



Health assurance

Healthcare giant Sanofi adopted Wolters Kluwer's TeamMate+ to integrate processes across a new internal control department and internal audit. It soon found that it opened up far greater assurance possibilities across the global organisation.

As one of the world's largest pharmaceutical and healthcare organisations, Sanofi is constantly developing and delivering new treatments for human ailments. However, as all medical scientists know, every intervention has a range of consequences for the patient – and these need to be tested and understood.

So when Sanofi embarked on scoping out a new internal control department and identifying and establishing a new standard for internal controls across the whole group, the task was, as Lynette Biddulph, head of evaluations, says, "daunting".

Any organisation of more than 100,000 employees of 145 nationalities, based in 76 manufacturing sites in 36 countries is complex. However, Sanofi also operates in a highly regulated sector in which some failings could, literally, be a matter of life or death. It encompasses businesses in research and development, manufacturing, pharmaceuticals and consumer healthcare and its products reach customers in more than 170 countries.

Biddulph was brought in to lead a new second-line-of-defence department and was asked to establish and integrate it and create a

methodology to assess the new control standard across the organisation. "Everything in this was new," she recalls. "There was no benchmark we could refer to, or examples we could use, and we knew the changes we made could have far-reaching effects."

At the same time, Sanofi's internal audit team was looking to upgrade its tools and some of its processes, so this provided an ideal opportunity to look for a tool that both departments could use, that would encourage sharing and integration of non-confidential information and that would help them to map and plan assurance across multiple departments and locations.

"We needed to coordinate this carefully – our worst fear was that internal audit and internal controls would duplicate work and possibly produce findings that clashed," Biddulph explains.

Control group

To achieve this, they turned to Wolters Kluwer's newly launched TeamMate+ solution. Not only were they early adopters of the technology, but they were also ambitious about using it across multiple departments, since they soon realised that the organisation had six separate departments doing similar assurance work that

could be integrated. The software had to allow them to communicate and share information and reports, but also to enable them to continue doing things their own way and to see the data that was most relevant to them.

Not surprisingly, this required some hard thinking. "We first planned to introduce internal audit and internal controls to the new system and then add the other departments later, but then realised that this was horribly complex," Biddulph recalls. "We had a huge number of controls and we wanted to apply these across six businesses in about 108 countries. It was impossible. So we went back to the drawing board and saw that the system could help us to find new ways to map controls to different departments rather than duplicate the same control in different assessments, and in this way reduce the overall number, while retaining the superficial differences in presentation and focus for different user groups."

The key to achieving this simplification and unification was to agree a common baseline – a "primary dimension" of control. This was difficult and time-consuming, involving key people from each of the relevant teams. "It was an immensely complex decision," Biddulph says. "We had to strip everything back to base principles, needs and questions and establish the common ground."

Once this was achieved, however, the software enabled them to identify duplications and integrate previously separate processes under a single control. The base core of controls therefore became more consistent and simpler, although teams could continue to see the processes and findings in the way they preferred and could generate the reports in the way most relevant to them.

"We found that we were all looking at the same things, but from different perspectives," Biddulph says. "There was some initial resistance, but people soon started seeing how it could work for them. There were massive changes taking place in the organisation as a whole and everyone could see that this system helped them to cope with



100,000

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these because it aligned and integrated previously separate areas.”

This was particularly important in forging common ground between departments that had previously not worked closely together. Historically, the Information and Technology team had exchanged lots of information with the Sarbanes-Oxley (SOX) team, but the new system also enabled them to identify common goals and align controls with the Industrial Affairs, Ethics Compliance, Internal Controls and Internal Audit teams. In addition, they began working more closely with the Medical Quality and Control team, although that is still not fully integrated.

“Now we are integrated we can have total confidence in our assurance findings, and we also know that all the relevant people have seen the information and have reached a common, informed decision,” Biddulph says. “Internal auditors, and others, can drill into information across the system, but we have a gentleman’s agreement to ask other departments or countries before accessing their data. This is a question of manners rather than ability.”

Such transparency and accessibility also carries risks that need to be managed, she adds. For example, confidential information needs to be safeguarded. “It is a particular issue for internal audit and for SOX,” she says. “We monitor internal audit’s findings around SOX to ensure that we respond to findings proactively, because that avoids future reporting issues, but we have to be careful that we don’t abuse this access.”

A policy of voluntary disclosure of issues already meant that managers often approached internal audit with potential problems, but Biddulph says that the internal auditors now have increased confidence that the system will highlight potential issues, alerting both them and the relevant managers who may need to act to resolve problems. This enables them to focus on other areas.

“The biggest benefit for me was the integration of separate projects and the ability to add any number of legal entities to it,” she adds. “Previously, I was often asked about whether a business in one country

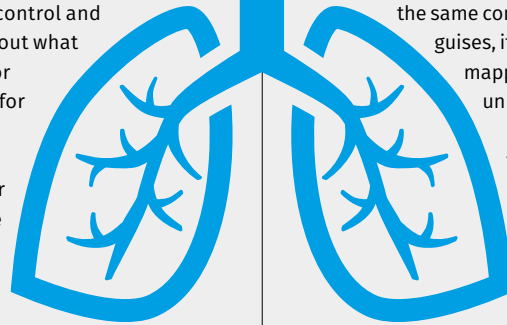
could change one control and then I had to work out what this would mean for internal audit and for SOX. Now you can implement one control and test for variants across the whole system automatically. External auditors tend to be concerned about cross-checking and reconciling SOX and audit reports and this has removed the headache of double checking all the ramifications of small changes.”

One surprise advantage was that mapping the different dimensions across the organisation also meant that she could identify a single process owner for specific controls. At the moment, each country has many process owners and this requires a country coordinator to identify the relevant process owner. In future, Biddulph hopes that the system will enable users to identify relevant process owners directly, making processes more efficient and timely.

Repeat prescription

Biddulph’s top tip for anyone else thinking of starting on a similar programme would be to start with an integration programme. “Get people round the table to agree about what is your primary dimension,” she advises. “We didn’t fully understand this when we started. We used the management structure of the organisation, but in retrospect we could have used our control standard because that is more stable. You need to work out your primary objectives before you add in all the tests and projects.”

For example, Biddulph explains, one of Sanofi’s key controls is segregation of duty, which is important across many functions. People from each department had to work together to identify that this control was common to all of them, even when it looked different in each area. Once it was identified as



the same control in different guises, it could be logged and mapped across all the units.

“It’s a complex task, but it’s actually a question of perspective. You need to stand back and say what is the baseline control here? It’s vital to get

this right – and it can be expensive to get it wrong,” she says. “If you identify the fundamentals you can add in changes and configure the way it looks and run all your tests without problems. If you later have to change the fundamentals, that’s a huge task.”

Adopting TeamMate+ has already led to real gains. Biddulph points to a staff survey last year that showed improvements in understanding and experiences working in the new system and says that feedback results improved “dramatically” last year. “We found that initial training, planning and working with other departments were all important to this,” she says. “We need to give people everything they need to feel confident using it, or they won’t use it to its full potential.”

There is still some room for improvement and development. In particular, Biddulph says that they are keen to improve the way that the internal audit team’s tests fit into the



TeamMate+ system, so that operations across different countries and businesses can spot problems as findings emerge and deal with them. However, she adds, first they have to ensure that this will not cause any confidentiality issues.

“We’re constantly looking at ways to improve,” she adds “and TeamMate+ has given us the tools we need to do this.”

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