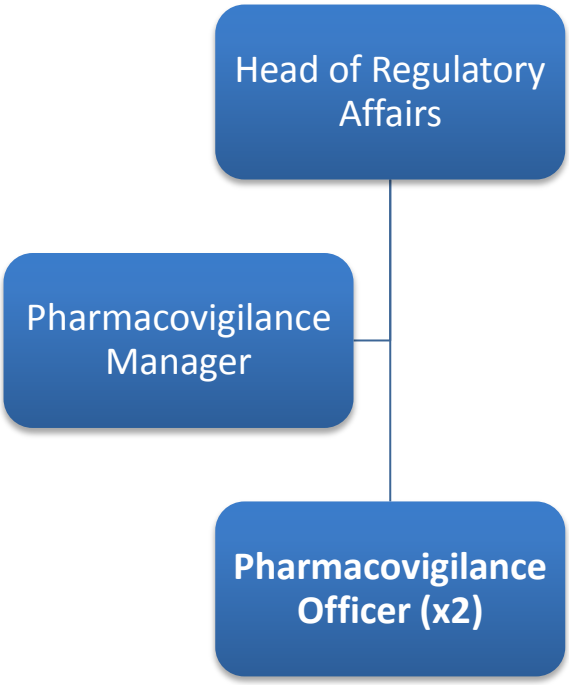
JOB DESCRIPTION

Job Title:	Pharmacovigilance (PVg) Officer
Band/Pay:	Band 5
Department:	Regulatory Affairs, Pharmacovigilance

Commercial & Strategy Directorate



Job overview

- Support the general maintenance of the pharmacovigilance (PVg) system (drug safety system) for TP products – ensures patient safety by monitoring and evaluating the clinical use of products
- Assist with ensuring TP is in compliance to UK & International PVg legislation

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Main duties of the job

- Support the PVg Manager with management of the company Pharmacovigilance System Master File which details all aspects of the PVg system and its interface with other company departments
- Manage the ASPR work flow process from downloads to review & collation
- Manage the literature searching activity & associated actions

- Assist with the management of PVg Agreements with distributors and third customers both nationally and overseas
- Collate Regulatory Agency queries and requests for further information and aiding in generating the responses of a product safety and clinical nature
- Further develop the PVg training programme
- Deputise upwards for the PVg Manager at the PVg Group meetings, PVg audits, Competent Authority PVg Inspections and other meetings as required

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About your new team and department

The role sits within the Pharmacovigilance Team as part of the Regulatory Affairs section of the Commercial & Stagey Directorate. It directly reports to the PVg Manager who reports upwards to the Head of Regulatory Affairs who also acts as Deputy QPPV. The role of QPPV is outsourced to a PVg consultancy company, Pharsafer Associates Ltd.

The Reg. Affairs Team is split into a regulatory/licensing section, pharmacovigilance, medical devices & artwork design/printing section. The department also consists of the Product Development Team and Customer Account Director.

The position of PVg Officer is an additional post alongside the existing postholder.

The whole team works closely together and creates a supportive, flexible, happy environment that is committed to delivering quality outcomes against targets.

About Torbay Pharmaceuticals

Torbay Pharmaceuticals (TP) opened a new manufacturing site in 2017 supported by a £26m investment. We aim to double the size of the business in the next 4-5 years.
Torbay Pharmaceuticals (TP) is a semi-autonomous business unit of Torbay and South Devon NHS Trust with its own Management Board.

Torbay Pharmaceuticals (TP) is a flagship business within the National Health Service and manufactures and distributes terminally sterilised injectables for the secondary care market in the UK and worldwide.

The business employs circa 200 people and has sales in excess of £20M per year.

TP is a holder of the following MHRA (Medicines and Healthcare Products Regulatory Agency) licenses:

- ✓ Manufacturers License
- ✓ Manufacturers License ‘Specials’
- ✓ Wholesale Dealers Licence
- ✓ Manufacturers Licence ‘Investigational Medicinal Products

TP is a holder of the following Quality Management Accreditations:

- ✓ ISO13485 – Medical Devices

Detailed job description and responsibilities

Communication and Working Relationships

- Process, monitor and submit adverse events cases involving licensed and unlicensed TP products to national & international safety databases
- Evaluate and prepare adverse reaction report in response to any unexpected safety issue during clinical use of TP products
- Follow–up any adverse events cases, where required, and submit additional information to the authorities
- Provide specialist knowledge-based assistance to staff at TP

Planning and Organisation

- Assist in developing, implementation and maintenance of procedures for all aspects of the PVg system including new PVg processes for new export opportunities overseas
- Assist with managing and maintaining PVg SDEA Agreements with approved distributors and/or 3rd party customers
- Review clinical and toxicological reports generated by industry experts and clinical/non-clinical papers arising from literature searches
- Assist in the preparation of safety variations to existing licences involving interpretation of highly complex analytical chemistry data and patient safety data

Analytical and Judgement

- Day to day running of the literature screening process where weekly literature searches are undertaken via scientific databases to identify any emerging safety trends, safety data, adverse events etc.
- Day to day running of the ASPR downloads, including MHRA portal & L2A Eudravigilance where appropriate, screening & triage within the signal detection process
- Generate line listings for safety reviews & reports where necessitated

Responsibility and Accountability

- Maintenance of the PVg system ensuring compliance with UK/EU legislation
- Assist with generating risk management plans for licensed products, for inclusion in product licensing applications, which assess a medicines safety profile including how risks to patient safety are prevented or minimised
- Assist in developing the product safety profile process and contribute to safety reviews to ensure the benefit-risk balance is always positive
- Coordinate the general documentation and signal generation information required for the quarterly PVg meeting
- Support the development and presentation of the PVg competency-based training programme to TP staff. This includes induction and annual refresher training incorporating any changes in the legislation

Responsibility for patients and client care

- Maintain the PVg safety database that holds critical patient and product safety data of TP products in clinical use

Policy and Service Responsibility

- Support the Head of Regulatory Affairs/Deputy QPPV & PV Manager in keeping all PVg processes and data in audit and inspection ready status
- Maintain PVg metrics for ASPR & literature searching activities & generate timely reports detailing compliance of the system
- Contribute to the development and implementation of policies using expert knowledge and the interpretation of national, European and Rest of World guidelines and legislation to ensure compliance for the pharmacovigilance aspects of TP
- Represent the department to a high professional standard in conduct, manner and appearance
- Strictly observe confidentiality and comply with procedures relating to the Data Protection Act
- Coordinate and lead on the implementation of any recommendations relating to regulatory compliance

Responsibility for Finance, Equipment and Other Resources

- Responsible for taking due care and attention for equipment and resources within the workplace

Responsibility for Leadership, Management, and Supervision

- Supervise lower grade staff when performing PVg tasks such as ASPR downloads, literature paper tracking etc.
- Identify training need and develop and deliver relevant coaching and training to ensure competence

Information Technology and Administrative Duties

- Management and manipulation of data using the electronic documentation system, (Q-Pulse) & any safety databases currently in use
- Management and manipulation of information databases (internal, national & European)
- Develop and implement procedures for the formatting of electronic documents, & validation of regulatory submissions using specialist documentation formats
- Submission of PVg documents via national electronic portals

PERSON SPECIFICATION

Attributes	Essential	Desirable
Qualifications and training	• Degree educated – life science degree or related (hons) • Demonstrable experience of working within the Pharmaceutical Pharmacovigilance Industry	• Chartered status • PIPA membership
Knowledge and experience	• Excellent knowledge of national and international pharmacovigilance legislation • Good knowledge of national and international licensing processes & legislation • Experience of working with global safety databases • Experience of L2A downloads, Article 57 submissions etc.	• Experience of generic manufacturing and branded pharma • Experience of working in a Pharmaceutical Quality System environment e.g. ISO 13485
Specific Skills	• Excellent communication and interpersonal skills • Experience of presenting complex information to large groups • Excellent project management & organisational skills • Ability to work under pressure to meet deadlines/targets • Self-motivated	

	• Excellent time management • Excellent planning and prioritisation skills • Ability be work independently with a high level of autonomy and as within a team • Able to deal with conflicts in demand, time constraints and deadlines • Experience of dealing with confidential and commercially sensitive information • Excellent IT skills – use of Adobe Acrobat Professional, Excel, safety databases e.g. Basecon, Argus etc.	
Requirements due to work environment/conditions	• Office or home working	

Physical skills	• None
Physical effort	• Computer/Keyboard skills: Adobe Professional, Safety databases, Q-Pulse, Excel spreadsheets • Attendance on specialist area study days, short courses etc.
Emotional effort	• Able to deal with conflict in demand, time constraints and deadlines • Ability to communicate PVg delays that may cause commercial delays, business impact • Ability to deal with urgent requests from Regulatory Agencies within strict deadlines of a highly complex scientific nature
Mental effort	• Able to concentrate for long periods on complex tasks or highly complex technical and clinical information • Ability to work with a level of autonomy alone and use own initiative • Ability to prioritise workloads and timescales