

# RED LINE Pharmacovigilance

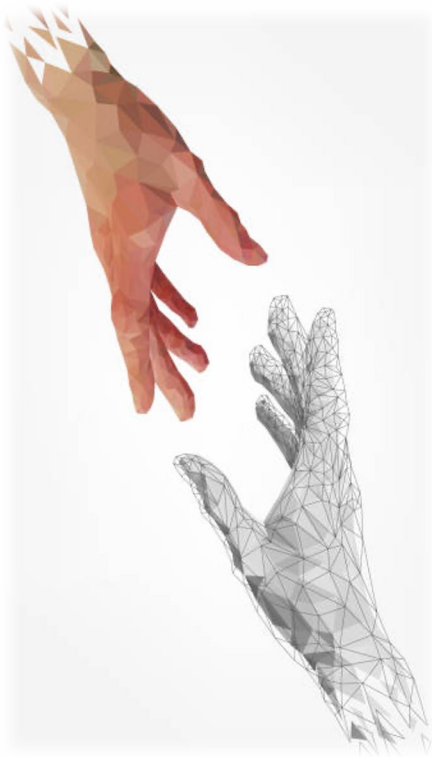
Pharmacovigilance Outsourcing Partner

Risk management services for the pharmaceutical industry.

RED LINE

PHARMAVOIGILANCE





# Good pharmacovigilance practice is dependent on a sound understanding of the key principles of this science.

## Legislation is global and the process is complex.

Red Line Pharmacovigilance Ltd is a small, emerging company established in 2010.

Our Managing Director, Shirley-Ann van der Spuy is a qualified pharmacist with a post-graduate qualification in pharmacovigilance and over 20 years experience in the pharmaceutical industry. Her portfolio is broad and her experience extends to many facets in the world of pharmacy, which includes community pharmacy, quality control, regulatory affairs, medical information and pharmacovigilance.

Our Technical Director, Ben van der Spuy has many years experience in project management and spent 12 years working for Accenture Services, managing large software development teams and budgets of tens of millions of pounds.

As co-owners and company directors, we believe in the philosophy of 'learning to walk before you run.' Our primary focus has been to build a strong foundation, the backbone of which is the provision of a quality service. We have purposefully managed a slow expansion process to ensure service levels are maintained and staff are not overstretched.

Our team has been carefully and meticulously selected. All staff have a strong background in the healthcare industry and a sound understanding of life sciences.

### Our mission statement:

***"One cannot change whether a drug causes an adverse reaction. What can be changed is whether a manufacturer did everything possible to detect it."*** - Strom BL, *Pharmacoepidemiology*, 4<sup>th</sup> Edition. 2005.

**"A good relationship with the MAH is critical."**

**RED LINE**

PHARMACOVIGILANCE

## We do business with clients who want to do things right.

***“It takes many good deeds to build a good reputation and only one bad one to lose it.”***

– Benjamin Franklin

At Red Line our focus is on maintaining our reputation of honesty and integrity. We are a company who don't compromise on quality. At the same time, we are committed to providing a cost-effective service to our clients.

We understand the monetary investment required for product development and commercialisation. We believe cost effective prices assist in promoting better compliance. If costs are not excessive the client can be confident their budget meets the needs for regulatory compliance and can better manage the costs associated with a medicinal compound.

Healthcare starts with pharmaceuticals, their research, testing and continued development to ultimately produce a quality medicinal product. These advances save or extend the lives of patients, ease the cost of healthcare for government bodies and change the outcome of many future generations. Red Line takes great pride in walking this path with its clients and ensuring the therapeutic goals of the medicinal product are always kept in focus.

We believe in forming strong collaborative relationships with our partners and provide a range

of services to support the pharmacovigilance process. Our team is proficient in adverse event case processing, literature monitoring, causality assessment and medical review.

We can manage your registration with Eudravigilance and conduct electronic reporting to regulatory authorities on your behalf. For smaller companies this function can be extended to include the management of the medicinal product dictionary (xEVMPD) portal.

Backend pharmacovigilance services extend to the writing of standard operating procedures, clinical dossiers, medical writing, risk management plans, periodic safety update reports, clinical expert statements and the compilation of reference safety documentation, such as company core data sheets, summary of product characteristics and patient information leaflets.

Complimentary services include medical information enquiry handling and copy approval. We have invested in a bespoke IT solution, a medical enquiry tracking system (METS), which provides a full history and audit trail of the medical enquiry handling process and reconciliation with linked departments.

Copy approval can be performed for any promotional materials to ensure compliance with the ABPI code and appropriate legal requirements. Where signatory resources are stretched we can provide final medical and non-medical signatory support.



**A range of scientific services tailored to cover human pharmaceuticals and medical devices.**



# Safety monitoring



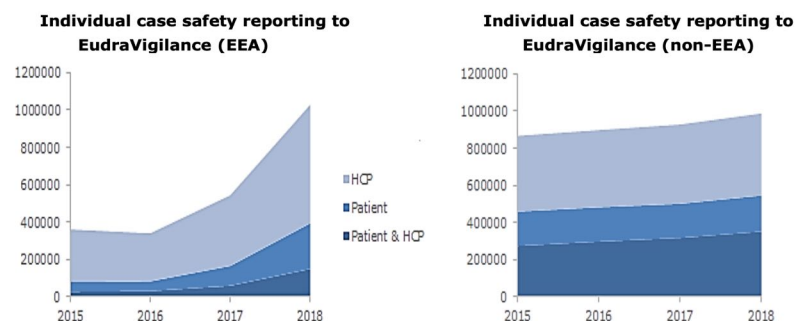
Once the medicine is authorised, EMA and national authorities continuously monitor its safety.

Pharmacovigilance is a discipline that has been around since the early 1960's and although it is still a young science, pharmacovigilance has undergone many changes over the last two decades. The principle change is that of risk management whereby companies continuously ensure the benefits of a medicinal product always outweighs any potential risk to the patient.

Since the thalidomide tragedy in the 1960's, which resulted in the disfigurement of thousands of children, drug safety has become a global concern. Worldwide regulatory authorities have collaborated to produce international guidance (ICH guidelines) to provide a framework for this discipline for the pre and post marketing phases of drug development.

## Report on pharmacovigilance tasks from EU member states and the European Medicines Agency (10 Dec 2019)

A significant increase in the reporting of adverse reactions was noted in 2017, with a 60% increase in cases reported to the EMA (1,471,596 reports related to adverse drug reactions, of which 543,548 were from the EEA) compared to the previous year. This growth continued in 2018 with a further increase of 37%.



The number of serious adverse events reported has steadily increased over the years, with 290,000 in 2015 to 424,000 in 2018. The majority of these cases are reported by healthcare professional. However, national campaigns to encourage direct reporting by patients have also resulted in an increasing number of reports year on year.

Patient reported ICSRs			
Year	Serious	Non-serious	Total
2014	29477	9770	39247
2015	34026	17100	51126
2016	37428	14450	51878
2017	60558	45456	106014
2018	51114	193048	244162

## Responsibility for Pharmacovigilance

### Marketing Authorisation Holder. (MAH)

The marketing authorisation holder is responsible for the pharmacovigilance tasks and responsibilities as laid down by local regulations and **assumes full responsibility and liability** for its authorised medicinal products to ensure that appropriate actions can be taken when necessary. The MAH must **establish pharmacovigilance system and appoint a QPPV** who is permanently and continuously at their disposal. The MAH must register the details of the QPPV to local regulatory agencies. The MAH must **ensure the QPPV have sufficient authority** to be able to influence and affect change to the pharmacovigilance and quality systems and is notified of any changes made to it, including contractual obligations with third parties.



### Qualified Person for Pharmacovigilance. (QPPV)

The appointment of a QPPV is a UK and EU legal requirement. This person is responsible for the establishment and maintenance of the MAH's pharmacovigilance system and must have sufficient **authority over the pharmacovigilance and quality systems** to act in full compliance of the laws of that country. The QPPV assumes the lead role in pharmacovigilance services and activities, the aim of which is to ensure that every medicinal product has the best possible safety profile. The QPPV acts as a single point of **contact for regulatory authorities** and is expected to be available on a 24-hour basis. The QPPV can act on behalf of more than one MAH. A **deputy QPPV is required** to provide back up support to the QPPV in times of absence.



### National Responsible Person. (NCP)

Although companies may appoint a QPPV, certain countries (including the UK) require the appointment of a **National Contact Person (NCP) or Local Responsible Person (LRP)** for pharmacovigilance. This person must reside in the respective country and **reports directly to the QPPV**. The details of the NCP must be registered with the local regulatory agency. This individual must be able to **facilitate responses to pharmacovigilance queries** raised by the **regulator in the local language**. In the UK, the NCP must have access to the UK Pharmacovigilance System Master File and be provided access to UK safety reports held on the global safety database. An appointed back up person or deputy is not required for this role for absences of <1 month.





### Pharmacovigilance.

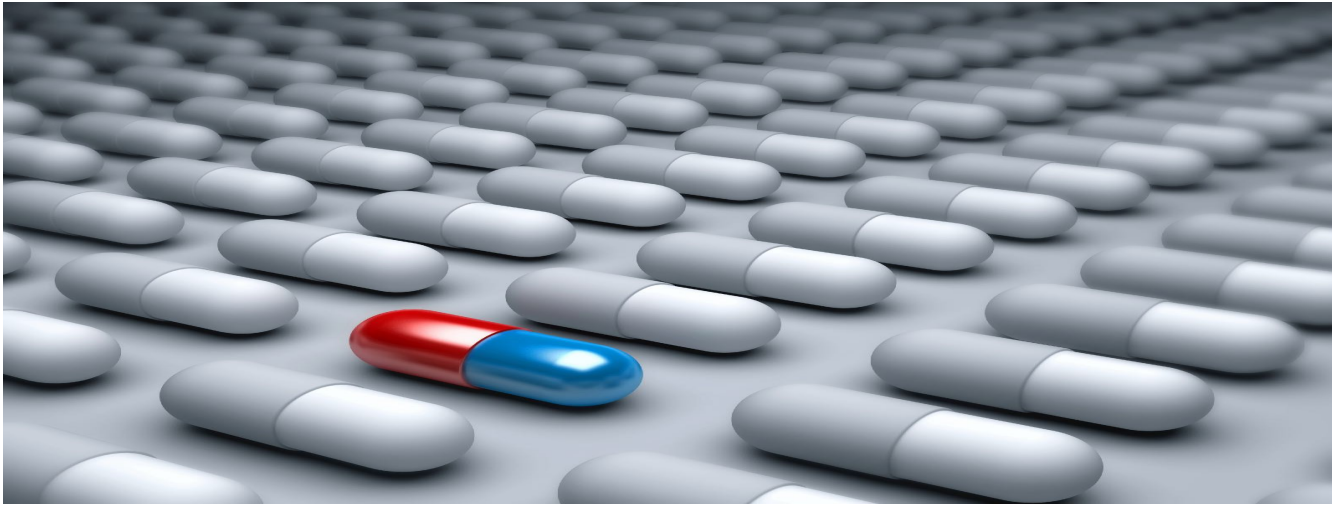
Individual Case Safety Reports (ICSRs) require a thorough review by the MAH. Each case must pass through a **pre-screening triage** to assign 'report-ability' and associated deadlines. Cases must undergo assignment of **MedDRA terms** to prepare for expediting. Each report undergoes **causality** assessment, **narrative** writing and a final **review by a medically qualified member of staff**. This process underpins the fundamental pharmacovigilance system and **getting it right from the start is paramount** to ensuring aggregate reports produced from the data generated is reflective of the true benefits and risks of the product. The electronic reporting of all adverse events is a mandatory requirement throughout the European Union.

### Medical Information.

We provide complementary services to clients enabling a seamless transition between **medical information**, product **quality complaint handling** and **adverse event follow up** and investigation. Medical information and pharmacovigilance teams should **work collaboratively** at all times. Representing the '*face of the firm*' staff members should be knowledgeable about company products and the **scientific service** they provide to healthcare professionals, members of the public and internal staff is valued. At Red Line we ensure our medical information team have past experience in the healthcare industry and a good grounding in life science. **High standards** and **quality patient care** is always our top priority.

### Risk Management.

The focus of pharmacovigilance has shifted towards risk management. New applications for marketing authorisations require the submission of a risk management plan. In addition to the requirement for companies to have a system in place to collect and report adverse events, they are expected to **monitor trends** with this data to enable a continued assessment of the **risk-benefit profile** during the entire life-cycle of the product. Companies are expected to act on **emerging safety information** or changes in the safety profile that negatively impact the end user. These changes are reflected in key **reference safety documents**, the Summary of Product Characteristics (SPC) and the Patient Information Leaflet (PIL). Pharmacovigilance impacts regulatory departments, marketing, sales and legal teams.



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