

RED LINE Pharmacovigilance

Pharmacovigilance Outsourcing Partner

Risk management services for the European pharmaceutical industry.





**“A good relationship
with the MAH is
critical.”**

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, 4th Edition, 2005.

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.

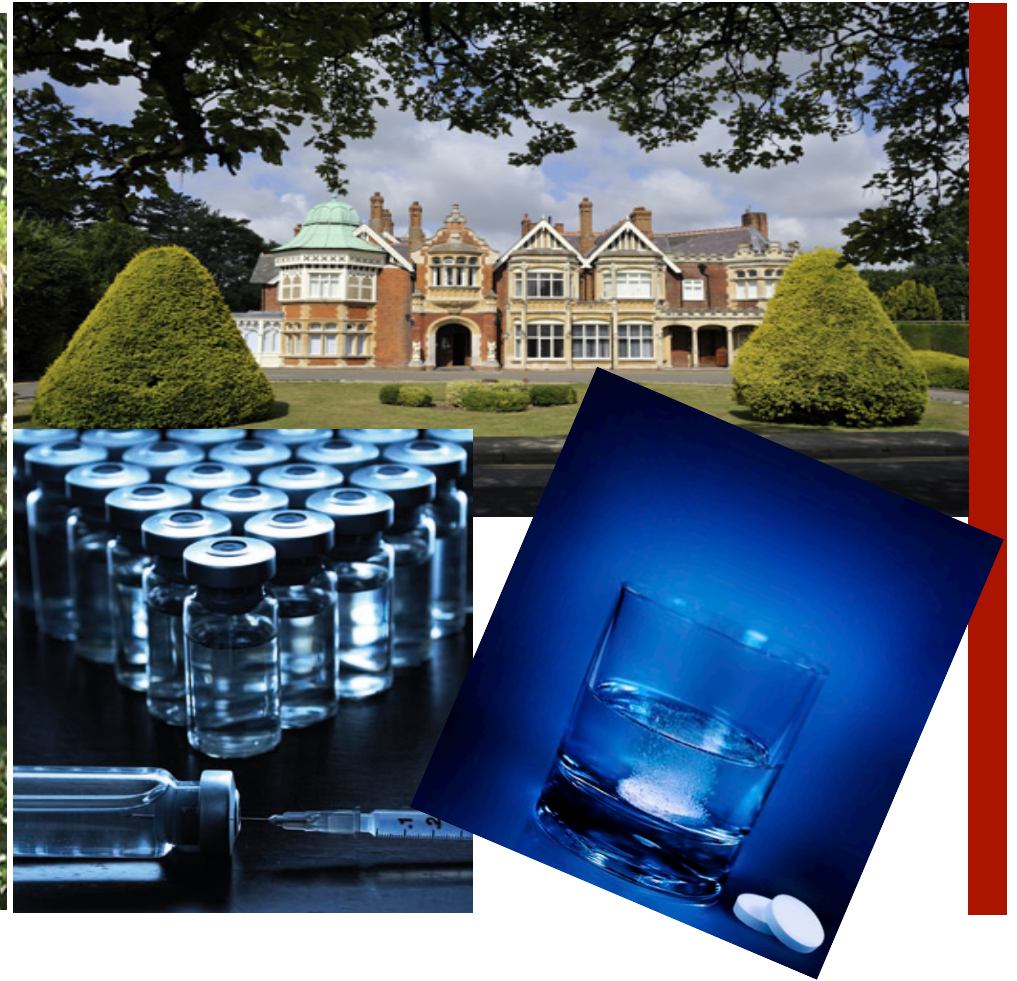
Backend pharmacovigilance services extend to the writing of standard operating procedures, clinical dossiers, medical writing, risk management plans, periodic safety update reports, clinical expert statements and the compilation of reference safety documentation, such as company core data sheets, summary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





Bletchley Science & Innovation Centre, a historically significant site for business.

Our offices are located within the grounds of the Bletchley Park Museum run by the Bletchley Park Trust. The Trust is working towards transforming Bletchley Park into a world-class heritage and educational site. Red Line is proud to support this worthy cause, with 30% of our rental income allocated as funding to the Trust. We feel this historically significant site, reflects the values of the modern world.

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 outweigh 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.



Pharmacovigilance.

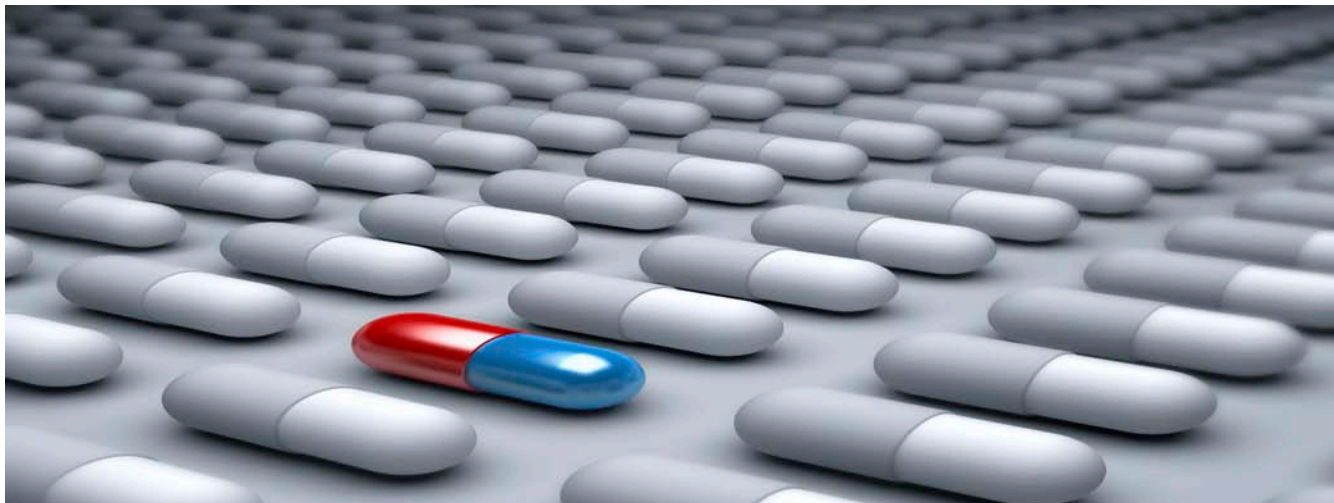
Individual Case Safety Reports (ICSRs) require a thorough review by the MAH. Each case must pass through a **pre-screening triage** to assign 'report-ability' and associated deadlines. Cases must undergo assignment of **MedDRA terms** to prepare for expediting. Each report undergoes **causality** assessment, **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.



RED LINE Pharmacovigilance Ltd

Suite EU3 & EU4, Science & innovation Centre, Sherwood Drive
Bletchley Park, Bletchley, Milton Keynes, MK7 8QR, United Kingdom

Tel: +44(0)1908 363436

Email: info@redlinepv.co.uk

www.redlinepv.co.uk



PHARMACOVIGILANCE

