

Pharmaceutical Industry Positioning Paper

Introduction

The pharmaceutical industry faces some unique challenges - increasingly stringent safety and quality regulations, combined with the effect of innovations in medical science and healthcare, and a complex and costly design-to-market process (from product concept and development to market delivery). The industry is also going through turbulent times as it has to cope with the challenges common to many other industries – how to deal with increasing competition, hold down costs, and expand market opportunities.

Regulatory compliance is one of the significant industry drivers for pharmaceutical companies. Regulations are enacted by government authorities to ensure public health and safety. The focus of regulation is on quality assurance and control in all areas – receiving, manufacturing, storing, packaging, despatching and delivering. Apart from the required quality and safety checks, the regulations also mandate extensive record keeping of procedures, processes and systems.

Because of health and safety regulations, the design-to-market process for pharmaceutical companies is lengthy, bureaucratic and costly, requiring regulatory approval at several stages during product development and testing. In recent years, companies have been exploring various strategies to improve speed-to-market and reduce costs of development, such as outsourcing certain activities.

The drive for product innovation is inherent in all companies, in pharmaceuticals however it is not only an internal objective but also has an external component. The external component comes from scientific advances which can have a break-through impact and create upheavals in established sectors; the second external influence is healthcare changes, which necessitate business changes. Internal innovation is driven in areas like manufacturing and packaging, and comes from demands for greater cost control, new marketing programs and improving safety requirements.

Competition in the pharmaceutical industry is intensifying and changing, but differs by sector. For manufacturers of ethical drugs (i.e. available only on prescription), patents meant there was no competition in the past. In recent years this has changed as generic drug companies and consumer groups challenge patent periods and extensions. In the nutraceutical sector (health supplements) and personal care products, the competition within product categories is increasing, and companies are striving to create new product categories and niches in which they can grow. In all sectors, customer requirements are propelling companies to deliver to an increasing number of smaller, specialised market segments which require specific products.

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The pharmaceutical industry falls under the “process industry” domain. Process industry operations are generally more complex than those in the “discrete industry” domain (the origin of ERP software), and the terminology is different.

Table 1: Terminology differences

Process manufacturing	Discrete manufacturing
Ingredients, materials	Parts, components
Recipe, formula, specification	Bill of material
Specification, batch sheet	Routing
Lot numbers	Serial numbers
Processing	Assembling
Bulk, intermediaries	Semi-finished product, sub-assembly
Yields	Scrap rates

Other differences are:

- Different units of measure in process manufacturing – litres, pounds, packets, boxes – which are all applicable but in different stages of the production and distribution chain. Discrete manufacturing measures single items and does not change the unit of measure.
- Process materials are more difficult to measure accurately, the quality can be inconsistent, and they can change over time.
- Once through production, the finished process goods cannot be broken back down to their basic ingredients, unlike discrete manufacturing.

Transferring terminology, procedures and application knowledge from discrete to process manufacturing is not straightforward, and the differences between the two should not be simplified when dealing with companies in this space.

Critical business issues for the pharmaceutical industry are:

- Compliance
- Quality and safety
- Production and process management
- Sales and distribution channels
- Cost management

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The primary goal of the industry is to get products speedily to market that are manufactured under consistent processes, to the correct formula and specifications, in the correct environment, with the appropriate controls applied, delivered to the correct channel (customers).

Compliance

The pharmaceutical industry is highly regulated. Each country has its own regulatory authority which authorises pharmaceutical manufacture, distribution and marketing. Regulatory compliance is a major management and administrative function that covers most areas of the pharmaceutical business, including:

- Business processes
- Information handling and storage, access and retrieval
- Computer systems
- Manufacturing, inventory and distribution
- Security and access control

All processes and procedures have to be documented and submitted to the regulatory authorities for approval. Change control is required to ensure that modifications to processes and procedures comply with legal and technical requirements. All automated systems, or changes to them, must be validated to show that they meet the necessary regulations and do not impact on quality or safety; this is usually done by the system supplier working to standards like ISO 9001 or the EU's Good Automated Practice.

Compliance legislation has been increasing since the 1990s, and the trend looks likely to continue as governments replace principles-based formalities with rules-based ones. Given that compliance necessitates the keeping of records and covers so many aspects of a pharmaceutical operation, the amount of information that has to be kept is large and heterogeneous. Records management is therefore becoming increasingly important.

Quality

Two factors enforce a high degree of quality control, assurance and monitoring in the pharmaceutical industry – complying with health and safety regulations, and reducing risk of product recall. As a result, monitoring, testing and inspection are carried out on materials and products at numerous stages.

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At every stage – arrival, storage, production, warehousing, delivery – tracking is essential to ensure that product characteristics can be controlled and validated, and that products get to the right destination by the right time. To have the appropriate information at each stage, tracking needs to be done on numerous characteristics and attributes. Some attributes that are tracked are content related (e.g., potency – the percentage of active ingredient) and should be logged automatically. Other attributes related to inspection and testing have to be verified, which requires that identification and authentication are included in tracking information. As multiple units of measure are common – a product can be purchased in one unit, stocked in another and sold in a third – tracking at different levels is also necessary.

At the inventory stage, proper storage of both raw materials and finished goods can be critical. In order to guarantee safety and quality, raw materials and goods may be allocated to a quarantine warehouse where special conditions are maintained, code dates (for re-test and expiration) on products are monitored, and receipt and release can be authorised.

Before goods are shipped, there are further quality assurance processes that cover packaging and labelling to ensure accountability and traceability, and to check that batches are not mixed during packing and delivery.

Pharmaceutical companies are not only obliged to track what happens in their own operations, but must have backward and forward traceability across the extended supply chain as well, to allow them to keep an audit trail of all changes that materials and products go through. As regulatory issues increase the need to track pedigree or facilitate product recalls, companies will be required to track products through the channel and find out at what stage a problem may have occurred.

Production and process management

Pharmaceutical manufacturers are obliged to follow Good Manufacturing Practice (GMP) as part of the regulatory environment. This enforces quality standards in operational and business processes, and requires the manufacturers to have policies and procedures for manufacturing control. One area where formal procedures are required is change management. Whether it is a business process change, an alteration to a label, or a switch of raw material supplier, pharmaceutical companies are obliged to follow a strictly controlled approval process that must include full documentation of all changes as well as version control.

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The production model for pharmaceuticals is complex because many of its constituents can be variable, such as:

- Raw materials which may vary between batches (e.g., quality, potency, purity)
- Formulas and routings that can change as a result of a process schedule
- Yield requirements
- Co-product and by-product production
- Recycle considerations and waste issues

Not only can input elements vary, but so can the end products due issues like packaging variations. As the variations of inputs and outputs increase, so do the number of Bills of Material (BOMs), and managing them becomes complex. In addition, tolerances of certain ingredients require the BOM to handle a high degree of precision (up to 6 decimal places). Because the BOM is dynamic, the actual process of production is dynamic, and consequently planning and scheduling is done with a short-term horizon.

Distribution and sales

The sales and distribution management for pharmaceutical companies have to contend with a multiple channel structure, e.g., doctors, wholesalers, retailers, consumer direct. Customer management is now becoming an important consideration in the pharmaceutical industry. Effective customer management is not only about current customer order information or handling history about it, but also improving customer service, such as an “Available to Promise” capability.

The customer market for pharmaceuticals is changing. Consumers are becoming more well-informed, it is harder for the direct sales force to find time with doctors, and retailers and wholesalers have greater power in negotiating prices. Consequently, some of the practices of consumer products companies are now entering the pharmaceutical industry, such as price and promotion management, and analysis of product and channel activity.

Cost management

Increased costs, due to regulations on development and manufacturing, have forced the pharmaceutical industry to review their existing practices. Where possible, companies are adopting aspects of lean manufacturing and Just-In-Time (JIT) inventory management. In other cases, companies outsource parts of the development or manufacturing process. For these practices to succeed, companies need to have access to information from suppliers and customers which can be linked into their internal systems.

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Improving the cost analysis of products is another avenue that has been explored. This entails defining cost elements at a greater level of precision than has been done previously to understand how items such as direct labour, ingredients, by- and co-products, energy, and maintenance contribute to costs.

One area of cost control which pharmaceutical companies have only started to examine is product life cycle management (PLM), particularly the hand-over from product development to manufacturing. Among the advantage of adopting PLM is that it can speed time-to-market, improve productivity within development, reduce hand-over costs, and increase return on assets by making more efficient use of existing manufacturing capability.

Conclusion

Pharmaceutical companies already know about the complexities and challenges of compliance that non-pharmaceutical companies are beginning to discover as they implement governance and corporate compliance regulations. Documenting procedures, monitoring processes and authorisations, and managing heterogeneous tracking records are not trivial exercises. The pharmaceutical industry has to deal with this in all aspects of the business. In addition, the industry has to cope with market demands that it be more flexible, cost- and price-conscious, and understand to customer requirements. This means that practices and systems need to be updated to enable the industry to be more agile and responsive, and yet maintain control over a complex and costly development and production process.