

## Ensuring compliance whilst improving operational efficiency and organizational capability

Balancing performance and compliance we enable our clients to be more effective and efficient in drug safety.

### Client Situation

With in excess of 100 years in the industry our client is a leader in the development of long-acting medicines. With a five year plan in place to grow and expand the business, following the significant downsizing that had been previously endured, our client first had to address the need for a comprehensive review of its Drug Safety and Pharmacovigilance processes, organization and supporting technology.

From a process point of view, it was evident that AE case handling process at the organization were stretched. Too many hand-offs and rework loops were adding to lead times and, as a result, reducing compliance. There was also unnecessary duplication of effort involved with legal cases, giving rise to significant workload. The processes adopted by our client were not geared towards collecting quality incoming data that was 'right first time' and the process metrics and data in place did not enable easy root cause analysis and continuous improvement.

The existing organization structure and roles did not promote efficiency or accountability resulting in poorly defined roles and responsibilities, and a lack of staff development towards current and potential roles. Roles that shared case processing responsibilities were structurally separate. Drug Safety and Pharmacovigilance were operating too close to maximum capacity, and the mix of permanent to temporary staff was not optimal.

Use of supporting technology was limited. Technology inputs, outputs and in-process deliverables were created manually, in-house tools were not fully utilized to support workflow, electronic case processing or metrics generation.

WCI were engaged based on their 'excellent reputation in the Drug Safety area' said the Executive Medical Director, to assist the organization in their process improvement project and to deliver the necessary solutions to the following objectives:

- **to support the development and implementation of a streamlined AE process**
- **to support the redesigned AE process with a new organizational structure; aligning roles, responsibilities and skills.**
- **to leverage available technology to support the change management programme.**



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### Solution

The key to the success of the project was to implement a fast track change control procedure enabling changes to be made promptly and, most importantly, in a controlled and compliant manner. It was also important to ensure that mechanisms were in place to communicate project status and accomplishments to all stakeholders and that staff felt committed and have a sense of ownership to the vision, new process and organization designs, technology implications and business model.

In February 2006 WCI Consulting Ltd began a seven month programme of work with the client at their headquarters. Initially engaged to undertake an analysis and redesign programme lasting a period of nine weeks, WCI's work continued to further deliver the implementation phase of the programme over a period of twenty weeks.

The Project team at the client was made up of a Steering Committee, a Sponsor and three supporting teams; a People and Change Management Team, a Process Team and a Technology Team, together with five WCI consultants in varying roles including: a client manager, a project manager, a PV process specialist, and organization readiness expert and a technology specialist. From the outset the relationship between the client and WCI was a collaborative partnership supported with a shared goal; "the team was excellent. Every one of your guys made a contribution to the success of the project" remarked a member of the client team. It was important to the success of the project that the WCI were integrated into the business although the consultants involvement was more concentrated at the beginning of each of the set milestones before, through skills transfer, responsibility was passed to client staff.

Through the utilization of meetings, workshops, coaching and training, the outcomes of which were documented into best practice and deviation formats, and subject matter expertise, a structured approach was devised; to optimise the parallel achievement of deliverables across the previously problematic identified areas; process, organizational alignment and technology.

Over the course of the project, a detailed AE case handling process map was developed; incorporating new and standardized case review functions, forms and templates as well as streamlined legal and medical record case processing methods. Quality and process metrics were refined and other PV processes, Periodic Safety Update Reporting and Signal Management were designed.

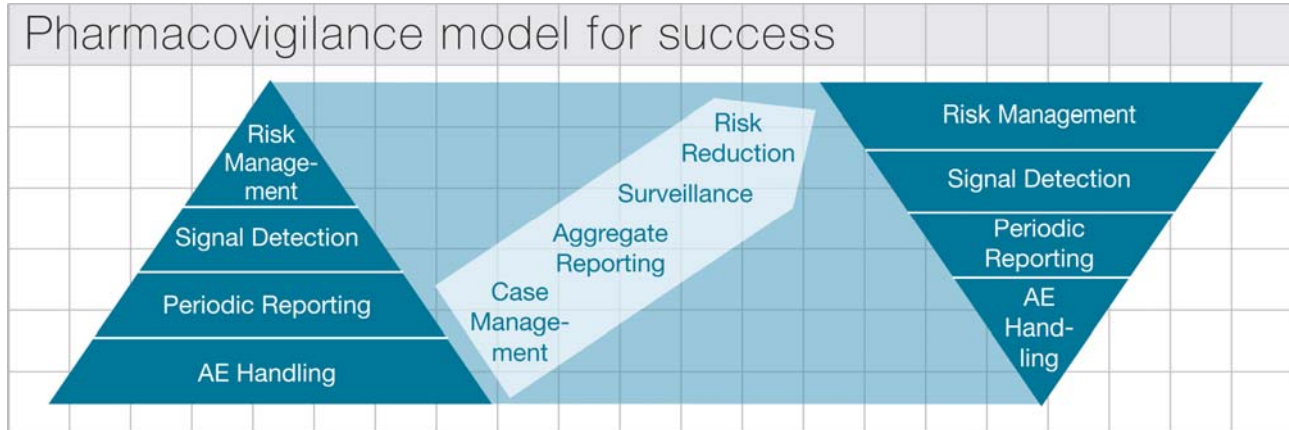
WCI facilitated the integration of identified opportunities into the new AE case handling process, whilst further detected opportunities are to be taken forward by the internal client technology team. In terms of people and change management a new strategy was developed and implemented for drug safety and pharmacovigilance. A rewards and recognition programme was delivered and roles and responsibilities of staff clearly defined.



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### Model for Success



A sound understanding of the effectiveness of safety processes as well as conformity to current operating practices is a must within any pharmaceutical organization. The root to successful pharmacovigilance is driven by processes, people and technology. In this instance, the client had a requirement to address all three issues and refocus; to invert the triangle to both anticipate and mitigate risk.

To improve the quality, compliance and efficiency of the AE case handling process, the model for success needed to focus on four key areas:

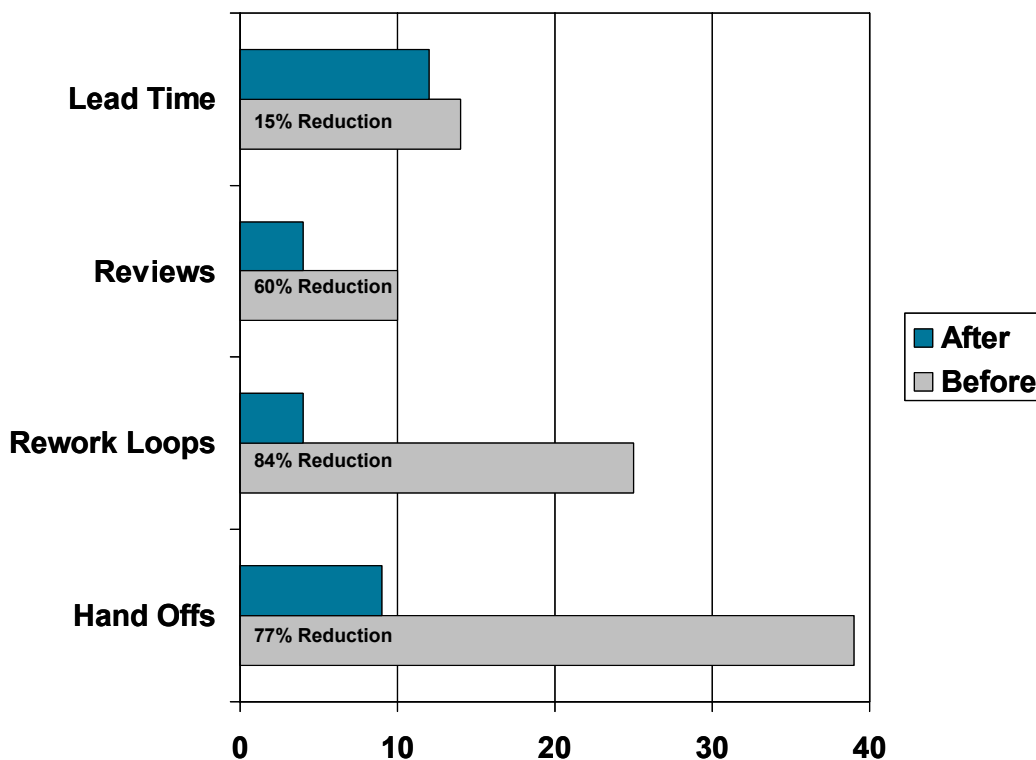
- implementing the redesigned AE case handling process and metrics
- aligning the Drug Safety and Pharmacovigilance organisation with the redesigned process and technology
- developing a comprehensive change management strategy to ensure changes are successfully implemented
- enhancing current technology and automating certain process steps

A step change in performance is achieved through a combination of change management and communication to successfully implement streamlined processes, align the organization and enhance information systems.

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### Benefits

The client met the challenge. The approach worked to deliver key implementation benefits supported by increased and consistent compliance across the business. Staff buy-in was achieved, with employees now highly motivated and trained with the appropriate skills to fulfil their role, as well as increased communications and defined requirements across interfacing departments. The result? An employee led drive towards accelerated and sustainable change. The introduction of scaleable processes and the use of existing resources, optimised in order to drive efficiency, productivity and cost savings together with the creation of a solid foundation on which to enhance pharmacovigilance and, in particular, signal detection and aggregate reporting capabilities.



Glenn Carroll, Project Manager for WCI remarked “not only was I extremely pleased with the client commitment to the success of the project, but also with the quality of implementation team members”