Case Study: Fast-tracking global patient safety reporting initiative for big pharma

YourEncore delivers a global inventory and safety reporting risk assessment of patient outreach programs (POPs) for a top 10 pharmaceutical company and completes the project 43%[1] faster than the company could have done alone.

Background

Anytime pharmaceutical companies establish a two-way communication channel with patients, providers, and other customers, for example through local promotions, patient outreach programs, or social media, vital product efficacy and safety information is exchanged. Companies have a responsibility to monitor and report on this information to maintain patient safety and avoid agency fines, which can amount to 5%[2] of company revenue in Europe, for example.

POPs and therefore safety monitoring and reporting obligations can proliferate if not well managed. Large pharma, in particular, is susceptible for the following reasons:

1. Global Scope: Implementing effective SOPs within one country can be difficult. Driving consistency across all global affiliates is even more challenging.
2. Social Media: Increased use and adoption of social media and other two-way communication systems are adding more information sources
3. Outsourcing: High use of third parties for marketing and patient outreach initiatives adds an additional level to monitoring and reporting.
4. Turnover: Restructuring and rotation programs in local marketing groups create 'orphan' POPs, which can become forgotten or undocumented.
5. Cross-functional coordination: Multiple functions - marketing, pharmacovigilance, quality assurance – need to work together for effective implementation of SOPs.

[1]YourEncore Analysis

[2]Gaffney, Alexander. "EMA Investigation into Roche Adverse Event Reporting Failures Finds no New Risks." Regulatory Affairs Professionals Society (RAPS), web. Nov 19, 2013

Opportunity

A top 10 pharmaceutical client, to maintain best in class safety and regulatory compliance, needed to update an inventory of all its POPs across 70+ countries. With a tight nine month timeline given by the CEO, the company contacted YourEncore for support.

Approach

To deliver this global initiative, YourEncore developed a custom POP inventory solution, which included a team of 20+ regional assessors, a centralized processing team including translation services, a medical writer, and technology accelerators.

Engagement Team

Team:

- Program Lead: Subject Matter Expert with strong organizational and project management skills to influence decisions and manage multiple project metrics.
- Assessors: 20 GCP auditors with extensive interviewing experience and investigative skills to navigate an emerging area with little precedence.
- Central Standards Team: Four resources with industry knowledge and robust process-orientation skills to standardize information and analysis.
- Medical Writer: One expert to consolidate individual country reports

Process:

Leveraging the client's internal assessment methodology, YourEncore deployed three to six-person assessment teams to 70 different countries to:

1. Assess known POPs for proper safety reporting compliance
2. Identify undocumented POPs for client follow-up

From a central location, YourEncore managed resource deployment, filed and sorted all POPs for centralized recall and analysis, and coordinated country translations.

Technology Accelerators:

A centralized team developed a standardized sorting and filtering method to identify potential POPs, increasing consistency and effectiveness of this activity across assessments.

Results

YourEncore delivered the initiative in approximately half the time it would have otherwise taken the client to complete the project independently[1].

Additionally YourEncore delivered recommendations to enhance the long term sustainability of a robust POP tracking system:

- **Completeness:** Uncovered over one thousand POPs not previously captured
- **Risks minimization:** Highlighted potential safety areas to the client for further investigation and remediation
- **Efficiencies:** Identified six key areas for continuous improvement in training, policy, process, and vendor oversight

By the end, YourEncore reviewed thousands of contracts and promotional materials, more than a million purchase orders, and over a thousand websites / social media sources.

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Key Role Profiles

"The unique industry experience, flexibility and skill sets of YourEncore's experts resulted in a complementary partnership that was critical to advancing our client's goals of safety compliance, while continuing to meet their high standards of support for their patients worldwide."

-Bruce Graves
-YourEncore Program Lead

Program Lead

- MBA; BA in Biology
- Accomplished GCP and Quality Assurance (QA) professional with 28 years of experience in Drug Safety Research, Clinical Research, Pharmacovigilance, Quality Assurance. For the past five years has been an independent GCP Quality Assurance Consultant / Auditor.
- Developed extensive experience as a QA, GCP expert over 17 years at Pfizer/Pharmacia Upjohn in Clinical Trials and R&D Quality Assurance.

Program Assessor

- BS, cum laude, Toxicology; BS candidate, Animal Science
- Expert has 30+ years of experience in global pharmaceutical development of small molecules and biologics; has led, managed or participated in over eight hundred Preclinical, Clinical and Due Diligence Reviews/Inspections/Audits and Preclinical Toxicology studies.
- Formerly, the expert was Program Director, Associate Director, Global Regulatory Affairs and QA-External Quality Assessments at J&J Pharmaceutical R&D.

Central Standards Expert

- PhD, Statistics; MSc Statistics; BA, Mathematics
- Expert has 16+ years of experience in statistical strategy and operational statistics in pharmaceutical clinical development, and several years of biotechnology experience in lipid and diabetes early phase studies, and in the cardiovascular therapy area.
- Former roles include Director, Statistics, Clinical at AASTROM Biosciences; Director, Statistical Sciences at Parexel International; and Associate Director, Clinical Statistics at Pfizer.

Medical Writer

- BS, Medical Technology
- Expert has 40 years of experience in medical research, communications, and continuing education; 10 years in pharmaceutical industry clinical research, medical information, medical communications and education; and 30 years as a freelance medical writer.
- Core competencies include regulatory document preparation, clinical research reporting, and medical news reporting. Held roles in a medical writing and communications capacity at top 10 pharmaceutical firms including Bristol-Myers-Squibb (BMS).

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