SERVICE SHEET

WAINWRIGHT associates

Pharmacovigilance

Pharmacovigilance

Continuously monitoring the safety of trial subjects and patients as well as meeting regulatory requirements forms the basis of your pharmacovigilance obligations.

Pharmacovigilance

Sponsors of clinical studies and holders of Marketing Authorisations for medicinal products are required to continuously monitor the safety of trial subjects and patients and meet ever more stringent regulatory requirements.

In addition, the post-marketing surveillance and vigilance reporting requirements for medical devices have recently been formalised with the implementation of a more structured EU-wide vigilance system.

Whether you are planning a new Marketing Authorisation Application, have new or established medicinal products on the market, or are working with investigational medicinal products or with medical devices, our expert team have many years of experience of pharmacovigilance work with the knowledge and the contacts as specialist consultants to assist you in meeting your pharmacovigilance obligations.

We can work on an on-going or *ad hoc* basis to address your specific needs.

Clinical study safety

We can assist with your clinical trial safety processes, from design and setup of safety procedures, to the creation and review of Serious Adverse Event narratives, reporting Suspected Unexpected Serious Adverse Reactions (SUSARs) to the national Competent Authorities and Ethics Committees and the creation and submission of Annual Safety Reports.

In addition, we can advise on or create safety updates to Investigator Brochures and Investigational Medicinal Product Dossiers (IMPDs) or create bespoke safety reviews in response to regulatory authority requests.

Post-marketing pharmacovigiiance

The pharmacovigilance requirements for the European Union are provided in great detail in the 200-plus pages of Volume 9a of the Rules Governing Medicinal Products in the European Union. Wainwright Associates can guide you through the complexities of Volume 9a and can advise and assist with the processes described therein including:

- Collation, assessment, follow-up and reporting (including electronic) of spontaneous adverse drug reactions received by the Marketing Authorisation Holder.
- Routine literature searching to identify potential adverse events related to the Marketing Authorisation Holder's products.
- Preparation and submission of Periodic Safety Update Reports.

WAINWRIGHT associates

It is a legal requirement to appoint a QPPV who resides in the European Economic Area.

Qualified Person for Pharmacovigilance

The appointment of a Qualified Person for Pharmacovigilance (QPPV), who must be resident in the European Economic Area, is a legal requirement. The legislation allows the QPPV function to be contracted out and one of our appropriately qualified and experienced consultants can carry out this role on your behalf.

Risk management and pharmacovigilance plans

One specific area of focus for EU Member State Competent Authorities at present is that of risk management and pharmacovigilance planning. Once an investigational medicinal product is approaching the Marketing Authorisation Application stage we can assist with the creation and development of the required Risk Management and Pharmacovigilance Plans.

Audits and pharmacovigilance inspections

It is a requirement that pharmacovigilance systems should be audited. Our team, who have recent experience of supporting companies through the Competent Authority inspection process, can audit your system and provide recommendations for improvements where necessary.

We can also help you to prepare for Competent Authority pharmacovigilance inspections, including preparation of the pre-inspection documentation and assistance during the inspection itself. We can work with you to prepare your response to any inspection finding.

Pharmacovigilance training

All staff involved with pharmacovigilance activities, including sales representatives and administrative staff must be able to demonstrate that they have been appropriately trained. We can prepare and deliver bespoke pharmacovigilance training to help you meet the specific needs of your organisation.

Standard operating procedures

All pharmacovigilance procedures must be fully documented, usually by way of Standard Operating Procedures (SOPs). We can assist you in the preparation of such SOPs, either by advising on content, reviewing draft SOPs or preparing SOPs on your behalf according to your particular requirements.

Medical devices

As of January 2008 new EU guidelines on the Medical Device Vigilance System came into effect in order to facilitate a uniform application of the requirements described in the three EU Medical Device Directives. Wainwright Associates can assist with the required Field Safety Corrective Actions and the creation of Field Safety Notices and notification to EU Member State Competent Authorities.

Contact us:

For a more detailed discussion on how we can help you, contact us on **+44 (0)1628 530554** or email us on **info@wainwrightassociates.co.uk**

www.wainwrightassociates.co.uk