

PROCESS ORIENTATION AND INFORMATION MANAGEMENT: THE CASE OF ACHIEVING SUCCESS IN THE PHARMACEUTICAL INDUSTRY

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Abstract

In today's business environment, organisations have recognised the importance of information. Consequently the use of IT is regarded as a primary means of enhancing business improvement. This has resulted in a number of organisations focusing on different means of structuring, and process orientation is considered to be the most suitable option. This paper explores issues related with managing information and the implications on key operational issues. Various concerns are exemplified by drawing examples from the pharmaceutical industry.

Introduction

Over the past few years organisations have seen a steady increase in expenditure on information technology (IT). In the UK, estimates for 1993 considered such expenditures to be over 1.5% of their annual turnover - exceeding £12 billion a year (Willcocks, 1993). Public sector spending on IT, excluding the Ministry of Defence, has been to the tune of £2 billion per year. The National Health Services (NHS) management executive alone, spends £350 million annually on IT. In most organisations such investments are being made on account of the inherent need to manage their information better. A study of the logistics in the NHS has shown that cost savings of £300 million per annum could be achieved by using an integrated IT service. The NHS management executive in fact has a vision to *informatise* the health services. The Information Management Group of the executive regards a centrally directed IT infrastructure as being essential for developing an integral care system for a vying internal market.

The use of IT to enhance business improvement has also meant that organisations start rethinking about the manner in which they conduct their business. This has a bearing on how different industries use IT. The pharmaceutical industry is the focal concern of this paper. This industry has traditionally been extremely functional in its internal organisation, however growing competition and pressures to shorten the life cycle of drug development has kindled interest to assess alternative ways of working. Since the pharmaceutical industry is a very information-intensive business, the use of information systems to support the running of the business is only natural. This paper explores issues related with information management and the implications for managing key operations in the pharmaceutical industry. A move towards process orientation is also identified. The underlying argument is that where a process-oriented approach is chosen, information management in fact plays a key role in ensuring success. It does this largely through integrative actions which, on the one hand overcome the tensions between functional and process approaches, and on the other, facilitate the necessary binding that is implied by a process orientation. The paper is organised into five parts. After a brief introduction, the second section highlights the importance of information in managing business processes. This is followed by establishing a link between business processes and value addition. The various concepts are illustrated by using a case example. Finally, a discussion of some key concepts is presented.

The importance of information in business processes

Information is important for the business processes of all organisations, and consequently the value of a business is to a large extent dependent on its ability to organise this information. The ability to do so involves the effective recording and processing of information.

The processing of information is an objective activity, which is sustained over a period of time (Avgerou and Cornford 1993). Furthermore, business is carried out not so much by 'doing things', but rather by 'communicating things' (i.e., by talking and writing). As the activity of a company grows, informal processes of communication need to be supplemented by more formal ones. Formal processes help preserve the "uniformity of action and the standardisation of meaning" (Stamper 1973). The complex interplay between the formal and informal aspects of an organisation determines the type of management system that is in place. Advances in new technology, together with emergent organisational forms, introduce new capabilities and 'connectivity' for information processing (Trubow 1993). It becomes difficult to ascertain clear lines of authority and decision making, and changes in accountability and responsibility for planning processes are common (Rockart and Short 1991). Hence, information management and business management have become indistinguishable from each other. This is indeed now the essential character of organisations, and it has become the central concept for understanding complex business environments (see, for example, Land 1992; Liebenau and Backhouse 1990; Klein and Hirschheim 1987; Stamper 1973).

In today's business environment, organisations have recognised the importance of information. Indeed, it is one of the most important assets of any organisation. All business activities involve the use of information in some way. At any given time an organisation may process vast amounts of information, which may be of different types. However maximum value can be achieved from the information resource if the organisation has the competence to recognise those pieces of information that are most critical for its functioning. Hence the context of use determines the value of information. To illustrate this aspect, let us consider the contents of an advanced manufacturing planning system, which includes not only bill of materials information, but also information about the routing of work from one point on the factory floor to another. This is information about business processes that add value to the operations. This idea that we need information about processes is fundamental. For anyone who has undertaken quality improvement initiatives based on process analysis, this idea will quickly make sense. However, for someone who is stuck in a business where things "have always been done this way", the idea will be difficult to understand, because the information about business processes is lost in the heads of people who have been doing different jobs - no doubt always in the same way for years and years. If we are to change the processes within a business, then it behoves us to understand and take stock of the "inventory" of information about these processes, whether it be written down, or is simply part of the working knowledge of those employed in the business. Until we do this, we will never know what we are trying to deal with.

Organisations function by means of human and automated systems that communicate with each other, either internally or externally, but always by means of information. Internal communication takes place between automated information systems, individuals and between groups of people or departments, within the same organisation. External communication takes place between organisations, which may be members of the same group of companies, and between other trading partners, their suppliers and customers. Increasingly, external communications are critical for assuring the future success of an organisation. This is partly because of the widespread availability of the right technologies (EDI and communications networks), but also because of the strategic advantages of sharing information across whole supply chains, in order to reduce inventory and as a means of accelerating the movement and availability of demand information.

The value-adding aspects of a business process

Information Porter (1985) is perhaps one of the first researchers to focus attention on the value-adding aspects of a business process. In fact, Porter's value chain has made a lasting effect on the way in which organisations view their business. In particular, it has contributed to the current interest in business processes and how we can manage them through improvement, redesign and redefinition. At the core of this concept is the notion of information management, because in reality, there are no conduits that pass through an organisation linked to a particular process. The idea is that a process works only because there is an associated information management activity in place. This concept of a process is linked to the social

constructionist viewpoint (e.g. see Berger and Luckmann, 1966). From a social constructionist viewpoint, a process is defined in terms of the meanings attributed to them by the social players (e.g. see Quaid, 1993).

The value chain considers the primary functional areas of a business (inbound logistics, operations, outbound logistics, sales and marketing, and service) and then assesses how value is added within the overall activity of an organisation. It also shows how the secondary supporting functions (e.g. infrastructure, human resource management, technology management, procurement and information systems) all contribute to the efficiency and effectiveness of these primary functions. However, in order to understand the true potential of a business, we not only need to explore the process structures within an organisation, but also the more abstract information structures as well. This is because experience with data exchange often leads to ideas about information sharing, as a partnership develops and the expectations of inter-organisational systems increase. Traditionally, business processes have been considered from a very narrow rationalistic standpoint. Such a conception has considered processes as a commodity (e.g. see Scherr, 1993).

Modelling business processes is a very natural thing to do, although to do it well requires some understanding of the basic rules and techniques, in order to avoid problems. The success of the value chain in the late 1980s and the early 1990s indicates how welcome it was (for many at least) as a means to get away from the functional organisation chart (as the dominant view of a business), and to be able to replace it with a process-oriented viewpoint. The value chain is useful because it is simple, because it provides a home for all business activities within a well-understood and widely accepted framework, and (as it is widely used) because it provides a basis for discussion and negotiation of business boundaries when we are looking for new ideas. The topology of the value chain can be developed to show how information and material flows through the business more explicitly.

Information management is more difficult to undertake, and has a more difficult history. For example, many business managers will have come across data modelling, but only a few will have favourable memories of it. Typically, data modelling is done badly, by analysts who have no finesse and little vision (or whatever other capabilities are required) to complete the task successfully. In fact, many consider good data modelling to be a means of managing information. However, there is a history of encountering difficulties with information management, which has led to continuing efforts to improve our understanding and abilities.

What is more important, is to note the degree to which organisations are succeeding with information management. There is evidence of activity: whether to simply assert the need for good information management and develop the technique (Bainey, 1983; Allen and Boynton, 1991; Beynon-Davies, 1992; Cesarini *et al*, 1990; Ichiko *et al*, 1989; Robinson, 1993; Potter *et al*, 1993; Parker, 1993; Armitage and McCarthy, 1987); or to analyse the benefits of modelling at the level of data integration (Goodhue *et al*, 1992). Work has also been carried out on improving the

effectiveness of database design and its implementation using knowledge-based techniques (Storey and Goldstein, 1993). The presumption in all these studies is that good low level data management will perhaps lead to establishing principles for managing information.

There is other evidence of the need to manage information more effectively in the wider sense. A recent survey shows that data-related issues now occupy the top two slots for senior management concerns (Niederman *et al*, 1991), and some current work is aimed specifically at extending data modelling to encompass the whole enterprise (Scheer and Hars, 1992; Moody, 1991; Marcus, 1993). Industries are striving to create industry-wide information models (Tippee, 1993). Needless to say, in the background, the methodology specialists work to provide ever more capable and standardised support environments and supporting software systems (Davis, 1992), but not everything is straightforward. There are implementation difficulties at the practical level (Tannenbaum, 1991; Hazzah, 1991) and at the architectural level (Narayan, 1992). In different sectors, we even find that cultural attitudes are a major factor; one example being that the banking community still seems to suffer from extreme conservatism, and reports indicate that information modelling (and hence information management) is not part of their repertoire of business analysis tools (Gandy, 1993).

The Case Study

Whilst as has been stated that the Value Chain is a simple to understand concept, it is found that a very straightforward application of it does not lead to useful outcomes. Instead, the real-world contexts have to be recognised in the model, as they in turn focus the application of the concept, and also return more meaningful and valuable results.

For instance, in the pharmaceutical industry, it has been found that no value chain of general application exists, and that furthermore, the chains in evidence do not exist in just one place, but often in several. When these factors are taken into account, then the management issues of process orientation become clearer in the model, and the added-value role of information management emerges more naturally.

The Nature & Scope of Process Orientation

Principally four main functions in pharmaceutical trading exist: Drug Discovery; Drug Development; Drug Manufacture; and Marketing, Selling, & Distribution. A process-oriented approach reveals not one 'Drug Process', but four (see Fig 1): Candidate Compound Acquisition; New Product Introduction; Product Supply and Distribution; Product Enhancement & Maintenance.

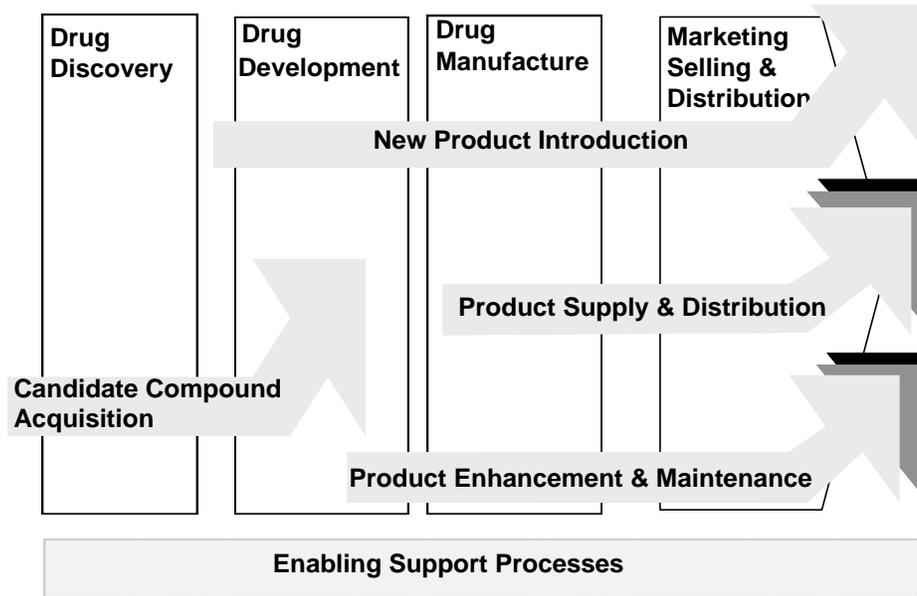


Figure 1, The Major Processes in the Pharmaceutical Industry
(The multi-headed arrows are meant to indicate market diversity).

Each process has its own characteristics: drivers, timescales, risks, cost structures and associated technologies and expertise. The nature of the value they deliver is distinct, but it is worth noting that three of them terminate outside the organisation - in the market place, and it is there that their value is assessed.

Traditionally, value can be added to a process in three ways: Cost, Speed or Quality. A summary analysis of the relative importance of these leverage points is shown in Table 1, (which, because 'Quality' is an umbrella term, also expands the improvement drivers in the area of process quality improvement).

Process	Cost	Speed	Quality	Example of Quality Consideration
Compound Acquisition	Low	Medium	High	Innovation Suitability
New Product Introduction	Low-Medium	Very High	High	Innovation Regulatory Compliance Decision-making Planning
Product Supply & Distribution	Medium	Medium	Medium	Regulatory Compliance Responsiveness Flexibility
Product Enhancement & Maintenance	Medium	Medium	High	Market Requirements Regulatory Requirements Change Management

Table 1, Summary of improvement leverage points in pharmaceutical processes

The Diversity of the Process Environment

The processes outlined above take place in an international environment, which means that they are spread out functionally/geographically, and not contained to just one site. This introduces additional management issues. In the specific company that this case is based on, the Research function occurs in three countries; Drug Development (depending on which activity set in the process is being considered) takes place in between one and six countries; Manufacturing occurs in between eight and 20 countries; and Sales, Distribution and Marketing in up to 80 countries.

Functional Emphasis

Notwithstanding the benefits of a more process-oriented approach (resulting in an improved focus on key issues, such as time-to-market, regulatory compliance, etc.), the emphasis on how activities are carried out will almost certainly remain functional. This is largely because of the necessary heavy reliance on technical expertise at all stages. Additionally, there is the pragmatic factor that confirms that functions are better for getting things done. These two factors historically have combined to create large 'islands of IT', each one dedicated to its function's transactional needs and to its owners' perceptions of value.

Ownership Factors

At a high level, ownership of resources and responsibilities is functional. At a lower level, this takes on a more geographical spread, and becomes more site-specific for ease of execution. The functional owners have to achieve economic balances between the demands of the differing processes that thread their way through the particular function. This is further complicated by the impact that any one particular drug can exert. The number of drugs going through the chain is small, and each one has its own peculiarities, which create tension between scientific process requirements and resource planning requirements. Additionally, the owners have a significant internal functional business infrastructure to manage (Human Resources, Costing, Documentation, Administration, etc.).

Two Kinds of Information

Pharmaceutical processes are information-intensive. A typical submission to a regulatory body will run to 120,000 pages. The output from the R&D activities as well as some others is almost exclusively that of information. Thus we need to distinguish between the instance where information is actually the deliverable from the process, and the second instance, where the information is the kind that is normally associated with the everyday running of an organisation. Both kinds need to be managed, but with distinct differences of approach.

The Issues

Given the advantages of process-orientation, it is nevertheless clear that the above factors, when taken together, will tend to disperse any efforts to focus on a single-linking process and will militate against those advantages that come from an integrated mode of working.

In summary, the issues that counter the benefits of process orientation are the following (in the context of an international pharmaceutical company):

1. There is not just one business process, but four distinct processes, which in turn thread their way through the same functional organisations,
2. Process characteristics are generally altered by the nature of each drug moving along the chain,
3. Besides being spread over a number of functions, within those functions, the activities within a process are also spread over a number of sites which are located in different countries,
4. The ownership of the resources needed to perform the activities are likewise functionally and geographically spread out,
5. Functional owners, whose prime goals are concerned with task performance (sometimes highly expert and expensive) and normal organisational administration (care of people, utilisation of assets etc.), tend to experience conflicts which arise from the demands of the different processes that impact their function, and on occasions, distortions that a major drug might well impose.

In order to achieve success, all of the above issues need resolving - not in a piecemeal fashion, but in some integrative way. We now examine the role and importance of information management in achieving such integration.

The Role of Information Management as a Process Integrator

Based on the contribution that better information management offers, in general, the support process in Figure 1 can be expanded into four interdependent layers - see Figure 2.

Document Management is a layer that is perhaps peculiar to organisations that have a heavy technology-base, coupled with long lead times for development. Additionally, regulatory requirements impose extremely tight controls on both documents and their management. A document in this sense is not a piece of paper, but is an information-entity in its own right - see further below the discussion on archiving. In general, the more extensive and robust the lower layers are, then the easier it is to develop systems and services that can rapidly address the key information issues in a process.

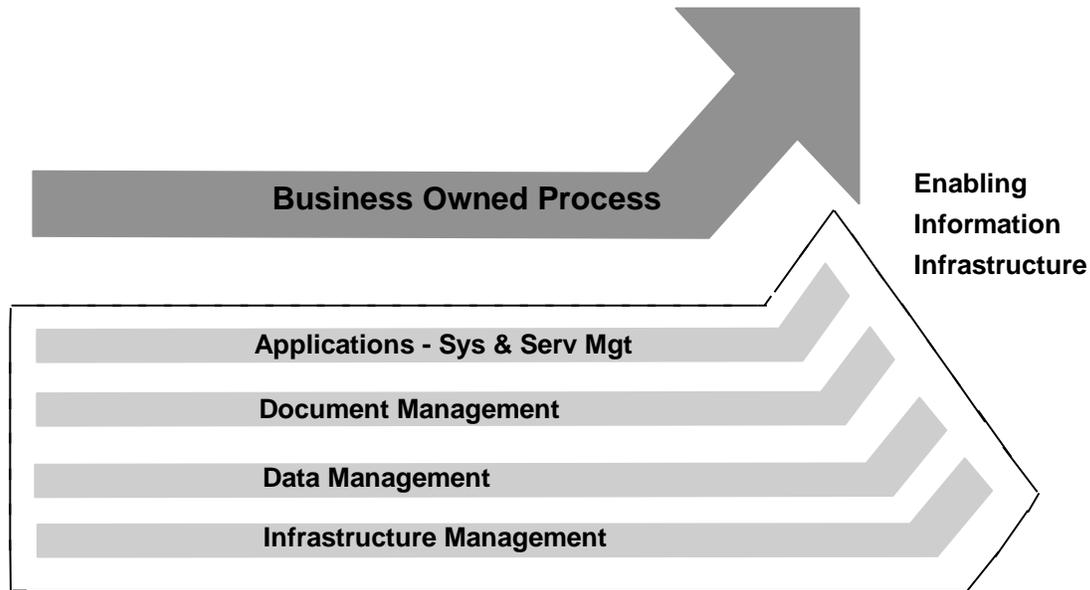


Figure 2, The Information Support Process Layer

A more specific explanation of how information management can be applied to the issues mentioned above is given below:

1. Assisting the Prime Processes

One of the major inhibitors to process flow is the cross-functional boundary. In an industry which is information-rich, this problem manifests itself in difficulties of information transfer (information being the product that is trying to cross the boundary in many instances - see above). The importance of managed information flow has been recognised in the industry, and the tools currently being deployed are the high-end document management systems.

By way of illustration, we consider the drug development archive in its electronic form. This is by no means a 'dead' file, but instead it is an evolving repository of information, which never stops being added to, and is most active in the eight or so years a drug is undergoing the development process. It is a logical archive and not a physical one, as the data owners are both functionally and geographically spread out. Access is at more than one level, and updating mechanisms comes under regulatory scrutiny. Its growth is not measured by the linear accretion of laboratory data corresponding to the progress of a drug through its stages, as at first, many stages move in parallel, and also results from downstream can cause earlier work to be re-examined, repeated, or even reworked to a different protocol. The archive provides a live linkage with the key scientific activities within the new product introduction process, by allowing electronic documents to be treated not as 'mimicked paper',

but as linked entities that embody related sets of knowledge, together with the use of navigation tools for exploring and presenting the knowledge across the process.

2 Geographical Spread

A second area where information management has an integrating role, arises from the way the organisation performs its processes. Since it remains primarily functional at the execution level, process linkage and progress activity is achieved by team-working - the grouping of necessary experts associated with a given drug to move it along the process chain. These teams are also both functionally and geographically spread out. When the operation of such teams is examined for patterns, there is a good case for treating them primarily as information managers - their activities tend to be planning, decision-taking, expert reviewing, problem-solving, etc., all of which are information-based activities. There is large scope to overcome the difficulties imposed by the geographical dislocation of teams through the use of IS/IT, and more importantly, to provide direct support to their information management activities, by means of packaging sets of relevant software into a unique package for that team to use.

Clearly, when a geographical spread is in evidence, coupled with the need to work in synchronisation, then the key players have to have knowledge in common of what is planned, what is being done, and at what stage things are. This has resulted in the application of information to the two classes of systems development: the first addresses the structured handling of scientific data that may have been collected on a world-wide basis (for example all pharmaceutical companies have, and continue to develop, sophisticated clinical trial data-handling systems that work across sites in many countries); and the second is the planning systems that co-ordinate the range of activities necessary for the process to be carried out in a managed and controlled way.

Recently, with the recognition that much information flows back up the chain of processes, attempts have been made to begin to structure and manage 'reverse' information flow. Such a flow has importance as it facilitates: learning, design improvements, the focus for follow-up drugs, etc.. Additionally, as it is recognised as being a way of improving the quality of process management, the role of information in facilitating better decisions is receiving closer attention - in all the three key areas: quality, cost and speed.

3 Resource Management

As stated earlier, functional resource managers have a difficult set of contending priorities to resolve. One fairly straightforward support for their activity is the introduction of a common systems platform to cover all the support tasks - thereby removing costly and annoying variety. For example, by addressing cost management, basic communications, personnel systems and similar support activities in a single common way, manager's time can be freed up to handle the peculiarities of individual processes or drugs. Furthermore, as more functionality

and intelligence is introduced into these platforms, so it becomes easier to deploy systems development teams in purely value-adding activities - such as rapidly constructing a system to aid an international launch team.

Conclusion

From the discussion so far, it becomes clear that a functional approach tends to encourage the development of sets of independent IT applications, whose focus is around the processing of transactions within the functional domain. On the other hand, a process approach encourages the creation of information systems that not only span functional boundaries and extract from and link to separate transaction systems, but also supports the production of high level process-planning data and the dissemination of knowledge throughout the process chain. The latter mode of deployment of IT moves the organisation more to a position where it is managing its total information assets in a more synergistic fashion. The information management world that is centred on process, will therefore differ a lot from the IT-functional world.

The description of the case above highlights the fact that the key concern for management has become one of positioning the use of information within the corporate body. Since the notion of information management has often been linked to the business processes that are in place, the central debate has become one of choosing between a functional and a process oriented organisational structure. However, such a perspective results in a narrow view for the improvement of business performance (e.g. see Davenport, 1993). Business processes have to be executed through, and by, functional organisation. Pure process organisations, will never exist, neither will pure functional ones. Where a functional organisation depends on technical excellence, functional structures will predominate. In these conditions, advantages from process orientation will be constrained, where process considerations and functional considerations tend to impact one another in an interfering fashion. This is especially true in the case where functional ownership and process ownership have conflicting priorities.

The findings from the case study show that, in order to gain the distinct business advantages that process orientation offers, the role of information management is an essential element of success. Information management helps bring about these advantages by operating in three key areas: technical, management and support. The mode of action is generally two fold, namely:

1. The Removal of Obstacles

- geographical
- physical
- cross functional boundaries
- streamlining basic support activities

2. The Direct Promotion of Process Flow

- movement of information as a product
- planning systems
- decision support systems aimed at process management
- transmission of knowledge up and down the value chain

This latter set are emerging as essential components of process-oriented operation.

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