The Great Brain Drain

The life sciences industry is drowning beneath a sea of new regulations and directives. As well as being immensely demanding from a risk management perspective, the associated administration is detracting from core activities. Even basic administrative tasks, such as checking updates to labelling, consume hours of PhD-qualified staff’s time – capacity firms cannot afford. This is having an effect on professionals’ morale. Organisations should take heed, or risk losing valued experts at a time when experienced regulatory and QA personnel are in short supply, warns Dr Jutta Hohenhörst of Schlafender Hase.

In life sciences, it can seem as though new regulations are being announced or coming into force every few weeks. On top of the authorities’ need to safeguard patients, consumers expect more transparency – about a product’s contents, origins and processes. All of this is creating more red tape for the industry: requirements that need to be serviced and managed.

The more rules there are, and the more frequently these change, the greater the risk of something going wrong. Similarly, the more products, variants and markets a company is dealing with, and the shorter the release cycles, the greater the controls needed across documentation, packaging and labelling to ensure nothing slips through the cracks.

The media archives are laden with examples of big names that have fallen foul of regulations, by simply failing to spot a misprint until it’s too late, or neglecting to meet new guidelines in a particular market. From children’s cough medicines to dietary supplements, the simplest error in how consumers should store or take the product could result in illness, harmful side-effects or even death.

Errors can creep in so easily. People make mistakes, especially if they’re tired, busy or stressed. In life sciences, the difference between “store this product at 2-8°C” and “store this product at 28°C”; “take 1-2 a day” and “take 12 a day”; or “do not chew and swallow” and “do not not chew and swallow” could be a matter of life and death.

Guarding against this kind of exposure is a full-time job, and a significant part of risk management in an industry where the smallest mistakes can be fatal. Even where companies have the most extensive and comprehensive regulatory affairs and quality assurance departments, the strain is being felt. The slightest change in regulatory requirements can create the biggest administrative backlogs, and increase the company’s vulnerability – e.g. to product recall, or worse.

Soaring Stress Levels
All of this extra work and responsibility is taking its toll on RA and QA teams. In many cases, it is highly qualified professionals – people with doctorates, and years of experience – who are being called up to check amended labels and patient literature to ensure it is compliant with the latest guidelines. Are the right details included in the right way, place and format to ensure up-to-date conformance? Is everything accurate and consistent?

At the same time that these administrative requirements are being increased, so too are regulatory and quality assurance professionals’ broader workloads. RA and QA teams have never been busier or as overstretched. Unsurprisingly, a 2014 survey of European recruitment and staffing trends in the life sciences sector (Recruiting & retaining a competitive workforce: Pharma, biotech & medical devices by Real Staffing: http://assets.realstaffing.com/images/site/Recruiting_and_retaining_a_competitive_workforce.pdf) found that quality assurance, regulatory affairs, along with sales & marketing, and research & development, are now the main growth disciplines. Regulatory affairs was the primary growth area for more than half of medical devices organisations, which has been subject to increased regulations in recent years; RA was similarly a major focus for pharma and biotech organisations across Europe.

But the same survey also identified a gap in the available talent pool. A third of firms across all three sub-sectors felt the size of the available talent pool had decreased. Close to half of companies cited a lack of available skilled talent, and in particular a lack of local talent. Deeper analysis revealed a growing concern among life sciences employers that failure to keep employees stimulated and motivated could result in key people moving on.

Poor Resource Management
Manual tasks are unrewarding, demotivating and a poor use of qualified professionals’ time. So it is far from ideal that the life sciences industry is using scientific writers with PhDs to check over content for regulatory/QA purposes, at great expense to the business. Avoiding a product recall or safety scare is clearly in everyone’s interests, but there must be a better way.

The cost per hour of work from the employee doing routine proofreading (e.g. checking that updated labels meet all the new regulatory criteria for a market, and are correct and consistent) doesn’t just include that person’s salary. It also includes tax, benefits, insurance, holidays, office space, training, recruitment costs and so on, which can more than double the gross salary figure. If graphic designers have to get involved, there may be additional fees for re-work if the resource being used is external.

When budgets are tight, and skills in regulatory affairs and quality assurance are at a premium, it isn’t very astute to be using experts to do menial tasks, however vital the outcome. In the worst cases, people who feel unchallenged or under pressure to do extensive manual tasks on top of already demanding workloads, will leave the organisation.

Studies suggest that losing a salaried employee can cost as much as twice their annual salary, especially for a high-earner. Adding to employees’ faltering morale is the stress caused by being at fault for an error – errors that are very easy to make, yet equally easy to avoid.

Retention Challenges
Turnover-Cost-Whitepaper.pdf) suggests that morale and culture have risen to become the largest casualty of employee turnover and a lack of engagement, followed by productivity, team performance and stress. Service quality can also suffer if people’s hearts aren’t in the task, which is the last thing firms need when attention to detail is everything. (A last-minute re-work of a revised product label because of a mistake identified late in the process takes time and could delay the production, with substantial financial ramifications.)

So what is the answer? Usually in these situations, technology comes to the rescue, alleviating heavily-repetitive manual tasks so that skilled employees can use their time and talents more constructively. In a sensitive proofreading context, that hasn’t always been possible – there are so many subtleties at work that companies haven’t been able to trust automated solutions to make the right judgement calls.

Then again, translation and proofreading of labelling requires a completely different skill set to many other regulatory tasks. Most RA officers are scientifically minded and don’t necessarily have well-developed communication skills needed to talk about their products to non-scientists (hence the call for usability testing of leaflets, implemented in 2005).

Similarly, proofreading can be challenging for a subject expert who, although having an understanding of what the content needs to say, may not be trained to question it. Although some larger companies run training programmes and exams, it doesn’t necessarily make sense to put everyone through the process. And, to return to the earlier point, given the wide array of other demanding tasks RA officers have to contend with which do require their scientific skills, proofreading is always going to feel like an unwelcome burden.

Technology Raises its Game
Although software can never take the place of a human expert in its ability to spot subtle variances in meaning, it can reduce the rounds of proofreading – releasing time for the specialists to focus on more challenging and rewarding tasks. And technology is getting better. In the past, attempts to automate proofreading and document comparison fell wide of the mark due to technology limitations, language restrictions, and insufficient accuracy to fit the purpose.

Traditional text comparison tools relied on converting content to PDF format for visual comparison, an approach that is inadequate for heavily-regulated markets. Converting from one format to another can introduce anomalies, and the process doesn’t allow teams to work from original documents, which
may be important mid-way through a drug approval process. In addition, document conversion for the purposes of comparison is a violation of GMP processes and can lead regulators to question the validity of comparisons, and the entire packaging review process.

Where file conversion is taking place, or comparisons rely on certain fonts, language or specialist content knowledge, accuracy starts to suffer. And when teams can’t depend on automation for the highest levels of accuracy, their confidence in technology diminishes until they stop using the software, undermining any return on investment.

But things have moved on, and it’s now possible to take a more intelligent approach to text comparison which is a lot more reliable and robust, meeting the stringent needs of life sciences. Not only can companies access the facilities cost-effectively ‘as a service’ via the cloud (instead of having to pay for licences up front), the software works by comparing the underlying universal code (‘Unicode’) rather than the actual text shown on the page. This means teams can accurately compare content, irrespective of the font or language.

Using Unicode means data is retrievable with a simple keyword search in a database or document management system, and allows content to be transferred to other applications without risk of corruption. This kind of approach offers unprecedented levels of accuracy and speed.

Buying Back Expert Time
Automation of regulatory checks doesn’t replace the need for human oversight, but it does allow professionals to focus their time where it is needed. This is because the software is able to home in on the subtlest changes and anomalies, avoiding the need to go through entire documents manually.

To give an idea, where it would take a human proofreader a week to spot all the differences between two versions of the novel Huckleberry Finn (which runs to approximately 500,000 words), and with no guarantee that all anomalies will be spotted, Unicode-based automated text comparison takes just three minutes to reliably pinpoint even the tiniest variations. A typical like-for-like document comparison will take a matter of seconds, versus 3-4 hours done manually by a human, even if the language is unfamiliar.

This frees up expert time for higher-level verification/decision-making and frontline regulatory/quality assurance work. Our own research has found that professionals can save two hours or more of their valuable time by using automation in the first instance.

Average savings translate to five hours a week on manual proofreading/text verification. Extrapolating this against the average salary of a specialist regulatory affairs employee (estimated at $85,000 or EUR 76,000), this works out at a yearly saving/productivity increase of $13,500 (EUR 12,000) per RA user.

Improving Job Satisfaction
Reducing reliance on manual processes isn’t just a risk avoidance or insurance strategy. In life sciences, the rise in merger and acquisition activity and the growing trend of smaller batch numbers and increased drug personalisation means label demands are soaring and becoming more complex to manage. Each new demand and each new regulation multiplies the burden on regulatory affairs, quality assurance and marketing to be responsive, accurate and thorough at a time when skilled employees have little or no capacity to spare.

As regulatory demands continue to increase, this is a situation that is going to get worse long before it gets better, so life sciences firms need to find new ways of managing the workload if they want to hang on to skilled personnel who now command a premium on the international market.

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