pure drug safety

pharmacovigilance

Professional, Flexible, Dependable

Fully understanding your needs and expectations inspires our TEAM to exceed them.

Choose PDS as your PV outsource service provider and you will benefit from working with a highly dependable partner, with the right levels of knowledge and experience to guide you through the complexities of Pharmacovigilance.

Our TEAM of PV professionals help you to deliver results at all stages of the drug safety process, across all phases of drug development, from Phase I through to Phase IV for innovative drugs, to generics, as well as medical devices, herbals and cosmeceuticals.

With over 60 years' experience working alongside national and international Pharmaceutical and Biotech companies, PDS has the knowledge and experience to deliver the results you need.

We can act as your virtual PV department to manage the entire drug safety process, or alternatively we can provide you with interim professional resources as and when you need them.

'PDS's proactive approach went beyond what was expected of them. Their professional team demonstrated a willingness to put our needs at the centre of focus, which was the key to a successful outcome.'

Global Head of Drug Safety
Generics Company

Dynamic pharmacovigilance services - choose the support you need, exactly when you need it.

'PDS proved to be an outstanding business partner and never failed to meet our expectations. The project was delivered on time and within budget'.

Submissions Manager,
EU Pharma Company

Working with PDS means you have a highly respected and trusted partner, with established lines of communication to the regulators.

Our flexible and dynamic pharmacovigilance services allow you to simplify your internal processes, eliminate recruitment and training costs, while benefiting from our broader pool of experienced PV professionals.

Maximise your internal resources by supporting them with PDS's vastly experienced network of consultants. Delegate critical tasks to our TEAM and let us help you to deliver the results you need.

Our TEAM's proactive approach identifies any potential roadblocks before they arrive, mitigating risk and helping to ensure you remain compliant.

Call on us to help with the key areas where you most need support and maximise your return on investment

PV Services

We will always endeavour to bring solutions to the table in a timely manner, rather than simply sit back and try to fix problems when they occur. PDS's clients benefit from our forward thinking, proactive and collaborative way of working.

Benefit from our experience in

- EEA QQPV & Deputy
- Drug safety strategy and planning
- PV project management
- Cross-functional team management
- Delivering to critical timelines
- PV/Quality audits/due diligence
- Medical/Scientific advice
- Pharmacovigilance training
- xEVMPD

Core services

- EEA QPPV & Deputy
- Literature searches and Signal detection
- Case Processing and Reporting
- MedDRA Coding
- PV Database
- Medical Writing – PSUR, PSMF, SmPC, PIL, SOP
- xEVMPD Services/IDMP Preparation
- PV Auditing and pre-inspection support
- PV Training

Whether you are looking for pre or post marketed surveillance, our highly professional TEAM has the expertise and experience to fully support your needs.

PV Services

We will always endeavour to bring solutions to the table in a timely manner, rather than simply sit back and try to fix problems when they occur. PDS's clients benefit from our forward thinking, proactive and collaborative way of working.

PDS will assess your company's needs in terms of volume of cases and advise of the most appropriate pharmacovigilance system.

If you do NOT already have a PV system, PDS will provide you with a user-friendly and low cost database without compromising the quality and compliance of your data: PV247.

'When faced with a time critical project choosing the right outsource partner is paramount.

PDS impressed us with their great knowledge, out of the box thinking and immense willingness to work together with our internal team. I would recommend them highly'

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Head of Drug Safety
EU Pharma Company.

PV Services

PBRERs, PSURs and DSURs

Regulatory authorities require continuous proof that the Pharmacovigilance system and monitoring procedure you have in place for your products is working in the best interest of the patient.

Since June 2016 the submission of all PSURs have to be made to the EMA's repository. This applies to all products.

Risk Management Plan (RMP)

Module V of the GVP Guidelines together with the ICH E2E emphasise the importance of a well-established and well prepared RMP.

PDS will support you in writing this mandatory document for your product whether this is a generic or an innovator one.

The Pharmacovigilance team at PDS have experience in writing and checking all the reports your company needs to stay compliant.

PDS can help you with the writing and submission of reports. We will also assess their compliance as well as help you prepare the Company Core Safety Information (CCSI) document that should accompany the reports.

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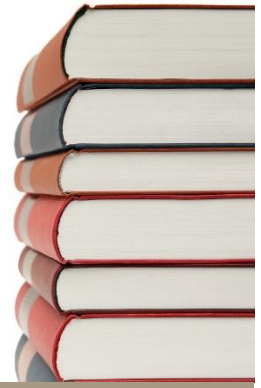
PV Services

Pharmacovigilance Training

PDS has provided pharmacovigilance (PV) training to pharmaceutical companies and their PV professionals for over ten years.

Our training portfolio covers the complete spectrum of pharmacovigilance meaning we are able to tailor training for people of all levels of knowledge and experience.



We provide a range of pharmacovigilance training including:

- General training on key aspects of pharmacovigilance such as:
  - Regulations
  - Drug safety
  - Clinical trials
  - PSURs/PBRERs
  - The importance of identification of AEs/ADRs.
- Topic specific trainings, on demand, in-house or via webinar e.g.:
  - Audits and inspections
  - Risk Management Plans
  - Signal Detection.

EU regulations require all PV staff to be appropriately qualified for their role and demonstrate the required level of competence.

Each PV professional must also have an up to date documented training record.

PV Services

Clinical trials

PDS can provide all necessary support during your clinical trial programme, including appointing a responsible person, 24 hour cover, follow up of SAE reports, expedited reporting to relevant authorities and reconciliation activities.

- Appointing a responsible person
- 24 hour cover
- following up of SAE reports
- expedited reporting to relevant authorities
- reconciliation activities

Prior to the commencement of your clinical trial programme a senior member of the team will establish your needs and document within a Management Plan how your PV process will work.

Device Vigilance Reporting

The team at PDS has experience in reporting incidents to relevant competent authorities associated with the use of devices. We can help evaluate incidents and implement the necessary corrective and preventative actions. Likewise the team can help with evaluating which events should be reported and those which should not, in line with the current Medical Devices Directive (93/42/EEC).

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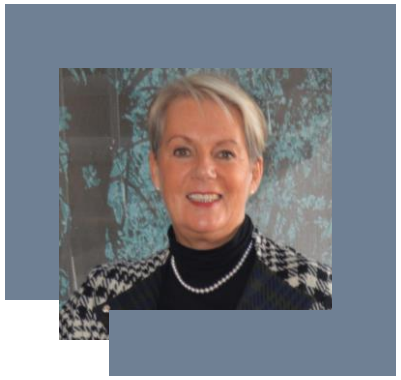
PDS was founded in 2005, initially providing Patient Information services. Over the course of the following decade we have grown steadily, whilst expanding our portfolio. Today we offer our clients a complementary range of professional pharmacovigilance and regulatory services.

As a partner of choice for numerous high profile life-sciences companies, (including some of the world's Top 5 pharma), we continue to build on our reputation for being a trusted outsource partner, committed to delivering detailed responsive solutions through strategic thinking, depth of professional ability and a commitment to the highest quality standards.



To find out more about how PDS can help you, get in touch today. Our TEAM look forward to hearing from you.

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