

PAREXEL Marketed Product Safety Services

PAREXEL's Marketed Product Safety services increase post-marketing safety compliance allowing for enhanced focus on key business objectives while improving risk management for marketed products.



70%

Today 70% of drug and biotechnology companies are outsourcing some aspects of their regulatory operations

PAREXEL Marketed Product Safety (MAPS)



Proactive safety management is vital for all biopharmaceutical products and medical devices. Incidents involving marketed pharmaceuticals and over-the-counter (OTC) medicines have become more prevalent in recent years, bringing the issues of safety monitoring and risk management to the forefront of public attention and regulatory scrutiny in the United States, Europe, and elsewhere around the world. These incidents highlight the importance of closely monitoring the safety of every drug – even those that have been on the market for many years – as an essential part of a robust risk management strategy.

The increasingly global scope of the pharmaceutical marketplace has compounded the industry's safety monitoring challenges. With most companies marketing their products in multiple countries, the volume of regulatory data to be tracked and reported has grown exponentially. Concerns about current pharmacovigilance practices have led to more stringent reporting requirements for marketed products. As a result, the typical pharmaceutical company's regulatory affairs staff can spend as much as 50 percent of their time on routine safety monitoring and reporting tasks for marketed products – leaving less time for support of new product pipelines.

As safety requirements for the marketed products sector become more salient, the current financial climate is generating significant pressure on the pharmaceutical industry to reduce fixed costs, increase the efficiency of routine operations, and concentrate limited resources on core competencies such as research, development and marketing. The conflicting demands for expanded safety management processes and lower fixed costs create a significant dilemma for industry executives, who cannot afford to ignore either imperative.

PAREXEL's Marketed Product Safety services address both of these demands with a cost-effective solution that allows pharmaceutical companies to accommodate the increasing volume of non-clinical, post-marketing safety reporting requirements – without increasing overhead expenses or compromising quality. By leveraging our existing global safety management expertise and infrastructure, PAREXEL's Marketed Product Safety team can partner with your company to lower the cost of routine safety monitoring and enhance compliance for marketed products. Equally valuable, your internal resources will have more time to concentrate on strategic safety and regulatory priorities that can increase revenue and protect the value of your assets.

As a global biopharmaceutical service provider and an industry leader in regulatory and pharmacovigilance consulting, PAREXEL has the knowledge, experience, and resources to deliver a full range of safety monitoring services that can be tailored to meet your company's specific requirements – whether your products are branded prescription pharmaceuticals, generic drugs, OTC medicines, or medical devices. PAREXEL's services include:

- Spontaneous and solicited Adverse Drug Reaction (ADR) event processing
 - Intake/event capture and processing
 - Medical review and quality assurance
 - Local language capabilities with staff on the ground in over 52 countries
 - Regulatory reporting of safety events
 - Product quality complaints and medical information requests
- Aggregate reporting, such as Periodic Safety Update Reports (PSURs)

- On-going signal detection and safety surveillance
- Medical and scientific writing services (including literature review and regulatory submission support)

With our extensive staff of safety experts, seven global safety “hubs”, and global presence, PAREXEL is ready to assist you, anywhere in the world.

Leveraging Strategic Outsourcing

In the same way that the industry has embraced strategic outsourcing for clinical trials, many pharmaceutical companies are turning to vendor partners to more efficiently provide the resources needed to handle the specialized requirements of post-marketing safety surveillance. Routine safety maintenance tasks are logical candidates for outsourcing because of the large volume of information and well-defined processes. A large pharmaceutical company might receive more than 100,000 spontaneous ADRs per year across dozens of products. This type of volume lends itself well to outsourcing to a specialized group that can cost effectively manage the process either on shore or in rigorously controlled offshore locations. Smaller companies also benefit from outsourcing by avoiding the cost of adding in-house resources to perform routine safety monitoring tasks.

The advantages of leveraging an experienced partner for post-marketing safety monitoring include:

- Decrease fixed costs by moving to a variable-cost model for these services
- Increase asset value by improving post-marketing safety monitoring, which reduces your company’s risk
- Improve overall performance by focusing your internal resources on key strategic priorities that will help get products to market faster

To achieve these substantial benefits, however, you must select a safety-services partner with the right experience, trained personnel, infrastructure, and quality control systems to efficiently handle your safety surveillance requirements at the

high levels of quality and compliance that are demanded by you. This is essential for success in today’s high pressure pharmaceutical environment.

PAREXEL – The Right Choice for Post-marketing Safety Services

No other company matches our combination of pharmaceutical industry knowledge, global safety resources, and ability to deliver flexible, scalable, safety services that are customized to meet the specific needs of your company. This makes PAREXEL the right choice to be your post-marketing pharmacovigilance partner.

Global Resources

As a result of over 25 years of experience in providing contract research and consulting services to biopharmaceutical, medical device, consumer health and generic companies, PAREXEL has an unparalleled network of global drug safety and pharmacovigilance resources that are ready to handle all types of post-marketing safety services. Our extensive staff of safety experts are strategically located at PAREXEL’s safety hubs around the world: US (Boston and Raleigh-Durham); Europe (London, Paris and Berlin); Sao Paulo, Brazil; Singapore, China, and Tokyo, Japan.

In addition, PAREXEL operates a Case Processing Center in Hyderabad, India, that is staffed by specially trained, multi-lingual drug safety physicians and medical operations staff. The Case Processing Center is specifically designed to handle very high volume case processing with the same high level of quality equivalent as the safety hubs. A stringent system of built-in quality control steps ensures that the highest safety and compliance standards are maintained.

A global system of lower cost intake and high level oversight allows PAREXEL to provide cost effective marketed product safety services without compromising quality. It also takes advantage of our existing depth of medical and regulatory knowledge to deliver safety services that protect the reputation of your company and the value of its assets.



Your advantages with PAREXEL

- Global resources to efficiently manage costs, work flow, and time zone differences
- Experienced management with extensive pharmaceutical and safety background
- Robust quality assurance and safety management oversight
- Customizable, flexible service offerings
- Scalable services for companies of all sizes
- Rapid start-up utilizing existing infrastructure and capabilities
- Expertise in safety services for generic medicines, OTC, and medical devices, as well as branded pharmaceuticals

cost-effective

Customizable Services

While some providers offer only standardized, “one-size-fits-all” services, PAREXEL’s services can be tailored to create a solution that fits your exact safety surveillance requirements:

- Dedicated resources and management for your company’s customized safety surveillance program
- PAREXEL’s industry-validated SOPs or the flexibility to implement your company’s SOPs, quality standards, and safety databases
- Spontaneous report intake in the US or in many other global locations
- Ability to utilize an existing client intake system, a third-party call center, or a combination of intake processes to suit your needs
- Leverage of PAREXEL’s Case Processing Center and safety hubs to provide complete case processing, including medical assessment and regulatory reporting
- Flexibility to provide all services individually or in any combination to meet your specifications and budget
- Expertise across a wide range of products, branded pharmaceuticals, generic drugs, medical devices, OTC medicines

Scalable Capabilities

PAREXEL’s services can be scaled to meet a wide range of safety management needs – whether your company is

a global pharmaceutical concern or a single-product company. Because we offer our services on an “a la carte” basis, we can provide solutions that are right-sized for your specific requirements. When your safety service requirements change, we can quickly accommodate your new circumstances by leveraging our strong network of global resources. These same resources also give us the ability to provide a quick start-up for any safety surveillance program.

Scalable strategic outsourcing can be particularly valuable to smaller companies that do not have the internal resources to handle routine safety surveillance and reporting requirements. With many small- to mid-size companies retaining their products from development through marketing – or acquiring mature products from larger or parent companies – the availability of flexible, outside safety services to supplement limited internal resources is more important than ever. Effective post-marketing safety surveillance and risk management is particularly important for smaller companies that may be dependent on the success of just a few products. As your company grows and your safety monitoring needs expand, PAREXEL can quickly scale-up your safety services to support and protect that growth.

Comprehensive Pharmacovigilance and Regulatory Affairs Services

In addition to our marketed product safety services, PAREXEL can provide a wide range of other pharmacovigilance

and regulatory affairs services to meet specific client needs, such as:

- Regulatory affairs and pharmacovigilance strategies and consulting
- Process assessment, gap analyses and Risk Minimization Plans (RMP) to meet specific regulatory agency or licensing partner requirements (including REMS)
- Medical writing services
- Peri- and post-approval clinical trials to support safety & marketing programs
- Registry programs

About PAREXEL

PAREXEL International Corporation is a leading global biopharmaceutical services organization, providing a broad range of knowledge-based contract research, medical communications, and consulting services to the worldwide pharmaceutical, biotechnology, and medical device industries. Committed to providing solutions that expedite time-to-market and peak-market penetration, PAREXEL has developed significant expertise across the development and commercialization continuum, from drug development and regulatory consulting to clinical pharmacology, clinical trials management, medical education, and reimbursement. With nearly 10,000 employees worldwide, PAREXEL is headquartered near Boston, MA.

PAREXEL
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that makes the Difference®*

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