

Outsourcing Contact Center Interactions for PV, DV, CM, and MI

Client

Mid-size

Industry

Pharmaceutical and Medical Devices

Business Challenge

Develop a sustainable operational business model for PV, DV, CM, and MI that will meet increasing business demands and escalating regulatory requirements.

Project Timeline

Pre-Implementation Due Diligence - 3 Months

Pilot Site implementation (US Market) – 6 months

Stabilization (US Market) – 6 months

Full Implementation with Staggered regional approach (EU, Asia, Australia New Zealand, South America, Canada) – 4 years

Challenge

A global pharmaceutical and medical device company was having difficulty gaining incremental staffing resources of highly qualified medical professionals to offset local resource shortages to meet the demands of continued business growth and escalating regulatory scrutiny for pharmacovigilance (PV), device vigilance (DV), complaint management (CM), and medical information (MI).

Approach

Identified, developed, and implemented a cost-effective outsourcing model that was scalable and sustainable to meet future changes in staffing and regulatory requirements. The approach used included the following key areas:

- Leveraged lower cost outsourced staffing resources to handle repetitive, high volume, low complexity transactions to allow the higher cost / higher knowledge internal company resources to focus on high complexity, higher risk, patient impact events or activities.
- Outsourced call center activities for PV, DV, CM, and MI which included interactions with various stakeholders (medical professionals, sales representatives, and consumers).
- Internal company information management systems selected and utilized an outsourcing company for data entry, data quality monitoring, and case surveillance.
- Identified a Business Process Organization Partner (BPOP) that had a large global footprint and could provide outsourced and off-shored call center support to improve efficiencies and reduce operational cost.
- Outsourced PV, DV, and CM activities included Contact management routing, Intake, Triage, and Logistics management as well as categorization / prioritization of potential high-risk events (Adverse Events, Product Malfunctions) for escalation for potential reporting.
- Outsourced MI activities included front-line customer support including answering calls, logging cases, and disseminating MI verbal and written communication.

- Maintained all critical decision making and control to decision making (report-ability, product safety, regulatory, risk management, etc.).

Results

The business challenge was addressed by utilizing an outsourced and off-shored contact center model. This change in business model resulted in several key improvements and benefits included:

- Overall cost reduction in Operational Expense of \$1.3 MM annually on a functional annual spend of \$8.0 MM.
- Leveraged core competencies of partner for Key Performance Indicators (KPI's) and functional metrics to achieve process improvements that were not possible with internal systems and resources. For example; reduction in initial complaint registration process cycle times from 5 days to same day.
- Freed up internal high cost resources to allow focus on critical work / decisions without being burdened by repetitive / lower value / high volume work.
- Established a strategic growth partner that was subsequently leveraged when company needed to grow business or had critical initiatives (regulatory actions / requests, recalls, acquisitions).
- Allowed for consolidation of process work done in decentralized structure to one centralized location that set the foundation for process improvement, process optimization, efficiency, while freeing up regional resources to focus on critical decision making (reporting) and critical relationships (regulators).
- Allowed adaptation of customer intake approach to evolving customer preference (e-mails versus calling).
- Allowed for the establishment of quality surveillance of process / personnel on data integrity and content as part of process resources that were not viable using internal resources.
- Freed up functional leadership to focus on process design robustness, Voice of Customer and Regulatory critical decision making to respond to regulation /expectation changes.
- Allowed functional organization leadership to become a strength in the eyes of regulators, by focusing on compliance issues, variability of process outcomes, managing regulatory audit outcomes to positive observations while leaving day to day transactions to outsource vendor.
- Redundancy / Back-up capabilities to take over during crisis (weather, system outage, etc.).

The new outsourced and off-shored model was deemed a company success story that resulted in gaining incremental staffing resources of highly qualified medical professionals, establishing a strategic partner for future growth, substantially reducing overall business operational costs. This project implementation and management process was benchmarked as best in class approach.