

# Regulatory Affairs Manager (Band 8a)

Recruitment Profile - This is a summary of the Job Description and Person Specification



Blood and Transplant

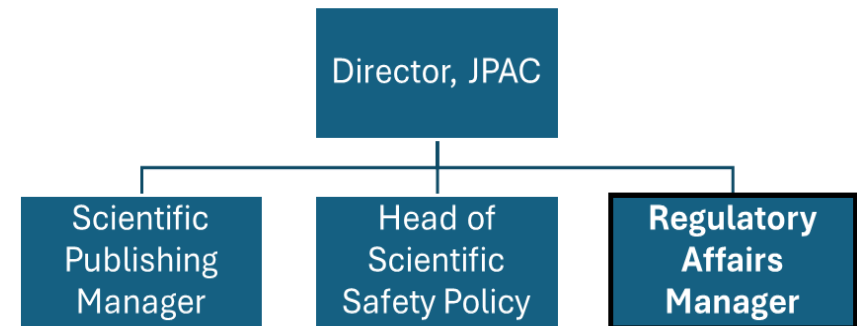
## About the Role

In this role you will lead on understanding and acting upon the implications of the EU Regulation on Substances of Human Origin (2024/1938) on legislation in Great Britain and Northern Ireland. Your responsibilities will include:

- Collaborating with colleagues in all four of the UK Blood Transfusion and Tissue Transplantation Services, Department of Health and Social Care, and departments of health in the devolved administrations, and with regulators including MHRA and HTA.
- Engaging with collaborators in Europe, including in the Council of Europe, European Blood Alliance and others
- Preparing and presenting advice and briefings on recommended actions
- Working with the Directors of Quality in the UK services in their roles of Responsible Person and Designated Individual and with the Chief Executives as licence holders, to ensure maintenance of licence

You will be required to travel and spend time away from base, which will involve working irregular hours and overnight stays when required, with prior notice

## Organisation Structure



## About Us

*Our three core principles are critical to our service, guiding everything we do and inspiring us to be the best.*

- *We **care** about our donors, their families, the patients we serve, and our people.*
- *We are **expert** at meeting the needs of those who use our service and those who operate it.*
- *We provide **quality** products, services and experiences for donors, patients and colleagues.*

**About You** - This section details the personal attributes we require for this role. You will need to demonstrate these throughout the recruitment process

### Behaviours and Values

- **Communicating** – Friendly and approachable, able to relate to staff, donors and patients from all backgrounds, promoting NHSBT positively
- **Collaborating** – Know the importance of your own behaviour and body language when communicating and working with others
- **Leading** – Professional in matters of confidentiality, security, integrity, honesty, performance, attendance and appearance
- **Customer focused** – Demonstrate and promote high standards of quality customer care to both internal and external customers
- **Performing** – Able to use and act on feedback from others on your performance and behaviour to increase your own self awareness
- **Innovating** – Consider, suggest and be open to alternative ways of working to make continuous improvements

### Skills and Abilities

- Be highly articulate and credible, consistently influencing and delivering inspiring, engaging, and meaningful information regarding future direction
- Build collaborative relationships and solve issues by engaging the right people at the right time
- Lead the team, accepting responsibility for achievement of business objectives and creating a shared sense of ownership for service delivery
- Engage widely with customers to seek input into setting strategic objectives and identifying new ideas and improved ways of working
- Demonstrate strong leadership, influence, and accountability for the achievement of results
- Recognise when change is required and demonstrate personal ownership for pursuing, communicating and implementing the change, whilst minimising the motivational impact on others

### Experience and Knowledge

- Substantial experience and knowledge of Quality Systems and their application within a regulated environment, preferably relating to Substances of Human Origin
- Experience of building successful working relationships with internal and external colleagues
- Substantial experience in senior management, including providing effective leadership and team management.
- Experience and skills of report writing
- Experience of exercising autonomy within the work environment
- Advanced level experience of working with information technology using Microsoft Office packages (Outlook, Word, Excel, Teams and PowerPoint)

### Qualifications and Training

- Educated to at least degree level plus post graduate diploma OR evidence of equivalent specialist knowledge and experience
- Hold a Masters level qualification or possess equivalent demonstrable knowledge and experience to Masters level within this specialist field
- Demonstrates commitment to own continued professional development (CPD)