



## Putting Information into Motion

*Information lifecycle management gives transparency of operations and customers over multiple products, markets and information types, making pharmaceutical companies more competitive, saving them money and ensuring worldwide internal and external compliance.*

Weak pipelines for development of new drugs and the expectation of widespread re-importation at discount prices are putting pharmaceutical company margins under pressure. They need to bring new drugs to market more quickly and increase the efficiency of their current operations.

As a new means for communicating internally and with partners and customers emerge, their usage quickly explodes, making it hard for managers and staff to run the business efficiently on a global basis. Most of information flowing through a typical 21st century enterprise consists of unstructured information, often in poorly managed systems, such as faxes, electronic mail, instant messages, text messages, scanned documents, word processor files, spreadsheets, presentations, instant messages, audio and video.

### POOR DECISIONS

Nobody ever intentionally makes a bad decision. Nevertheless, more often than pharmaceutical companies would like to admit, their directors, managers and supervisors make decisions that are based upon poor or incomplete information. Unfortunately, these can significantly harm their organisations, both financially and through loss of reputation.

The problem is that in the 21st century pharmaceutical companies are very complex, with large number of departments and geographical markets, each with its own systems, such as research, development, manufacturing, marketing, sales, distribution, procurement and licensing. This may be overlaid with different therapeutic areas, like cardiovascular, central nervous system, gastrointestinal, infection, oncology, pain control and anaesthesia. The information is held as many different data types and stored in a wide range of servers and storage devices. Much of the data is held in specialised systems, including publications databases, competitor databases and clinical trails databases.

As one industry executive put it: *'The pharmaceuticals industry is more of an information than a manufacturing business. We produce vast quantities of information about every pill we manufacture. Information is our lifeblood and a vital asset.'*

It is impossible for a pharmaceutical company to manage its business in the 21st century without holistically managing the myriad of information types exploding around the world. Transactional information must be combined with all other information types to give a 360 degree view of markets, diseases and customers. Only this will put the information into a context as part of a wider business process.

### MANAGING THE INFORMATION LIFECYCLE

The solution is to develop an information lifecycle management (ILM) strategy. This ensures everybody in the company gets all the information they require, when they need it, in the format they want and in the right context. This is achieved in the most efficient manner at the lowest possible operating cost. The result is that the company operates with the best possible information available to it, at the lowest possible cost and at the lowest possible risk, whilst still complying with all internal and external regulations.



ILM is closely linked to different business processes and with solving business problems. It could be finding information within the company on which to develop a strategy for launching a particular drug into a new national market, assessing operations for risk management, complying with food and drug regulations or discovering facts connected with a legal dispute.

This is a much broader view of ILM than many players in the information technology industry take, especially the storage hardware vendors. They see it as a new way of packaging hierarchical storage management, which merely involves moving data from online storage to cheaper offline storage.

## COMPLIANCE

21st century pharmaceutical companies are subject to a wide range of regulations, including Food and Drug Administration (FDA) requirements, the Data Protection Act, cross-border transmission of data, complex taxation legislation, environmental protection, etc. Many different government agencies are requiring them to keep data longer, to authenticate it and to keep it secure. Different types of data have to be kept for different periods.

The Sarbanes-Oxley Act requires pharmaceutical companies to have well designed management information systems and strong internal controls. This is in order to ensure the accuracy and completeness of the financial information they publish.

In the United Kingdom, a new Combined Code for Corporate Governance has followed the Higgs Report. It requires boards to 'be supplied in a timely manner with information in a form and of a quality appropriate to enable it to discharge its duties.' It also recommends that 'non-executive directors should scrutinise the performance of management in meeting agreed goals and objectives and monitor the reporting of performance. They should satisfy themselves that financial information is accurate and financial controls and systems of risk management are robust and defensible.'

Pharmaceutical companies also have their own internal governance rules, corporate social responsibility policies, business rules, commercial policies and operating procedures. For example, they have policies on ethics, staff recruitment, age discrimination, sexual harassment, sexual discrimination, giving quotations, allocating leads to brokers, procurement and dealing with consumers. The board needs to ensure that all these regulations and policies are being consistently and uniformly adhered to in every part of the organisation at all times.

## COMPETE!

The pharmaceutical industry is highly regulated and its managers sometimes feel that this is placing a burden upon them. However, no government should ever ask a company to report more detailed or more accurate information than it should already be closely monitoring, in order to compete successfully, develop its pipeline and to meet its objectives and its responsibilities to its shareholders, clients and other stakeholders.

If a pharmaceutical company meets its own operational needs for information, it should more than meet the needs that any external agency would ever put on it. If a company uses ILM properly to meet its own internal requirements for information, compliance with external regulations should be virtually free.

The Butler Group, an independent analyst, recently wrote: 'compliance is not just about being seen to have procedures and systems in place, it is about actively demonstrating that the organisation is using the data that flows through its operational processes to improve the way it functions. Although many regard compliance as a cost centre, it is about running a better business and those that do it well will possess a significant competitive advantage.'

## SOFTWARE SUPPORT

In the 21st century, you don't install software and miraculously get control of the organisation. Technology on its own does nothing. ILM is a way of life and an approach to solving business problems that is supported by technology. It requires organising people properly, putting in the right business processes and then using technology to support those processes.

The AXS-One Compliance Platform™ supports this by allowing pharmaceutical companies to capture all the various information types that circulate through its different departments and offices, irrespective of how it is generated, where it is generated and the form it is in, in a transparent fashion that is not invasive to computer systems.

According to the same industry executive: 'Information is critical to key decisions across many areas, which requires a system that can understand the information and deliver it to the relevant parties.'

All this information is stored in a 'repository' database that has the ability to search, drill down or mine the information across multiple data types. Most importantly, it puts all of this information in the context of a business process.

"We put information into motion," says Bill Lyons, chief executive officer of AXS-One. "We put it to work, helping you to run your business more effectively."

This could be determining the potential of a new research area, developing a national marketing programme, reducing administration costs, shortening the supply chain response time, risk management, compliance, legal discovery, etc. Only this approach could bring together all the information from around the world on the treatment of a particular disease in a particular age group using a particular drug.

For compliance, AXS-One software helps companies to codify their written business policies and regulatory requirements, so that they are electronically enforceable. It then provides electronic audit to ensure they are complied with and provides the security necessary to ensure that evidence can be reproduced irrefutably. The software is industrial strength and scales to petabytes of information in a way that few, if any, other companies in the world can do.

Most pharmaceutical companies already invested heavily in document management systems to handle their drug tests. AXS-One software integrates with this in order to incorporate it into a single enterprise-wide system and adds electronic mail and other new content types.

According to Forrester Research, the independent analyst, information technology will be spared in the looming pharmaceutical downsizing. It says that predictable savings from infrastructure and licensing consolidation and the 'must-have' improvements in automation of FDA submissions and regulatory affairs will keep IT professionals out of the cross hairs for now.

## COST SAVINGS

Pharmaceutical companies that adopt ILM across the whole enterprise quickly recover their investment through improved operations. They need fewer computers, less storage, less expensive storage and less network capacity. A smaller number of people are needed to maintain the computers and storage devices and they suffer fewer failures and can recover better.

Less time is required to record new information policies and to provision new storage. Better information also eliminates errors, improves knowledge sharing, thereby reducing the time to market for new drugs.

AXS-One believes that its software does this better, faster and cheaper than any other product, so its total cost of ownership for storing petabytes of data is orders of magnitude lower than other IT companies. In particular, its software needs approximately half the IT environment that its competitors need.

## CONCLUSION

ILM allows a pharmaceutical company to manage information across the whole organisation, rather than store it in separate best-of-breed departmental and therapeutic systems that are separate from enterprise-wide communications systems. It can combine transactional information with electronic mail, medical databases and other unstructured information, so companies are in a better position to make decisions, launch drugs into new markets, manage the business, react to changes in different markets, minimise operational risk and preserve their reputation.

Companies will not only meet their business objectives, but they will do so in a very cost efficient manner. Furthermore, internal and external compliance in a highly regulated industry will come free.

ILM will result in better corporate management, because directors and senior managers have access to information across all the company's departments at their fingertips. Putting data in motion is important, because in order to reduce the time to develop new drugs and launch them into national markets, pharmaceutical companies need access to information in every department in the enterprise.

'Good housekeeping makes an organisation more efficient and cost-effective,' says the Butler Group. 'If looked at as an opportunity to improve business processes and procedures, then information lifecycle management has the potential to be a great differentiator for organisations.'

## ABOUT AXS-ONE

AXS-One provides process centric solutions for corporate governance to extend collaboration between employees, partners, customers, and suppliers, while preserving investments in existing systems and implementing high-volume, interoperable, scalable, and secure business solutions for the global 2000. Its Web Services-based technology has been critically acclaimed as best of class.

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