

Everything You Wanted to Know ABOUT PHARMACOVIGILANCE BUT HAVE BEEN AFRAID TO ASK

From the time humans begin taking an investigational new drug, pharmacovigilance measures play a critical role in every phase of a product's lifecycle. However, understanding pharmacovigilance requirements can be daunting even for seasoned industry pros. This overview will answer all the questions you ever wanted to know about pharmacovigilance, but were afraid to ask.

What is pharmacovigilance?

Pharmacovigilance, sometimes shortened to "PV," is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications and biologics.

What are the basic components of a pharmacovigilance strategy?

A robust pharmacovigilance strategy requires expertise in the following areas: medicine, regulatory, and technology. It involves the following main elements:

- ▶ Strong processes/SOPs
- ▶ Individual Case Study Report Capture and Processing
- ▶ Literature Screening
- ▶ Signal Detection and Assessment
- ▶ Risk Management
- ▶ Periodic Safety Writing
- ▶ Regulatory Expedited Reporting
- ▶ Safety Database

When should a manufacturer consider a pharmacovigilance plan?

Drug developers need to consider their pharmacovigilance approach prior to human testing (Phase I) and throughout the duration of product development and the post marketing product lifecycle.

How does pharmacovigilance impact brand loyalty and commercialization?

Manufacturers must comply with myriad pharmacovigilance regulations in order

to obtain and maintain the authorization to commercialize their products. A robust and complete pharmacovigilance program supporting continuous enhancement of the product safety profile is crucial to ensuring patients and healthcare providers are well-informed on product safety. Proactive pharmacovigilance where data are centralized across trials will allow early identification and management of any risks, thus ensuring optimal patient access to a drug with the highest safety.

What are the key considerations in the United States?

In the U.S., all pharmaceuticals, including drugs and biologics, as well as medical devices, are subject to federal regulations, enforced by the FDA. During clinical development of a product, the FDA is focused on development of a safety profile and requires, similar to Europe, the submission of expedited reports for serious and unexpected adverse events and confirmed signals occurring in association with the drug or biologic under development.

Unlike Europe, the FDA is focused on new molecular entities and on serious and unexpected adverse events occurring after marketing. Also, unlike Europe, not all newly approved pharmaceuticals are required to have a risk management plan in place at the time of marketing. The FDA has a robust signal detection program in place, and pharma companies and manufacturers of medical devices are subject to these regulations.

What are the key considerations in Europe?

The European Medicines Agency (EMA) is the coordinating agency for all members of the European Union (EU) and the European Economic Area (EEA), which includes all 28 member states of the EU plus Iceland, Liechtenstein, and Norway. The EU/EEA has undergone major changes in its post-marketing legislation culminating with a major change in pharmacovigilance requirements, which began in July 2012 though the publication of the good pharmacovigilance practices (GVP) modules.

Contributed By:



VERONIQUE BASCH, PHARM.D.

Executive Director, Global
Pharmacovigilance
United BioSource Corp.

The EMA is requiring that all applicants name a qualified person for pharmacovigilance (QPPV), and set up a pharmacovigilance system master file (PSMF), which will describe all aspects of their PV system. The GVP also details requirements for signal detection and management, literature screening, and risk management, with requirements which are often more stringent than FDA regulations.

The EMA (unlike the FDA), now requires all serious adverse events, both those labeled and those unlabeled, to be submitted within 15 calendar days to the EMA and other national regulatory agencies, as well as submission of all case reports of non-serious adverse events within 90 calendar days of receipt by a marketing authorization holder.

While Europe and the United States are getting closer and more harmonized, there are still some areas where the regulations differ and require specific expertise to ensure compliance. It is advised to consult with local experts in pharmacovigilance.

Regarding medical devices, the EU/EEA is focused on reporting incidents in association with the use of devices, but the general approach is similar to that of the FDA regarding those incidents that either result in serious injury or death or result from a malfunction in a medical device with the potential for serious injury or death. Legislation continues to evolve regarding medical devices, and there is no one simple answer to medical device reporting.

How do we develop a global solution to product safety?

Global solutions must be based on two

criteria: fulfilling the regulatory requirements in the geographic areas in which medical products and devices are developed and marketed, and tailoring approaches to fulfill regulatory requirements with the unique products of the individual company

Manufacturers should ensure that global compliance objectives are identified and addressed, and that high-quality signal detection, prioritization, and evaluation are in place to identify actual risks (called Identified Risks), as well as Potential Risks.

What are the benefits of outsourcing pharmacovigilance services vs. maintaining the responsibilities in-house?

Manufacturers of all sizes can benefit from outsourcing pharmacovigilance activities. The expertise, systems and flexibility provided by a vendor can complement current activities or even provide an entire team without the need to hire individual staff members. The concentration of various experts within a provider's team will allow for best-in-class support in the medical, regulatory, and technologic aspects which all are critical to setting up a compliant PV system.

UBC is an expert in navigating pharma-

covigilance requirements. We have a team of more than 100 professionals stationed around the globe committed to pharmacovigilance programs of all sizes. UBC welcomes the opportunity to collaborate with you to explore the design and implementation of pharmacovigilance programs that best support your product and patients.

What role does pharmacovigilance play in specialty pharmacies?

Specialty pharmacies are playing an increasing role in patient support and disease management programs, which requires compliance with the guidelines that exist in the global pharmacovigilance landscape. Manufacturers and authorities expect that AEs highlighted through client contact are duly recorded and reported. It is critical to ensure adequate training of pharmacy staff to be able to detect, document, and communicate reported safety information.

What role does pharmacovigilance play in Reimbursement Hubs?

Reimbursement Hubs have frequent communication with patients and must have procedures in place to report potential AEs. The

reimbursement hub staff, like the specialty pharmacy staff, is expected to be fully trained on recognizing and forwarding AEs appropriately. These processes are key so authorities and manufacturers can track the safety of the product as well as identify potential signals proactively. ^{PV}

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