The What, Why and How of Knowledge Process Outsourcing

Mature biopharmaceutical products with established safety profiles frequently represent lower risk, allowing manufacturers to outsource higher volumes of safety and regulatory activities. But the industry-standard practice of ad-hoc Business Process Outsourcing (BPO) still requires significant sponsor-side human and expertise resources, especially around project startup and oversight, and often fails to realize the greatest possible efficiency.

Knowledge process outsourcing partnerships (KPOs) can realize significant advantages in cost efficiency, expertise, and long-term stability. PAREXEL is in the vanguard of this model, managing the full outsourcing of all pharmacovigilance (PV), risk-management, and regulatory activities for our clients’ established and in-line products. Stepping into this role, PAREXEL is a partner to our clients with a shared governance structure, led by a team of experienced professionals and technical experts, to customize and jointly evolve programs that answer to business priorities.
Key benefits of Knowledge Process Outsourcing

- Cleaner data
- Cost savings through systemic efficiencies
- More efficient and effective responses to adverse reactions
- Reduced oversight requirements, allowing sponsors to focus on what matters most

In this whitepaper we will answer three questions:
1. What is KPO?
2. Why should I consider KPO for my company?
3. How is a successful partnership defined?
KPO transfers the end-to-end Pharmacovigilance and regulatory compliance process for a product to PAREXEL, allowing sponsors to sharpen their focus on strategic activities. This includes all operational Pharmacovigilance services, from case processing through aggregate reporting and safety surveillance, as well as development, implementation, and follow-up of risk-management programs and subsequent regulatory activities such as the preparation of agency submissions. The partnership includes appropriate governance and management, thus allowing the sponsoring company to truly rely on PAREXEL stewardship and to focus on strategic oversight and critical decision-making activities.

Transfer of the complete operation from sponsor to PAREXEL can happen incrementally by product. In implementing a program of this kind, PAREXEL understands the importance of a seamless transition of responsibilities to ensure business continuity and minimize disruption to ongoing activities, milestones, and interactions with Regulatory and Pharmacovigilance’s internal and external suppliers and customers.

The diagram below illustrates the workflow of the holistic solution by PAREXEL team responsibility.

---

**Figure 1.**
PAREXEL has found that consolidation of all Pharmacovigilance and regulatory activities yields significant efficiencies and benefits. Opportunity costs, synergies, and the development of expertise combine to decrease costs and increase quality.

The opportunity cost advantage

Consolidating all Pharmacovigilance and regulatory activities in a single partner enables sponsors to recover significant value in opportunity costs. When a sponsor’s best people are freed from day-to-day oversight of outsourced Pharmacovigilance vendors on individual product assignments, they can spend more of their time on valuable strategic product development and marketing initiatives. This is a critical point, because the real benefits are not just in the relative cost of the services (the comparison of in-house costs vs. those of PAREXEL in carrying out the same activities). It is in the gain of value in the sponsoring company’s staff focusing on activities that will support the sponsor’s growth.

The same opportunity cost gain is not realized when implementing a Business Process Outsourcing (BPO) approach. In a BPO relationship only specific operational processes are outsourced and the sponsor’s individuals would still be required to spend considerable time in an oversight role. Furthermore, it’s likely under the BPO approach that the sponsor would then have multiple Pharmacovigilance and Regulatory partners which add more overhead and management, effectively diminishing the benefits of outsourcing. KPO frees these resources and gains in opportunity cost are realized.

Operational efficiencies include, among other advantages:

- Program management and co-ordination
- Meetings, communication, and training
- Consistency of processes / template development
- Safety database set-up costs

Continuity of expertise

Your dedicated medical and regulatory team

The use of dedicated teams for this holistic process drives PAREXEL’s medical and regulatory resources to become resident experts in their assigned products. They react rapidly to new data and potential safety signals or regulatory relevance. Since the team is keenly aware of key issues in areas under close surveillance, they can generate follow-up questions efficiently. Similarly, staff that already has product expertise and familiarity with issues such as product recalls and accurate coding of commonly reported events can implement and assess better risk management activities.

Knowledgeable case processing staff

Product knowledge is an important aspect of efficient case processing. The expertise gained by case processing staff in a product’s profile, indication, and therapeutic area leads to faster and more accurate Pharmacovigilance case processing. Likewise, knowledge of a product’s indication and therapeutic area facilitates efficient and accurate case intake. This is especially true of verbal intake from a call center. Thorough understanding and familiarity with a product’s label and/or core data sheet allows Pharmacovigilance staff to
recognize and identify both typical and atypical adverse events quickly and accurately. The coding of events gains in consistency across all cases for an assigned product. This extends efficiency to the aggregate reporting process, as well as to the preparation and completion of annual reporting. The BPO model cannot yield this depth of product knowledge.

Realizing synergies in data and intelligence

The KPO model makes significant efficiencies possible in Pharmacovigilance case intake, processing and reporting, which can then extend to aggregate reporting and signal detection/risk management. The synergy that the KPO model provides far outweighs the benefits of high volume, ad-hoc BPO where a single process or several single processes are outsourced regardless of the product.

Synergies between case processing and aggregate reporting teams

Single process outsourcing is typically executed in high volume silos. The KPO model removes these silos so the PAREXEL case processing team and the PAREXEL aggregate reporting team can work more effectively and efficiently, yielding:

Cleaner data

The benefits of the KPO model continue into Aggregate Reporting and Signal Detection/Risk Management activities. As individual cases are processed, events are coded consistently and accurately to provide very clean line listings after data lock for aggregate reports. This saves time and effort typically spent on data clean up.
Effective monitoring

In the KPO model, the aggregate reporting team can work with and share product knowledge with the case processing team for real time understanding of product trends and developments. This is also very conducive to real time signal detection, allowing more effective risk management activities.

Maximizing total lifecycle value

Consolidation of all Pharmacovigilance and regulatory activities for products to a single partner provides key advantages over the lifecycle of a product.

Greater flexibility

Within the BPO model, outsourcing decisions that were reasonable during the initial planning of a process or workstream need to be revisited by the sponsor each time steps within a process, workstream, or function change. The KPO approach is agile and requires less oversight and partner management, since the partner owns the end to end process and is more independent.

Consistency across sponsors

Products can have very complex lives, even changing owners over their lifecycle, but their safety must never be compromised. The KPO model can ensure the long-term value of products by providing consistent safety management. For example, PAREXEL currently manages regulatory and safety services for a product that has been transferred from one sponsor to the next and is in the process of transfer to a third sponsor. PAREXEL is the only stakeholder who has remained with the product through its development and post-marketing safety and regulatory phases.

Proven governance practices for partnership success

In place of day to day involvement by the sponsor’s staff, oversight is supported by agreed-upon criteria, including project metrics and continuous quality control and auditing. The partnership is strengthened by close communication between the sponsor and PAREXEL, confidence based on the “Trust and Verify” model and the continuity of the relationship.

A robust governance structure, established in partnership between PAREXEL and the sponsor:

- Supports efficient decision-making, planning, and reporting
- Builds trust and reinforces the right pathways to ensure that the partnership’s goals and plans are achieved
- Provides strong support for the program across both partners’ organizations

Transparency

PAREXEL understands mutual transparency. A high degree of accountability is central to establishing a partnership that will allow both parties to share any economic efficiencies.

PAREXEL is accountable for:

- Effective project management
- Achievement of agreed upon key performance metrics within each project
- Realization of planned financial benefits

These elements of the partnership are monitored by joint governance.
**Governance**

PAREXEL recommends a governance structure that includes an Executive Steering Committee, comprised of the sponsor and PAREXEL executives, who will be responsible for defining a strategy, providing direction and oversight, and making strategic decisions on an ongoing basis. In addition to the Executive Committee, we recommend managerial level and operational levels as modeled below:

Strategic Committee responsibilities:
- Review the sponsor’s pipeline and determine portfolio forecasting
- Plan for resourcing based on projections and therapeutic requirements
- Consider how innovation can push the partnership forward
- Review strategic company changes relevant to the partnership such as new services and therapeutic areas.

The Strategic Committee has online access to a Partnership Portal, with a balanced scorecard for various classes of metrics (financial, quality, timeliness, and innovation) to help guide their analysis and decisions.

**Guidance**

Upon partnership initiation, PAREXEL prepares a charter outlining its overarching objectives. We also develop guidance documents, and details regarding the strategic oversight, operational oversight, and shared meetings. The charter defines clear lines of communication and escalation, and establishes a single point of contact per product. The guidance documents extend to the operational level teams working on products to ensure a consistent and standardized approach to management in line with the established goals of the Executive Committee.

**Qualified Person for Pharmacovigilance**

PAREXEL maintains an in-house network of highly experienced pharmacovigilance professionals who can be named as client’s European Qualified Person responsible for Pharmacovigilance (EU QPPV) and deputy QPPV. Available to authorities on a 24/7 basis and ascertaining legal liability for the operation of the PV system, this allows clients to focus their efforts on other strategic matters with the assurance that the EU QPPV will maintain the required oversight to ensure ongoing compliance.

---

**Integrated team structure**

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strategic</strong></td>
<td>• Direction and oversight&lt;br&gt;• Vision and goals&lt;br&gt;• Relationship management&lt;br&gt;• Resolution of escalated issues&lt;br&gt;• Approval of scope changes</td>
</tr>
<tr>
<td><strong>Managerial</strong></td>
<td>• Oversight of global matrix team&lt;br&gt;• Quality review of deliverables&lt;br&gt;• Project Team, status tracking and financial management (metrics)&lt;br&gt;• Resource projection &amp; allocation&lt;br&gt;• Project level tracking&lt;br&gt;• Ensuring process integration and training</td>
</tr>
<tr>
<td><strong>Operational</strong></td>
<td>• Provision of content expertise&lt;br&gt;• Day-to-day interface at functional level&lt;br&gt;• Stay in alignment with overall program plan and milestones</td>
</tr>
<tr>
<td>The sponsor and PAREXEL</td>
<td></td>
</tr>
<tr>
<td>Program management</td>
<td></td>
</tr>
<tr>
<td>Regulatory &amp; PV operational team</td>
<td></td>
</tr>
</tbody>
</table>
The strategic value of PAREXEL Knowledge Process Outsourcing

The key to successful strategic outsourcing is finding a partner with the right global safety experience, processes, and infrastructure to deliver a flexible range of safety monitoring services, while maintaining quality and compliance. PAREXEL’s Knowledge Process Outsourcing model (KPO) can manage the full outsourcing of all Pharmacovigilance, risk-management, and regulatory activities for established and in-line products. PAREXEL has demonstrated leadership in this market, focusing our expertise to provide clients with a unique service partnership that offers both flexibility and cost effectiveness with guarantees of regulatory compliance.

PAREXEL International has been in the vanguard of strategic partnerships with the biopharmaceutical industry for more than 30 years. As the industry has evolved to meet the challenges of a changing global marketplace, PAREXEL has drawn on extensive experience to develop partnership models that help biopharmaceutical companies increase efficiency, accelerate time to market, reduce costs, and expand their reach into new markets around the world. We strive to build long-term relationships based on proven processes, verifiable metrics, robust governance, mutual accountability, and a commitment to continuous improvement. PAREXEL also offers a unique depth of experience, therapeutic area expertise, and technology leadership that differentiates us from other service providers.

By embracing this new approach for strategic partnerships and leveraging PAREXEL’s global expertise, sponsors can maximize their resources and gain a competitive edge at a time when even a small advantage can deliver large marketplace dividends.

To learn more about how partnering with PAREXEL will help you to achieve your ambitions, contact +1 781 487 9900 or visit http://www.parexel.com/services-and-capabilities/late-phase/pharmacovigilance/

For more information, contact Gary Coward at Gary.Coward@PAREXEL.com

PAREXEL
Right where you need us •

©2012 PAREXEL International Corporation. All rights reserved. PAREXEL and Right Where You Need Us are registered trademarks of PAREXEL International Corporation.