JENSONR +			
Job Description Number:	JRP-JDP-012	Version:	V2
Job Title:	Medical Information & Pharmacovigilance Officer	Effective: XX-May-2022	

Job Title: Medical Information & Pharmacovigilance Officer

Location: Barnstaple

Purpose of Job

- To work cross functionally within the Company providing medical and technical support in both medical information and pharmacovigilance.
- Support the EEA QPPV in the execution of high quality and robust pharmacovigilance.
- To provide pharmacovigilance support regarding monitoring/managing clinical safety and pharmacovigilance activities
- To assist the Company and clients on a daily basis, to ensure all pharmacovigilance responsibilities are fulfilled in accordance with current legislation and company guidelines.
- Liaison with and support of other departments (including Regulatory and Quality) and key clients to maintain pharmacovigilance integrity.
- Support the PV Operations Manager in the provision, and development of the scientific service, PV and medical information service and other related activities.

Qualifications and Role Requirements

- Medical degree or Life Sciences/Health related qualification with medical knowledge, or equivalent experience.
- Awareness of benefit risk assessment strategy in patient safety.
- Knowledge of relevant information sources such as printed publications, unpublished sources, databases, websites, and external bodies.
- Ability to analyse and appraise clinical, biomedical, and scientific reports in a systematic, accurate, fair, and balanced way.
- Pharmacovigilance awareness and experience (not essential).
- Ability (with supervision) to solve routine problems and issues constructively.
- Ability to make basic decisions with an understanding of the consequences.
- Demonstrates computer literacy, particularly in the use and management of relational databases.
- Ability to achieve personal objectives whilst meeting departmental standards of development.
- Ability to work under supervision in a matrix organisation.

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Personal attributes

- Ability to communicate effectively with a wide range of clients, adapting to an appropriate level of need.
- Ability to prioritise, plan and organise workload according to customer and business needs, and work within agreed timelines.
- Ability to solve routine problems and to manage issues constructively.
- Ability to act autonomously where appropriate, take initiatives and make decisions with a clear understanding of the consequences and potential next steps.
- Ability to communicate verbally and in written format, concise and meaningful information to support actions, decisions, and proposals.
- Demonstrate computer literacy, particularly in the use and management of relational databases.
- Meticulous and pragmatic attention to detail.
- Awareness of the ABPI code of practice Awareness of PIPA guidelines
- Awareness and understanding of legislation concerning pharmacovigilance codes of practice in relation to the role

Relevant Regulation and related issues

- Directive 2001/83/EC
- Regulation (EC) No 726/2004
- Regulation (EC) No 520/2012
- Commission Implementing Regulation on the Performance of Pharmacovigilance Activities Provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC
- Guideline on good pharmacovigilance practices modules
- Human Medicines Regulations 2012 and Statutory Instruments.
- Medical Device Regulations 2002 and Statutory Instruments.
- Post-Brexit MHRA Guidance for Medicines and Medical Devices.

Relationships

Responsibility to:	PV Operations Manager
Direct relationships:	Other pharmacovigilance and regulatory staff
	Other technical staff
	Jenson UK Director
	Chief Executive Officer
	External customers
	Regulatory Authorities
	External consultants and contractors
Indirect relationships:	External development partners and staff of external customers

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Limits of Role

The post holder is not expected to authorise expenditure. If required, this will in agreement with either the Pharmacovigilance Manager or Jenson UK Director.

Main Duties and Responsibilities

Pharmacovigilance

- Work within the PV team to ensure collaboration, compliance and completion of pharmacovigilance activities in a timely manner.
- Identify and assess ICSRs for processing, determining appropriate prioritisation criteria, in-put into the Drug Safety database and tracking systems and construct a case narrative ensuring compliance with Pharmacovigilance requirements and reporting timelines.
- Assess, record and process solicited data ensuring compliance with Pharmacovigilance requirements and reporting timelines.
- Determine and perform suitable follow up to complete solicited or spontaneous ICSRs according to company guidelines and reporting requirements.
- Conduct expedite reporting in accordance with worldwide regulatory agencies and Competent Authority requirements and company guidelines ensuring data is processed swiftly and appropriately within required timelines.
- Contribute to the review of cumulative safety data for signal management.
- Retrieve, assess, review and log literature search outputs.
- Liaise with key partners to draft and co-ordinate safety data exchange agreements to ensure both parties reach a timely and compliant agreement as required.
- Liaise with key partners, and other stakeholders/third parties regarding safety data collection and data reconciliation.
- Contribute to all activities prior to, during, and resulting from external inspections and internal/external audits including close-out activities.
- Contribute to and support resolution in any required corrective and preventative actions relating to Drug Safety.
- Contribute to the preparation and review and update of standard operating systems and guidance documents relating to pharmacovigilance operations and clinical safety.
- Involvement with all day-to-day Drug Safety activities as required, including quality review.
- Contribute to the preparation and conduct of audit, both internally for the Company and externally for and of clients.
- Ensure all communication received by PV from regulatory agencies (e.g., MHRA) are forwarded to senior team members so that they may be answered in a complete and timely manner and contribute to responses to communications as required.

Support the EEA QPPV in execution of oversight activities by:

- Conducting routine compliance checks
- Conducting quality review
- Act as a source of pharmacovigilance expertise for the Company in meetings, for other functional departments.
- Support the EEA QPPV in identification of emerging safety concerns and handling follow up actions
- Provide appropriate training in Pharmacovigilance and handling safety information to the Company and clients
- Mentoring and training of new employees as required on Pharmacovigilance

Medical Information and Regulatory Affairs

- Be the first point of contact for receipt of medical information enquiries via telephone, email or letter
- Ensure the 24-hour helpline is functioning and managed appropriately
- Ensure that the medical information in box is monitored regularly, and that all enquiries are dealt with appropriately and according to internal procedures
- Inform management of important safety issues as they arise which require attention
- Provide a response to medical information enquiries using appropriate documented sources of information or approved published literature
- Log, track and monitor enquiries for trends
- Provide summary data for QPPV and Company (MAH) oversight, including attendance at monthly client teleconference as appropriate
- Support the PV Operations Manager in the preparation and update of Medical Information SOPs and guidance documents
- Ensure that all FAQ sheets/ reference documents are kept up to date
- Support management in training new starters on how to manage medical information requests, and in the provision of annual refresher training

General responsibilities

All employees of JensonR+ Ltd have a responsibility under the Health and Safety at Work etc Act 1974 to ensure their own and other's safety whilst at work and to be aware and work within the framework of Jenson's Health and Safety Policy and the associated Standard Operating Procedures.