PV Services

EXTEDO eRegulatory Affairs

Pharmacovigilance Services

Improve your internal processes and ensure compliance with pharmacovigilance regulations

Are you aware of the changes regarding pharmacovigilance regulations? Are your processes streamlined to ensure compliance with new reporting timelines? Are all processes reflected in the respective SOPs and does your Pharmacovigilance System Master File describe your pharmacovigilance system adequately?

Benefits

- Ensure compliance through a full understanding of current and upcoming pharmacovigilance requirements
- Optimize pharmacovigilance processes and interfaces to ensure a proper and timely handling of mandatory activities
- Implementation and updates to SOPs covering pharmacovigilance processes
- Ensure a PSMF is available that describes your pharmacovigilance system

With the introduction of the so-called “Pharmapackage” within the EU in 2012, a large amount of new pharmacovigilance requirements were introduced. In many companies, the implementation of these changes is still very much ongoing as the updates affected not only the pharmacovigilance processes themselves, but also impacted other groups such as Regulatory Affairs, Quality Assurance and Clinical Research. These processes are part of an overall drug safety environment which has to be described within your Pharmacovigilance System Master File (PSMF).

One of the main new challenges is the timely electronic reporting of non-serious adverse drug reaction cases. EXTEDO understands the necessities of adequate processes in combination with an easy-to-use safety database which enables the capturing, assessment and reporting of cases as well as the tracking of reporting timelines.

Tailored services for pharmacovigilance

EXTEDO’s Pharmacovigilance Business Process consulting services are tailored specifically to your needs. Based on many years of experience working with drug safety rules and regulations, EXTEDO’s team will help you to identify gaps in your pharmacovigilance processes and help you to develop and implement appropriate strategies PSMF to resolve them.

Our team provides the following services:

- **gap-analysis of your pharmacovigilance processes**

  A pharmacovigilance system is a complex network of processes with numerous tasks and responsibilities. Changes in legal requirements or internal structures necessitate rework and adaption of these processes. Similarly, updates to technical infrastructure, e.g. a new safety database, may also trigger process changes. EXTEDO will analyze your pharmacovigilance processes and will highlight any gaps and improvement opportunities.

- **advice on processes / resources**

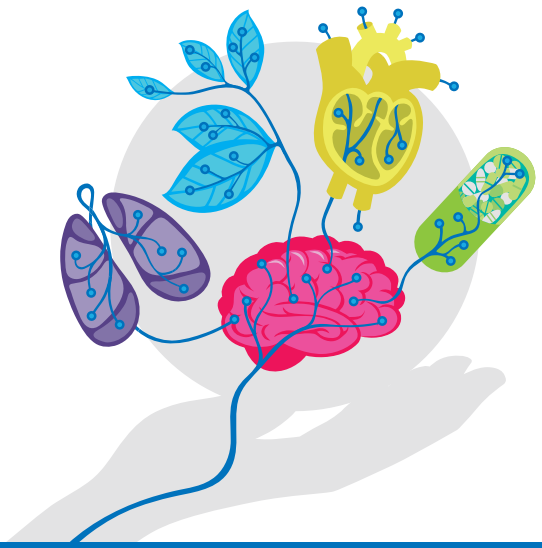
  Based on your needs and the results of our gap analysis, EXTEDO will provide individual best practice consultancy. Working together with your experts, EXTEDO will identify optimization opportunities for your pharmacovigilance processes and resources. In addition, we will provide advice on concrete improvement possibilities and how to implement them.

- **support for the implementation and optimization of existing processes**

  With pharmacovigilance systems being complex and consisting of many different processes and tasks each organization will have their own priorities as to which changes need to be made first. We provide you with the guidance you need to make these critical decisions, and to implement your chosen solution.

Ensure regulatory compliance and operational excellence

Helping your organization to meet legal requirements is just one aspect of EXTEDO's services – on the path to pharmacovigilance compliance; we identify areas where processes can be improved, thus ensuring maximum efficiency and operational excellence.



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About us

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 1000 maintained customers across 65 countries to deliver Effortless Compliance™.

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