



Manufacturing in the Global Pharmaceuticals Industry (3rd edition)

Key drivers, company strategies and regulations

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Published and Distributed by
URCH Publishing Ltd
PO Box 27554
London SE4 2GZ
UK
email: info@urchpublishing.com
web: <http://www.urchpublishing.com>

Executive Summary

There are a variety of views on the most important function within an organisation. In recent years, industries whose organisations have been marketing led or customer driven have been cited as the ideal. Within other industries, including the pharmaceutical industry, there is an alternative view that a company should be research driven. It is probable that the most successful organisations are those that manage to remove functional silos and integrate all activities of the company on an equal footing.

Manufacturing-led companies' days are over

What is clear is that the days of the manufacturing-driven organisation are over. Even in the former socialist economies, where manufacturing quotas were all that was considered, there is a growing recognition that productivity in isolation from sales is meaningless. However, in an industry as highly regulated and quality critical as the pharmaceutical industry, the ability of the manufacturing function to deliver consistent quality is a prerequisite for remaining in business.

Pharmaceutical manufacturing is in a state of flux. From a global perspective, there is excess capacity in manufacturing facilities for finished dosage forms. The situation is not so clear-cut for active pharmaceutical ingredients and is certainly not true for biotechnology manufacturing, where there is currently a shortfall. For the past two decades, multinational companies have been undergoing a process of rationalisation. This trend is set to continue as mergers and acquisitions create larger companies with duplicate resources and facilities around the world. Hence there is a part of the industry that is shrinking.

There are local companies, particularly those in the emerging markets, trying to expand into exports and recognising that to do this requires an ability to satisfy the ever-increasing quality standards of both the home and export markets.

Decision-makers' backgrounds are commercial not technical

In all companies, there are major decisions being taken on subjects such as where to manufacture, what to make and how much to invest. In most, if not all, companies, the majority of board members approving these decisions have backgrounds in the commercial or financial rather than technical disciplines. However, it is essential that they all have a broad understanding of the issues, to ensure that decisions are taken on an informed basis.

Pharmaceutical manufacturing is an expensive process. It is important that investment in manufacturing is recognised as just that – an investment – rather than an expense that brings no returns. The question 'Why should we invest this money?' should be balanced by an understanding of the implications of not making that investment.

Not a core competency in many companies

For many companies manufacturing is not seen as a core competency. It is considered merely as one of the activities that must be carried out efficiently and effectively for a company to perform. However, the effect on the stock value and image of the company of

not getting it right has been amply demonstrated in recent years. The level of fines being levied by the Food and Drug Administration in consent decrees makes it financially very painful for companies that fail to comply with standards.

The objective of this report is to provide an overview of pharmaceutical manufacturing for the benefit of non-technical decision makers. Thus their decisions on the future of manufacturing within their organisations can be made from a more fully informed basis. It may also serve as a reference text for companies in the emerging markets that are starting out on the journey towards international standards of quality in manufacturing.

Earlier versions of this report have dealt primarily with manufacturing of finished dosage forms. However, in the past 5 years, the situation has changed considerably for the manufacturing of active pharmaceutical ingredients. Similarly, there has been a significant growth in biotechnology companies. Both these changes are reflected in this report.

The report reviews the situation around the world with regard to pharmaceutical companies and discusses some of the historical developments in reaching that point, including an overview of key issues facing the industry. It examines the relationship between manufacturing and sales and presents an overview of the current manufacturing base from a geographical perspective.

Key issues facing manufacturing facilities are examined and the options available to companies in developing a strategy for manufacturing are discussed.

There is also a discussion on the topic of quality management. This is followed by an overview of the quality requirements with respect to manufacturing, presented geographically and dealing with the major regulatory bodies worldwide.

The report also tackles the more practical aspects of manufacturing. There is a review of the main dosage forms being produced and the related technologies, both current and developing. There is a discussion of the relative merits of greenfield sites versus refurbishment. The topic of validation is dealt with in great detail, as this is an area of significant expenditure that is often misunderstood by senior management. The section concludes with a presentation of both the costs and benefits of validation.

The likely shape of pharmaceutical manufacturing over the next decade

A completely new chapter has been added, dealing with the so-called 'New Paradigm'. This looks at the move by industry regulators to encourage a risk-based and scientific approach to manufacturing. It charts the recent history of this approach, overviews the key guidance documents and considers trends for implementation with industry.

The report closes with a discussion of the likely trends over the next decade and attempts to predict the shape of pharmaceutical manufacturing in 10 years' time.