

Bandaging Snowden's Leg?

When a pharma CEO said “We'll be adding 250 new people to our Quality Assurance and Control organisation to address concerns identified by the FDA” he was ‘bandaging Snowden's leg’ – a syndrome (described in Heller's “Catch 22”) in which zealous attention is focused on a peripheral problem while life leaks away from an un-noticed, central trauma. In the book, Snowden dies. And the prognosis is not much better for a corporation which makes compliance its objective instead of getting down to the real needs of the business.

WCI's Wilf Gilich explains how such a situation can arise and how it can be saved by the right business attitude.

Compliance counts, but...

Make no mistake, compliance matters. Regulators enjoy rising public confidence, much of it fuelled by well-publicised pharma failures. If you don't hit the mark, the consequences can be swift and severe. In the USA, the FDA can come in and take control. They'll make sure you comply but what about a lasting solution to the problems?

If desperately chasing compliance is not the answer, then how **do** you stay compliant and raise business performance? Perhaps the place to start is by answering the question ‘Why aren't we compliant anyway?’

Where did it all go wrong?

The compartmentalised, silo structure of the traditional pharma organisation has meant that there is very little comeback for producing inadequate compliance ‘output’.

In trying, from the best of motives, to compensate, the Quality (QA/QC) community continually add ‘band-aid’ workarounds. Complexity mushrooms to the point where the system collapses. And with the Quality community now seen as solely responsible for Good Medical Practice, the company neither achieves compliance nor performs the way it should in business terms.

Re-engineer now!

To avert disaster, you have to start looking for the root causes of problems. That means addressing the operational process from the ground up, making it leaner, more efficient, more competitive. Compliance has to come from within the operational processes such that:

- Everyone has compliance built into their work, responsibility can no longer ‘drift’
- Information is central, accessible, constantly updated
- Communication directly across functions is facilitated and the norm. It does not travel up, across and down ‘silos’ being filtered and interpreted at every point.
- Compliance data and records arise automatically from the operational system.

Re-engineering must, and can, take months not years. And with IT solutions now available, putting the right information in the right hands at the right time is easier and less costly than ever before.



Simplify what you do

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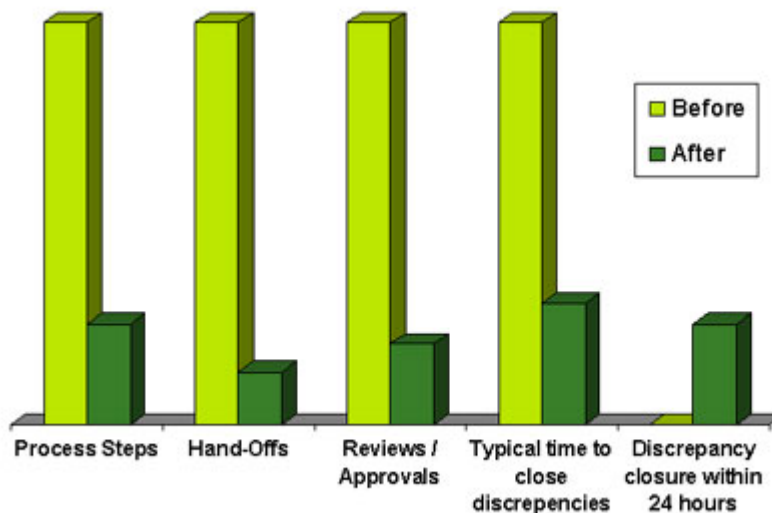
New programmes capture data, much of which was already there, unrecognised, unused and unshared. And they speed and simplify collation, access and decision-making.

The silo mentality made serious re-engineering politically and administratively impossible. Have the irksome realities of tougher regulation at last provided an unanswerable justification for this commercially vital change?

The patient made it!

WCI worked with a large pharmaceutical company recently to transform their processes; integrating compliance into the operations process has resulted in measurable benefits (see Figure 1.0 below)

Figure 1.0



Our clients have stopped bandaging Snowden's leg and have operated in the central trauma. They have done so at low organisational cost. And far from adding 250 unproductive employees, the overall additional complement was... exactly zero!



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