

When a multinational consumer packaged goods company experienced significant struggles reestablishing their human health safety vigilance organization

We designed and implemented leading practice initiatives which enabled \$5.3 million in annual recurring cost savings

The challenge

Following an FDA audit, a leading consumer packaged goods company realized the need for integrated product vigilance and quality systems across their product lines. Resources from a previously dismantled pharmacovigilance (PV) team were reassembled and their PV safety platform updated, however a lack of strategic direction became readily apparent as divergent work processes at the regional bases stagnated productivity and churned key management team members.

There was no clear definition of roles and responsibilities which created confusion and uncertainty in cross-departmental processes and system requirements. This created significant workflow issues and pervasive delays.

Widespread disagreement on critical business objectives perpetuated ineffective and inefficient business operations. Resultant regional and departmental distrust bred redundant work efforts, poor communication, and operational silos.

The lack of a defined organizational strategy promoted inefficient tactical resourcing – staffing was unproductively leveraged to "get the work done somehow" rather than seeking solutions to address the root causes.

Incongruent processes and system integration resulted in undocumented workarounds, inefficient core workflows, and poor information integrity.

How we helped

Aspire designed and implemented a suite of leading practice initiatives designed to harmonize people, process and technology elements across the organization including regional bases in Asia, Europe, and North America.

This suite included:

- A redesigned global organizational structure connecting roles and responsibilities to the overarching organizational goals
- A modular performance dashboard unifying long-term strategic vision and critical business objectives to drive operational excellence and build competitive advantages
- Dedicated strategy and talent development teams to augment resource competencies
- Globally standardized work methodologies and optimized technology systems to align business objectives and regulatory requirements with processes and enhanced reporting capabilities

New, revamped documentation concisely reflects PV business operations to improve regional consistency. Integrated global OTC and non-OTC adverse effects case management processes significantly enhance data integrity.

In addition, benchmarking and substantive workflow reviews were employed to identify potential cost savings as well as organizational synergies with contractors and external partners.

Value delivered

The streamlined, strategically focused human health safety vigilance organization facilitated:

- Improved case intake systems providing significant increases in data quality and yielding a 40% reduction in processing time
- Enhanced vendor management systems yielding a 30% reduction in aggregate spend
- Reallocation of resources to signal and risk management teams driving organizational competitive advantages
- \$5.3 million in annual recurring cost savings



Driving business transformation in a changing world

Optimizing management practices and operational agility for a leading consumer packaged goods company



Vision

Align people, process and technology with business objectives and regulatory requirements to become the premier pre- and post-market human health safety partner



EVALUATE

Identify and quantify opportunities to achieve organizational goals



Undefined roles and responsibilities



Operational silos



Inefficient resourcing practices



Undocumented workarounds



Poor information integrity



CRFATE

A business transformation plan designed to integrate product vigilance and quality systems



Integrated vision and strategy



Organizational redesign



Global work architecture



Technology platform optimization



Governance and metrics



GENERATE

A streamlined and strategically focused human health safety vigilance organization

40% Reduction in case processing time

30% Reduction in vendor spending

\$5.3 Million in annual recurring cost savings

Does your organization need help adapting to corporate life events with approaches that are sensitive to business cultures?

Let's chat about cutting edge process innovation methods and human-centered design to achieve lasting, effective change.



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