
## Regulatory Affairs Consultant

**Reference:** 0403-23

**Salary** £54,421 to £82,227, per annum, depending on experience

**Contract Type:** Fixed Term (Until 31/03/2025)

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

# Job description

## Job Purpose:

Aston University is currently seeking an experienced Regulatory Affairs Specialist to act as a consultant for the West Midlands SPARK Programme, modelled after Stanford's model for preclinical acceleration. This exciting position provides a unique opportunity to contribute to the dynamic field of healthcare innovation, playing a crucial role in driving and facilitating preclinical development projects led by academics, clinicians, and regional companies.

You will support the onboarding process for a diverse portfolio of preclinical projects onto the SPARK programme, ensuring appropriate regulatory strategies are developed that give each project the best chance at reaching clinical trial stage, or market authorisation where clinical trials are not required. This will include making sure the regulatory strategy of these projects stands up to due diligence carried out by educated investors.

You will do this by utilising your experience in at least one of the following three fields; Diagnostics Development, Medical Device Development (Minimum Class 2) or Therapeutics Development. You will have specific experience working with the Research and Development teams of companies in the sector.

You will be expected to collaborate closely with a broader consortium of stakeholders, fostering growth and advancement of the regions bio/medtech sector. This will involve providing ad-hoc consultancy to regional SMEs and groups not necessarily part of the SPARK Programme.

Where possible you will partner with the SPARK project manager and project teams to streamline the onboarding process onto the SPARK programme, assisting them in creating robust, industry-standard pathways compliant with existing regulations.

## Main duties and responsibilities

- Support the new SPARK Innovation Accelerator Programme at Aston University
- Develop and implement regulatory strategies for MedTech and biotech projects in the SPARK programme.
- Provide guidance and support to project teams on regulatory requirements and compliance throughout the product development lifecycle.
- Collaborate with project partners at a regional level to ensure regulatory compliance and alignment.
- Build relationships with regulatory authorities and industry associations to stay up to date on regulatory developments and influence regulatory policy.
- Represent the Innovation Accelerator and its projects at industry conferences and regulatory meetings.
- Develop template documents that enable project teams to develop their own Quality Management Systems as efficiently as possible.

## Additional responsibilities

- Engage in continuous personal and professional development in line with the demands of the role, including undertaking relevant training and development activities to develop themselves and support the development of others.
- Ensure and promote the personal health, safety and wellbeing of staff and students.
- Carry out duties in a way which promotes fairness in all matters and which engenders trust.
- Promote equality of opportunity and support diversity and inclusion as well as working to support the University's environmental sustainability agenda and practices.

# Person specification

| | Essential | Method of assessment |
|---|---|---|
| **Education and qualifications** | ▶ A Bachelor's degree in a scientific or engineering discipline. | Application form |
| **Experience** | ▶ Experience in regulatory affairs within the MedTech or biotech industry<br>▶ Strong knowledge of global regulatory requirements and guidelines for medical devices and/or pharmaceuticals, including knowledge of the EU Medical Devices Regulation (MDR) and In-vitro Diagnostic Regulation (IVDR) and/or US FDA regulations.<br>▶ Experience in developing and implementing regulatory strategies for innovative medical devices/diagnostics or biotech products, including product classification, risk assessments, and clinical study design.<br>▶ Experience in managing regulatory submissions and approvals, including preparing and submitting regulatory filings to regulatory authorities such as the FDA, MHRA, or EMA.<br>▶ Experience of building and maintaining effective relationships. ·<br>▶ Experience of building credibility through excellent written and verbal communication skills. | Application form and interview |
| **Aptitude and skills** | ▶ Excellent project management skills, including the ability to manage multiple projects simultaneously and work effectively under tight timelines. | Application form and interview |

| | Essential | Method of assessment |
|---|---|---|
| | ▶ Strong communication and interpersonal skills, with the ability to collaborate effectively with internal and external stakeholders, including project partners, regulatory authorities, and industry associations.<br>▶ Ability to influence and negotiate with regulatory authorities and industry associations, and to stay up to date on regulatory developments and industry trends.<br>▶ Willingness to travel as needed to project partner sites and regulatory meetings. | |

| | Desirable | Method of assessment |
|---|---|---|
| **Experience** | ▶ Experience of implementing an audited Quality Management System<br>▶ Experience of Successful Grant Writing<br>▶ Experience do you have of 510(k), PMA submissions, notified technical file reviews etc. | Application form and interview |

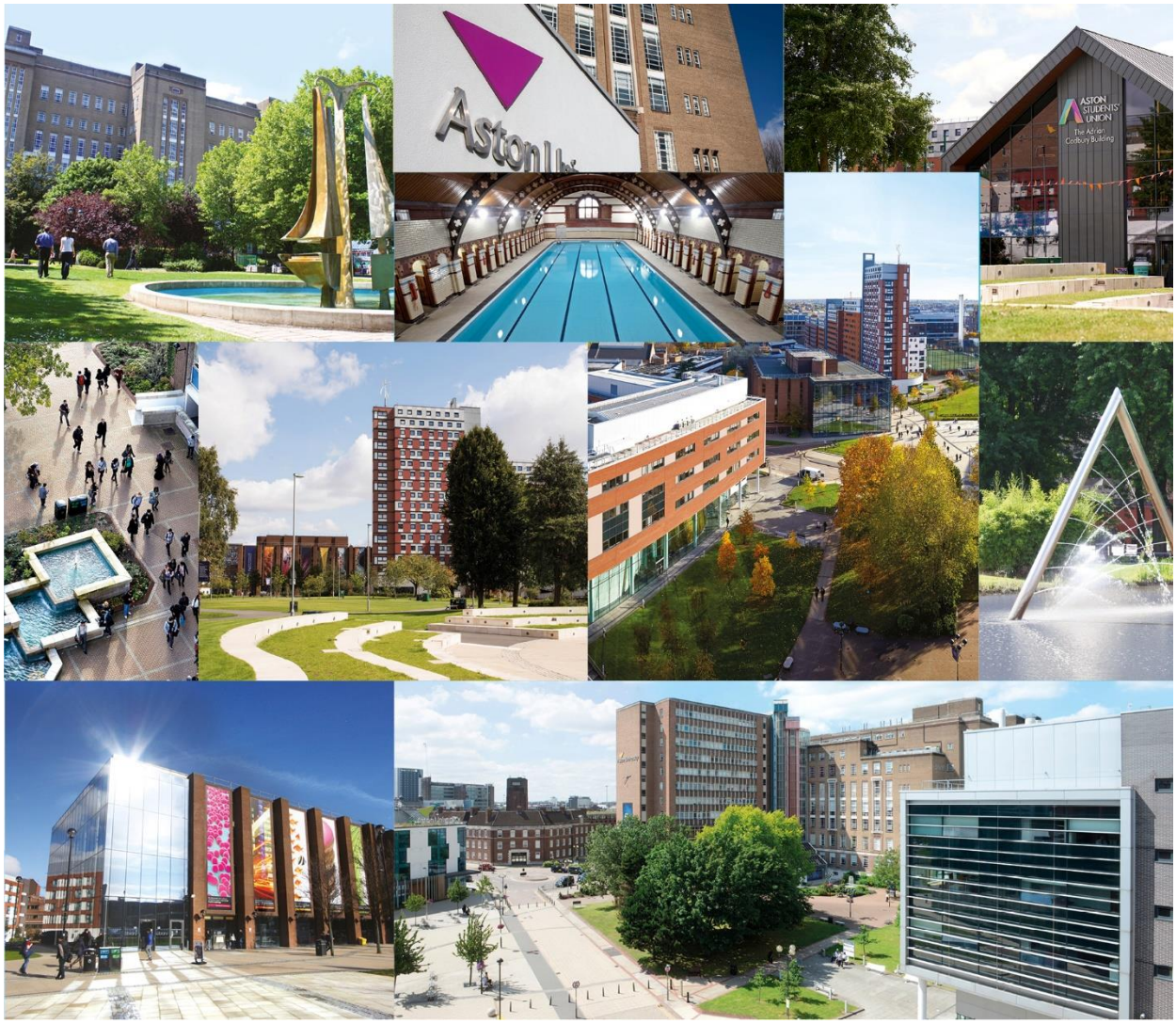
# How to apply

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

Applications should be submitted by 23.59 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 jobs@aston.ac.uk.



# Contact information

**Enquiries about the vacancy:**

Name: Luke Southan
Job Title: Technology Transfer Manager
Email: l.southan@aston.ac.uk

**Enquiries about the application process, shortlisting or interviews:**
Recruitment Team via jobs@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:** https://www2.aston.ac.uk/staff-public/hr/Benefits-and-Rewards/index

**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:

**Post-Brexit transition period / EU Settlement Scheme**
The post-Brexit transition period ended on 31 December 2020. If you are an EU/EEA citizen and you were a resident in the UK before 31 December 2020, you and your family members (including non-EU citizens need to apply to the EU Settlement Scheme to continue to live, work and study in the UK beyond 30 June 2021. The deadline for applying to the EU settlement scheme is 30 June 2021. You can apply via the Government webpage https://www.gov.uk/settled-status-eu-citizens-families
Irish Nationals do not need to apply for settlement as they retain the right to work in the UK.

**New immigration system for EU/EEA and Swiss Nationals who were not resident in the UK before 31 December 2020**

A new immigration system has been introduced for people arriving in the UK from EEA countries with effect from 1 January 2021. In addition to those who have always required a visa, EU citizens moving to the UK to work will need to get a visa in advance. You can find more information on the following website. Candidates should check their eligibility to enter or remain in the UK in advance of making any job application via the UKVI website https://www.gov.uk/browse/visas-immigration/work-visas. Before applying you should ensure that you meet the requirements, including meeting the English Language requirements. If you do not meet the eligibility criteria, any application for a work visa would be unsuccessful.

If you require a visa to work in the UK the most common types of visa are:
**Skilled Worker Visa**
https://www.gov.uk/skilled-worker-visa

**Global Talent Visa**
If you are a leader or potential leader in one of the following fields you may be eligible to apply for a Global Talent Visa:

- Academia or Research
- Arts and Culture
- Digital Technology

Please click the following link for further information and to check your eligibility for this visa.
https://www.gov.uk/global-talent

**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

**Aston University**
**Birmingham**
**B4 7ET, UK.**
**+44 (0)121 204 3000**
**aston.ac.uk**