

# The silver lining



Adam Sherlock

**As storm clouds gather over the western economy, canny pharmaceutical firms are recognising that new calls to automate administrative processes present a rare opportunity – a chance to refocus the business, offload some tedious back-office work, and embrace the latest technology – without any drain on their existing resources. Intrigued? You should be, says Adam Sherlock.**

## ...eCTD: burden or opportunity?

The huge dark cloud forming above the western economy at the moment is providing quite a catalyst for change among pharmaceutical organisations, which are already under growing pressure to streamline their activities because of intensifying competition and tightened regulations.

The upshot is that many firms are automating their administrative activities in an unprecedented way. Those at the cutting edge are treating the combined challenge as an opportunity to drive greater operational efficiencies and to hone their competitive edge, by refocusing their core resources and reducing their time to market.

Specifically, the growing requirement to support new standards, such as the electronic Common Technical Document (eCTD) electronic standard for regulatory submissions, has sparked a new interest in intelligent IT systems, which accurately and efficiently automate paperwork. These have particular appeal when they are combined with broader document management efficiencies to allow easy, flexible data access, structured, managed workflow; and simplified document sharing.

## ...the SaaS effect

Yet, deploying such solutions is not without its challenges. It requires technological expertise, and may detract from the day-to-day business. It also demands a generous IT budget, and time – which, for many organisations, is not on their side, especially as they rush to meet regulatory compliance deadlines.

This is why the pharmaceutical industry is currently experiencing a surge of interest in externally hosted software solutions, which give them access to all of the latest technology they need, but without the need to buy it, manage or support it. By procuring their software as a service (hence the acronym SaaS – Software as a Service), they gain speed to market and all the functionality they could wish for, but without the need to bust their capital budgets or hire a team of IT experts.

It isn't just the pharmaceutical industry that has woken up to the benefits of SaaS. Across many industries, including even the most conservative, the way organisations buy and manage their software has changed significantly in recent years, as firms have begun to take advantage of ubiquitous high-speed network connections to allow external software experts host and maintain their IT resources remotely.

This has freed them up to exploit the latest technology, without worrying about how they will pay for it, how long it will remain "current", or whether they have the right people in place to run the systems and look after them when they go wrong.

By letting someone else – dedicated, experienced experts – take care of all of this for them, they are simplifying their responsibilities, enabling them to focus anew on their core business.

## ...paving the way for change

Such are the abundant commercial advantages associated with this "utility computing" model of IT sourcing, that it has now won over the traditionally quite reserved life sciences market. Even here, organisations have now come to see SaaS as the solution to their immediate business challenges, particularly in relation to new industry requirements on licence submissions.

Drug licence submissions are a thorn in the side of the pharmaceutical industry – a distraction firms could well do without. Failure to adhere to stringent industry specifications could land them in hot water. Getting the processes and documentation right is vital, particularly now that the eCTD standard for drug licence submissions has become mandatory in many countries.

The requirement to submit applications in standard electronic formats has caused many pharmaceutical companies to investigate new software systems that not only take the pain from the increasingly arduous submissions process, but offer a whole host of other benefits too, while maintaining accuracy and improving efficiency through easier archiving and information re-use.

Faced with the seemingly clear choice between buying a ready-to-go off-the-shelf system or developing something customised in house, many firms have been unsure which way to turn. Until today, that is.

Now, they are discovering that there is a third option, and one that could prove ideal for pharmaceutical companies under pressure to implement something quickly that will help rather than *hinder* the business.

## ...speed to market

The remotely-hosted SaaS delivery model tackles all of these challenges head on. It offers pharmaceutical firms unprecedented speed to market with a whole host of new functionality, at minimal risk – and without internal staff needing to be skilled up on the latest technologies. Costs – often calculated on a pay-as-you-go basis – are predictable and spread out, while ownership and support of the software and hardware systems remain someone else's problem. Who could argue with a business case this compelling?

Such are the opportunities presented by procuring software this way that remotely-hosted software and services are being seen as the key to the dynamism and agility pharmaceutical firms now crave as they strive to maintain their positions in a competitive and unforgiving global market.

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### ...the tide is turning

While in the early days of hosted software services, some more conservative organisations were nervous about potential security breaches if they entrusted their systems and data to a remote third party, the practice has now evolved to such an extent that even the most cautious organisations – from banks to public sector departments, are exploiting SaaS – because of the potential benefits.

Such has been the rise in interest and adoption of SaaS that global analyst firm Gartner Group maintains that this is now fast becoming the software delivery model of choice, with *more than 50%* of all software purchases expected to be made on a subscription rather than licence basis this year.

A remotely-hosted software system harnesses the familiar interface of the web, though passing through many layers of security to keep sensitive data completely safe. Because this is held and managed centrally, users can access, work on and share documentation from their office desks as usual – from wherever they are.

This gives organisations an unprecedented level of flexibility in how and when they work, while freeing them up from the burden of owning, maintaining and upgrading the software. If they want to take the benefits even further, they can farm out some of the actual processes, too. Professional managed services now exist to support almost every function, from drugs application submissions, clinical trials and post-submission tracking, to medical writing, regulatory consulting and training.

Another attractive benefit of SaaS in the pharmaceutical industry is the flexibility it offers to scale capacity up and down to match the peaks and troughs of activity across the drug development lifecycle.

Given the sheer scope of the molecule-to-market drug development lifecycle, and the relatively sporadic need for different software systems at the various stages, this is a substantial plus enabling companies to switch on and pay for only the functionality they need, as they need it. The rest of the time, instead of lying dormant and incurring support costs, the software is simply “switched off”.

### ...a cast-iron business case

As far as the purse-holders in the business are concerned, all of this adds up to potentially significant cost savings.

Experts agree that when software is bought and paid for up front, businesses can expect to spend US\$3 (€1.89) on administration and support costs for each US\$1 they spend on the product itself. Imagine being able to eradicate the support costs with one fell swoop.

With a SaaS implementation, firms have the potential to eliminate not only each US\$1 in ownership costs, but also up to US\$2 of the US\$3 spent on supporting services. In their place, they can expect to fork out a nominal set-up fee, followed by a modest and predictable pay-as-you-go service charge – potentially adding up to savings in the region of hundreds of thousands.

As already indicated, agility and responsiveness are a huge benefit too. While organisations rolling out their own software internally might have to wait up to 12 months before a new system has been

specified, fully validated and entered into production, for many businesses this is simply too long.

Happily, with the externally-hosted business model, they could have access to the functionality they need as early as the next day. This is because the systems they’re tapping into are already up and running. Gaining access to them is akin to subscribing to digital television.

### ...competitive advantage

It was this unprecedented speed to market that presented the primary driver for global pharmaceutical group Boehringer Ingelheim when it invested in a SaaS delivery-based system last year, to help it meet the impending deadline for eCTD electronic submissions.

To do this, the organisation needed to standardise on an appropriate technology solution right across the group. Crucial decision factors included whether the software and related services could be provided in record time, on an outsourced, externally-hosted basis. The tight FDA deadlines precluded using an in-house system – which would require extensive integration and the need for an entire team to be assembled to manage and support the technology.

There were other attractive benefits, too. Boehringer Ingelheim opted for a SaaS solution not only due to its guaranteed fast availability, but because this solution also allowed the company to cut internal support costs by some 40%, resulting in considerably lower overall cost and investment than an in-house solution.

Boehringer Ingelheim has implemented eCTDXPress from ISI – a specialist web-based software system, aimed at creating and managing eCTD lifecycles, and reviewing eCTD submissions.

As well as meeting FDA requirements, standardising the software and eliminating paper output from the applications process will help Boehringer Ingelheim reduce the heavy costs associated with drug development by shortening R&D and regulatory lifecycles, and reducing time to market.

.....  
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 .....

### ...R&D economies

According to the Tufts Center for the Study of Drug Development in the US, each day that can be shaved off the development process potentially saves US\$37,000 in out-of-pocket development costs, while resulting in an additional US\$1.1 million in daily prescription revenue for an average-performing drug. Since first deploying ISI software for supporting electronic submissions over five years ago, Boehringer Ingelheim has cut at least two weeks off the submissions cycle. For a blockbuster drug worth €1bn a year, a two-week time-to-market market advantage is worth a lot.

The SaaS model is not just appealing to vast global enterprises, however. Indeed, it has a great deal to recommend it to smaller biotech firms – especially those without the budget to invest in sophisticated, advanced software, or which lack the internal expertise to manage it.

As the SaaS market continues to develop, and experts appear in particular vertical markets, such as the pharmaceutical industry, the choices are becoming broader too. For instance, instead of simply offloading the management of the software to a third party, firms now have the option to outsource part or all of the administrative processes with which the applications are concerned.

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**...process outsourcing**

Again, this offers savings on internal resources, allowing companies to focus even more on their core activities. Under-resourced or efficiency-conscious organisations can now tap into services such as medical writing, regulatory consulting and training, to name just a few. It may be important, then, when choosing a hosted service provider, to look for a supplier with the skills and experience to provide these additional facilities.

A further plus for Boehringer Ingelheim was that ISI offered the firm the flexibility to bring the technology in house if there came a point when this was deemed to be beneficial. The transition would be very simple, maintaining complete continuity of the systems being used, with any differences in output related purely to the change of location and ownership of the software and hardware. This offered the group maximum flexibility.

Yet the advantages of SaaS delivery have much to recommend the model on an ongoing basis. By eliminating potentially distracting, time-consuming, resource-draining support work, organisations

have an opportunity to refocus their energies, regain control of their IT costs, and move forward more dynamically. Procuring the latest technology as a pay-as-you-go service helps address all of this and more, lending support to analyst predictions, that this software delivery model is taking over. Certainly, there seems little doubt that SaaS will continue to make the headlines during 2008 as increasing numbers of life sciences firms wake up to the benefits and recognise this as the easiest and fastest fix to their current set of challenges.

Letting someone else manage your IT systems, and even the very administrative services they support, could be the key to the dynamism and agility pharmaceutical companies now need to survive and prosper in this increasingly competitive and unforgiving market.

What's more, those who identify and embrace the opportunity sooner rather than later stand to gain from having a head start over their competitors. While everyone stands to benefit, it will be the early birds that net the biggest worms.\*

*Adam Sherlock is Business Development Director of ISI Europe*

## Czech Republic transposes EU Tissues and Cells Directive after two-year delay

Over two years later than the April 2006 deadline provided for by the European Commission, the Czech Republic has finally transposed

EU Directive 2004/23/EC on the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

The Act on safeguarding the quality and safety of human tissues and cells, which was adopted by the Czech Senate in July this year, will now be signed by the President and will come into force 60 days after its publication in the Official Journal.

**...ethical issues not covered**

The Act is aimed at setting quality and safety standards related to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human application. The legislation does not, however, cover ethical issues related to the procurement of human cells and tissues, for example obtaining consent for the procurement, as these problems are governed by a separate Act on public health, the Act on transplantation as well as other national legislation.

**...authorisation required**

In accordance with the newly adopted piece of legislation, all parties involved in the procurement, handling, storing and distributing human cells and tissues will be required to obtain authorisation from the country's medicines agency (SUKL). The agency will have to assess filed applications and issue a decision within 90 days from their submission.

**...hefty fines**

The medicines agency will also be responsible for the inspection of tissue banks, hospitals and laboratories involved in the handling of human cells and tissues for human application purposes. In the case of their non-compliance, the SUKL will have the power to cancel the authorisation issued for the establishment infringing the Act. The new legislation also provides for financial penalties for non-compliance amounting to CZK3 million (€125,899).\*



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