



# COLLABORATE TO ACCUMULATE

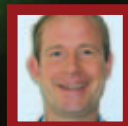
Globalisation, mergers and acquisitions, expiring patents, and expanding markets are just some of the factors transforming the way that the pharmaceutical industry operates. These shifting dynamics bring opportunities for companies to collaborate and raise productivity on an international basis, writes Rudiger Dorn, managing director for Microsoft's Worldwide Life Sciences Industry Group.

**THREE IT PILLARS FOR OPERATIONAL EXCELLENCE**

- Integration: aggregate production data from disparate applications
- Visibility: convert data into knowledge
- Collaboration: share information with the right people at the right time

As the pharmaceutical industry matures, mergers and acquisitions, and outsourcing are increasingly common. Parent companies want to capitalise on the knowledge held in the companies they acquire. To do this they need to create synergies in the way that information is stored, analysed and communicated. In all likelihood, they already have divisions in several countries, but now they have new departments and staff who are accustomed to a different working culture, supported by different technology.

Likewise, when companies merge, teams may need to share findings and secure common documentation processes on an international basis. When one department experiences a specific problem with a production line, how does the production manager tap into the knowledge of a colleague 1,000 miles away who has experienced the same problem? How does he or she know that the knowledge is even available?



**Author**

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As in any industry, mergers and acquisitions produce companies with heterogeneous IT systems. Rapidly expanding companies often acquire new systems by default, rather than according to a company-wide strategy. Legacy systems may stay in place longer because IT is managed by disparate teams. When no one has a global view of the infrastructure, establishing consistent systems that make information visible to everyone is a considerable challenge.

### Regulation and innovation

Globalisation is expanding companies' geographical reach and the possibilities for outsourcing to partners on other continents. In an industry already subject to stringent regulations, this makes accountability increasingly complex and opaque. For any life sciences company, meeting regulatory requirements, and thereby guaranteeing the safety of patients, needs to be achieved in a way that does not inhibit innovation and investment in new techniques. Rigorous documentation is essential for adherence to guidelines such as current Good Manufacturing Practice. Even the slightest change to a process involves re-registering the product. The FDA's Process Analytical Technology (PAT) initiative is designed to help companies deploy new technologies in a way that meets faster regulatory approval. Nonetheless, this remains a challenge – one that will continue to evolve as the industry globalises further.



## The industry needs to move away from disconnected processes towards a uniform IT infrastructure.

Emerging standards and open connectivity are viewed by the industry as the most promising way forward to address these challenges. Modular systems can reduce the compliance effort and allow faster innovation cycles. Microsoft is supporting the development of open standards that reduce the heterogeneity and complexity of business solutions. This includes work with key vendors and standardisation bodies to design solutions that build on companies' existing IT investments.

### Patent expirations

Global consultancy IMS Health predicts patent expirations on blockbuster drugs worth more than \$43 billion in annual sales by 2009. All four of the top selling drugs will face generic competition by 2012. With reliance on blockbuster drugs soon to end, big pharma is under increased pressure to strengthen product pipelines. This means increasing R&D productivity and, in turn, attrition rates. Boosting investment in research means reducing costs elsewhere. While manufacturing represents only 20 per cent of the cost of any drug, pharmaceutical companies are increasingly aware of the potential cost reductions in production. By reducing waste and driving down costs, companies can increase the operational efficiency of equipment improve use of assets and raise return on investment, making more money available for R&D.

In addition, a company with efficient production processes is better placed to balance supply and demand. Generating the

right amount of product to maintain stock levels and meet patient demand is a complex process. The higher the rate of batch failure, the larger the stock of finished goods required to secure the downstream supply chain. Again, reducing errors and improving compliance are critical to the timely delivery of safe drugs to the market.

### Efficiency, agility, and compliance

Streamlining the manufacturing process involves:

- Reducing errors and waste
- Increasing plant flexibility
- Decreasing the cost of compliance

Gathering, collating, analysing and sharing insights into the manufacturing process is crucial to these aims, because they determine how quickly decisions can be made. In particular, pharma and biotech companies need to adopt a preventative, rather than reactive, approach to production issues. Technological changes that can help companies achieve these aims are:

- Amplifying the value of existing systems like PAT by integrating the information they hold
- Analysing and presenting the data to maintain a single, real-time picture of the truth
- Giving employees the tools to collaborate on this knowledge

### Communication networks

If a production lot goes into quarantine, the production manager needs to establish the source of the irregularity quickly. This means contacting the raw materials supplier and the inbound quality control department. This information is equally critical for sales people and those managing the supply chain because delivery agreements with hospitals might be affected.

Meanwhile, the production planning department must be aware that extra product is required to compensate for the batch in quarantine. With communications spanning the whole plant, mobile employees, external suppliers and customers, making fast decisions can be a challenge.

### Locating data in a varied IT landscape

Typically, the above process involves searching for information in several different applications, such as a Laboratory Information Management System (LIMS) or Manufacturing Execution System. What's more, employees have different degrees of access, so they may have to find out who has higher access rights and contact them for the information before collating it in a spreadsheet. They then email the spreadsheet to others, who save a version on their desktop, possibly with their own modifications. This fragmented information-sharing process is time consuming.

It also creates the potential for human error as information is copied and modified by recipients to produce multiple versions of the truth.

### Information integration

To achieve operational excellence, the industry needs to move away from disconnected processes towards a uniform IT infrastructure. This will help companies integrate information from various sources and help staff make well-informed decisions. It's a case of securing and accessing expertise both within and between individual sites, so that valuable insights are not lost in a maze of machinery. Being able to record information in a place where others will see it is important in any industry. But in the highly regulated, competitive world of pharmaceuticals, transparency is crucial.

Showing regulators that a reliable, standardised system is in place – producing a single version of the truth – will speed approvals and time to market. It is much easier to assure patient safety if one system visualises all elements of the production line. In addition, if production history is easier to trace, problems are easier to resolve. Production managers are better equipped to limit the impact of batch failure, and to take preventative action.

The 2007 Microsoft Office system and Microsoft SharePoint Server 2007 address these issues. Together, they form a unified solution for managing unstructured and structured information. Using this suite of products, a company can integrate information from multiple systems for presentation in a single portal. Employees can view relevant information to their role, without long searches. If this approach is applied to every site, the IT team has a much simpler infrastructure to manage. Implementing standard features across the company takes the complexity out of maintaining and developing the system.

### Contextual insight

Naturally, amassing data in a central repository is just the beginning. For employees to act on this information, it is essential that they can use the same interface to conduct analyses. Also, the level of detail required and the visual format of information may vary according to an employee's role.

Office SharePoint Server 2007 offers version control, audit trails, workflows and revision history, all features once programmed and maintained separately. In an integrated environment, all production staff can use these tools to make qualified decisions. Any modifications they make are traceable, and the history of all content remains intact for future reference.

Information appears in a dashboard that contains a range of formats: scorecards, graphs, spreadsheets and batch summary reports. These form a basis for making forecasts, comparisons and assessments.

### Collaborating on common knowledge

If a company deploys PAT systems, the production manager will receive a warning if a production line is likely to produce a faulty product. But the speed of response and the amount of waste that occurs depend on the collaboration systems in place. A system that alerts everyone to the problem automatically, through the same interface, means employees can act quickly on the basis of common knowledge. Again, there is less room for error and fewer delays arising from complex chains of communication.

In conjunction with a number of Microsoft products, Office SharePoint Server 2007 can transfer an alert highlighted by a LIMS or PAT system, and send it to everyone dealing with that particular batch.

Likewise, specialist, product-specific knowledge is only valuable if it can be shared, so the central repository that holds the data should also act as a secure communication system.

In this way, a company can develop communities between teams with equivalent roles across international plants. These teams can generate product-specific information with complete visibility of each others' input. With this single version of the truth, the risk of inconsistencies and errors is lower, and the opportunity for problem solving through shared insight is higher.

### Modular architectures

Achieving regulatory compliance and flexibility is a vital element in containing costs and shortening product cycles. If a company wants to shift production capacity between plants or run multi-product lines, it must consider the validation effort involved.

Service-oriented software architectures from companies such as Microsoft can work in conjunction with existing technology in the form of modules that can be rapidly added or removed. With this flexible infrastructure, capacity can be reallocated quickly, with lower cost of compliance and no need for new code. This also avoids the costs of purchasing, patching and upgrading. In turn, this reduces time to market, optimises asset utilisation, and keeps stock levels consistent.

### Centralised IT for a global perspective

Pharma needs to move away from a plant-by-plant approach to a central management model. This requires close collaboration between IT and operations departments to achieve a global view of performance. A common, powerful system that staff can use to collaborate on the basis of shared insight is key to this aim.

By aggregating data, increasing its visibility, and encouraging collaboration, pharma can raise the efficiency of production. Reducing waste and human error increases ROI and the investment that can be made in R&D. Transparent information that offers auditors a single valid record of the production process speeds compliance. In turn, faster approvals and a preventative approach to production issues helps companies to achieve the right balance between supply and demand. **WPF**

