliant with IVDR and international standards.

The role will involve advising multiple project teams and regional SMEs, helping to accelerate the development of innovative diagnostics towards clinical evaluation and market access.

The postholder will report to the SPARK UK Director and collaborate closely with wider SPARK Midlands and Midlands Innovation teams.

Some travel across the Midlands region will be required.

### Main Duties/Responsibilities

- ▶ **Evaluating performance**
- ▶ **Develop and advise on regulatory strategies** for diagnostics projects, ensuring alignment with IVDR (EU) and FDA regulatory frameworks.
- ▶ **Support project teams** across the Midlands region to navigate regulatory requirements for diagnostics, including classification, performance evaluation, and quality management system (QMS) requirements.
- ▶ **Provide consultancy support** to regional SMEs, project teams, and academic researchers on regulatory submissions and investor due diligence expectations.
- ▶ **Develop guidance materials and templates** (e.g., technical file structures, PMS plans, clinical performance study protocols) to help streamline diagnostic regulatory submissions.
- ▶ **Deliver training and workshops** to project teams on IVDR and UK diagnostics regulation pathways.
- ▶ **Collaborate with the SPARK UK Director and regional partners** to integrate regulatory best practice into the SPARK Midlands programme.
- ▶ **Monitor regulatory updates** and provide advice on evolving requirements relevant to diagnostics innovation (e.g., UK Medical Device Reform, IVDR amendments).
- ▶ **Engage with regulatory authorities** (e.g., MHRA) and relevant industry bodies to ensure project teams are informed of best practice and upcoming changes.
- ▶ **Assist teams in establishing Quality Management Systems** aligned to ISO 13485, where required for project advancement.
- ▶ **Represent SPARK Midlands and Midlands Innovation** at regional and national regulatory affairs meetings and events.

## Person specification

|                                     | Essential   | Method of assessment           |
|-------------------------------------|---|--------------------------------|
| <b>Education and qualifications</b> | <ul style="list-style-type: none"> <li>▶ Bachelor's degree in a scientific or engineering discipline (e.g., Biology, Biotechnology, Biomedical Engineering).</li> </ul>   | Application form               |
| <b>Experience</b>                   | <ul style="list-style-type: none"> <li>▶ Extensive experience in regulatory affairs for In Vitro Diagnostics (IVDs).</li> <li>▶ Strong knowledge of IVDR, UK Medical Devices Regulations, and international standards (ISO 13485, ISO 14971).</li> <li>▶ Experience supporting projects through diagnostic approval processes.</li> <li>▶ Experience preparing technical documentation for regulatory submissions.</li> </ul> | Application form and interview |
| <b>Aptitude and skills</b>          | <ul style="list-style-type: none"> <li>▶ Excellent written and verbal communication skills.</li> <li>▶ Strong project management skills with the ability to manage multiple projects simultaneously.</li> <li>▶ Ability to work collaboratively with diverse stakeholders across academia, NHS, and industry.</li> <li>▶ Willingness to travel regionally across the Midlands.</li> </ul>                                     | Application form and interview |

|                                     | Desirable   | Method of assessment           |
|-------------------------------------|---|--------------------------------|
| <b>Education and qualifications</b> | <ul style="list-style-type: none"> <li>▶ Postgraduate degree (MSc, PhD) in a relevant field.</li> <li>▶ Regulatory Affairs Certification (e.g., RAC Devices, Topra).</li> </ul>                         | Application Form               |
| <b>Experience</b>                   | <ul style="list-style-type: none"> <li>▶ Experience supporting grant-funded academic or SME innovation projects.</li> <li>▶ Experience supporting QMS implementation (ISO 13485).</li> </ul>            | Application form and interview |
| <b>Aptitude and Skills</b>          | <ul style="list-style-type: none"> <li>▶ Knowledge of post-market surveillance and vigilance requirements for IVDs.</li> <li>▶ Experience engaging with regulatory authorities (e.g., MHRA).</li> </ul> | Application form and interview |

## University values

All staff are expected to demonstrate/promote the University's values and expectations, which are an integral part of our strategy and underpin the culture of the University. In addition, our leaders are expected to be accountable, help to execute strategic visions of the University and share and set clear expectations that inspire those around them.



## How to apply

You can apply for this role online via our website <https://www2.aston.ac.uk/staff-public/hr/jobs>.

Applications should be submitted by 23.59pm on the advertised closing date.

All applicants must complete an application form, along with your CV.

Any CV sent direct to the Recruitment Team and Recruiting Manager will not be accepted.

If you require a manual application form, then please contact the Recruitment Team via [recruitment@aston.ac.uk](mailto:recruitment@aston.ac.uk).

## Contact information

### Enquiries about the vacancy:

Name: Randhir Tindal

Job Title: [Regulatory Affairs Consultant – Medical Devices](#)

Email: [R.Tindal@Aston.ac.uk](mailto:R.Tindal@Aston.ac.uk)

### Enquiries about the application process, shortlisting or interviews:

Recruitment Team via [recruitment@aston.ac.uk](mailto:recruitment@aston.ac.uk) or 0121 204 4500.

## Additional information

Visit our website <https://www2.aston.ac.uk/staff-public/hr> for full details of our salary scales and benefits Aston University staff enjoy.

**Salary scales:** <https://www2.aston.ac.uk/staff-public/hr/payroll-and-pensions/salary-scales/index>

**Benefits:** [Benefits and Rewards | Aston University](#)

**Working in Birmingham:** <https://www2.aston.ac.uk/birmingham>

**Employment of Ex-Offenders:** Under the Rehabilitation of Offenders Act 1974, a person with a criminal record is not required to disclose any spent convictions unless the positions they applying for is listed an exception under the act.

**Eligibility to work in the UK:** You should ensure that you meet the eligibility requirements, including meeting the [English language standards](#). If you do not meet the eligibility criteria, any application for a work visa would be unsuccessful. Please see UKVI guidance for further information on eligibility, knowledge of English requirements and approved test centres <https://www.gov.uk/tier-2-general>

With the end of free movement for EU/EEA/Swiss nationals from 1 January 2021, the UK's new immigration system applies to all non-UK/Irish nationals who require a visa.

Where an individual is subject to UK immigration control, they will require a visa to work in the UK.

The following individuals do not need a visa for the UK, but do still have to prove their right to work before employment can commence:

- **British Citizens or Irish Nationals**
- **EU/EEA/Swiss nationals with Settled or Pre-settled status under the EU Settlement Scheme**
- **Non-EEA nationals with Indefinite Leave to Remain/Settlement in the UK**

The main routes available for those who need a visa to work in the UK are **Skilled Worker**, **Global Talent** and the **Graduate Route**.

You can find further information about each of these visa routes on our candidate immigration page.

If you will conduct research in your role, you may need to apply for and obtain ATAS clearance before Aston can issue a Certificate of Sponsorship for your visa application. Please see below for further details.

### **Academic Technology Approval Scheme (ATAS):**

If you will conduct research in your role and you apply for a Skilled Worker or Temporary

Worker GAE visa, you may need to apply for and obtain ATAS clearance before Aston can issue a Certificate of Sponsorship for your visa application.

This process can take at least 6 weeks to process, and Aston will consider this when confirming your expected start date. Processing times will increase between April and September and can longer to complete.

There is no fast-track option available. ATAS certificates will be processed in order of receipt.

You can find more information about ATAS on our candidate immigration page.

## **Before you start and Right to Work**

### 90-day entry vignette

If you have applied for your visa outside of the UK, you will receive a vignette in your passport which is usually valid for 90 days. Please make sure to travel to the UK within the 'valid from' and 'valid to' dates on this visa. If you entered the UK before or after these dates, you would not 'activate' the visa and you would need to leave and re-enter the country.

You will also receive a decision letter confirming details about your immigration permission and where to collect your Biometric Residence Permit.

### Cost of Living - Estate and Letting Agents

There are numerous Estate and Letting Agents in and around Birmingham that can help you find suitable accommodation. The Midland Landlord Accreditation Scheme provides a list of professional agencies and landlords who have applied with them for accreditation. Whilst accreditation is not a guarantee of quality, it provides some reassurance about the standard of the service they provide.

You can also use property search websites such as Rightmove or Zoopla.

## **Equal Opportunities**

Aston University promotes equality and diversity in all aspects of its work. We aim to ensure, through our admissions policies for students, and our staff recruitment and selection processes that we encourage applications from all groups represented in the wider community at a local, national and international level.

The University will endeavour not to discriminate unfairly or illegally, directly or indirectly, against student or potential students, staff or potential staff. This commitment applies to all functions of the University and to any stage of an individual's career.

An Equal Opportunities Monitoring Form is included within the application form. Data you provide on the Equal Opportunities Monitoring Form will be included in a general database, for statistical monitoring purposes, enabling the University to monitor the effectiveness of its

Policy, Codes of Practice and Guidelines on Equal Opportunities in Employment.  
Individuals will not be identified by name.

**Data Protection**

Your personal data will be processed in compliance with the Data Protection Act 2018 and the General Data Protection Regulation ((EU) 2016/679) ("GDPR"). The University's Data Protection Policy and Privacy Notices, including the Job Applicant Privacy Notice can be found at <https://www2.aston.ac.uk/data-protection>. Your application will only be used to inform the selection process, unless you are successful, in which case it will form the basis of your personal record with the University which will be stored in manual and/or electronic files. Information in statistical form on present and former employees is given to appropriate outside bodies.

Full details of our terms and conditions of service and associated policies and procedures are available online at <https://www2.aston.ac.uk/staff-public/hr/policies>

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