

Redefining the safety reporting system: A Case Study

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In early 1995 Zeneca Pharmaceuticals decided to re-engineer its flailing adverse event process. This was to become one of the most rigorous and effective applications of business process re-engineering to safety reporting procedures undertaken in the pharmaceutical industry.

Within Zeneca Pharmaceuticals, the Product Safety Group (PSG) is responsible for ensuring that safety data are collected and entered onto the company's international database. In addition to the consequent and ongoing evaluation of the safety profile of each medicinal product, PSG must produce information allowing Zeneca to meet regulatory requirements for the notification of suspected adverse drug reactions (ADRs) on an international basis. By early 1995, this procedure was showing signs of strain.

In January of last year, new European legislation became effective, requiring all companies marketing medicinal products within the EU to establish pharmacovigilance systems and procedures capable of collating information on all suspected ADRs at a single point within the EU. Companies were also required to submit expedited reports for serious ADRs within 15 calendar days of first receipt of information. This legislation (Council Regulation 2309/93 and Council Directive 92/39/EEC) carries severe penalties for non compliance.

Against this legislative background, PSGs workload had been steadily increasing, with the number of ADRs subject to expedited reports growing significantly. In 1994, just 480 ADRs required expedited reports for regulatory purposes; in 1995, the number climbed to 2,300. Heavier workloads have also resulted for the EC regulators' requirement for Periodic Safety Updates.

Zeneca was aware that, in addition to the growing volume of work, established methods of working within PSG were causing difficulties. For example, by the end of 1994, only 24% of the adverse events (AEs) sampled in analysis were dealt with correctly from the start, so that a lot of work had to be redone, wasting both time and resources.

The average lead time from first receipt by PSG to final data storage was 16 calendar days, with the actual processing time accounting for as little as two hours. At any point in time approximately 1,000 AEs were in progress – 10% of the entire annual volume of work. The overall activity involved 11 different people in 51 'hand-offs', with 62% of the 278 steps in the process not adding any value. Process re-engineering was badly needed.



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Poor Performance

The first phase of the restructuring task was to identify the problem. Four fundamental reasons were identified for poor process performance:

- Duplication of input data resulting in too much paper in the system.
- A compartmentalised physical layout of the department, which hindered the smooth flow of work and caused excessive delays.
- The functional nature of the organisation, with resultant lack of process awareness and a reactive operational style.
- The process followed an over complicated path, making it difficult to manage.

The New Process

Having identified the reasons for poor performance, four main recommendations were proposed:

- Reform dispersed functionally organised staff into autonomous cells, processing each AE for start to finish without interruption.
- Co-locate all interdependent staff and so minimise the number of 'hand-offs' and eradicate errors at source.
- Create flexible close-knit implementation teams with responsibility for timely completion of the whole process.
- Locate all support requirements and expertise at the point of need.

The changes resulting from these recommendations were implemented in August 1995. The results have been impressive. Zeneca's ability to meet regulatory requirements has been significantly improved, with lead times reduced from 16 to two working days.

There has been a significant reduction in process steps, from 278 to 85, 'hand-offs' are down from 51 to seven, and the distance that each event 'travels' within the group has been reduced from 4,070 metres to 145 metres. The work-in-progress backlog has been eradicated, and PSG now submits 4.5 times as many expedited reports in a quarter of the time, with only a 50% increase in staff numbers.

Prior to the re-engineering, Zeneca's local operating companies (pharmas) were required to notify all serious AEs within one working day of first receipt of information. Preliminary reports were usually filed, most lacking in substantive detail, leading to later additions, amendments or even cancellations – all very time consuming. Now, pharmas are allowed



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one week in which to submit reports to PSG, during which time they are expected to gather detailed information on a 'right-first-time' basis. This change has contributed significantly to the smooth running of the new AE process.

Zeneca has seen a 'step change' improvement in its performance by adopting a manufacturing solution – the introduction of a cellular structure within an open plan environment. Difficulties in compliance have been resolved and now the group is working on the continuous improvement of the new process in order to maintain performance while at the same time enhancing the quality of the input data.

Stronger Position

Zeneca is a key example of the successful application of business process re-engineering. Previously, the staff were concentrating on the task rather than the process; they were working hard, but not as astutely as they might have done. Today, the process dictates the work path; staff are more aware and motivated, and the work is being pushed through quickly, the organisation being devoted to progress rather than delay. The marked improvement in the performance of this critical process has put Zeneca in a strong position from which to build in the future.

Consultancy for the re-engineering was carried out by [WCI Consulting Limited](#).



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