

# Challenges and opportunities in enterprise-wide optimization in the pharmaceutical industry

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## A B S T R A C T

Enterprise-wide decision support applications have received increased attention in the chemical process industry in the last decade. In this paper applications, which have real or potential relevance to the pharmaceutical industry, are reviewed. Specific attention is given to the three key phases in the life cycle of an innovative drug product, namely, product development pipeline management, capacity planning and supply chain management. The status of published research in these domains is reviewed, some gaps in the literature are identified and opportunities for further research effort by the process systems engineering community suggested.

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## 1. Introduction

The dynamics of an innovative enterprise can best be viewed and understood in terms of the life cycle of its products which are its life blood. As shown in Fig. 1, product life cycle begins with product development and then successful products transition to the activities associated with product launch, a period of growth in sales, achievement of market maturity and then terminates with a decline phase.

The particulars of these phases and the activities associated with them necessarily will be specific to the technology sector in which the enterprise competes. However, common to all sectors, the phases in the product life cycle are executed by a number of functional groups in the enterprise including R&D, manufacturing and supply networks which in turn are supported by financial planning, marketing and sales, facilities management and health, environment and safety organizations. The efforts of these entities are driven by strategic decisions involving capital expenditure allocation, growth and marketing strategies, product and technology portfolio management, supply chain design decisions including manufacturing and distribution network structure and selection of strategic partners. These strategic decisions typically follow some sort of stage gate process which defines the given tactical decisions needed at a certain point in development such as production planning and ultimately to the operational level in terms of short

time horizon decisions such as manufacturing schedules for specific plants. The complexity of enterprise level decisions derives from the fact that strategic decisions made at any given phase of the life cycle of one product must engage multiple functional units and require integrated implementation at tactical and operational levels across the full portfolio of products. These decisions are further complicated by external and internal uncertainties. As shown in Fig. 2, external pressures and sources of uncertainty range from those in product demand, input pricing, actions of competitors, actions of governmental bodies, bargaining power of suppliers and buyers, threat of new entrants in the field and global economic dynamics (Porter, 1980). The pharmaceutical industry is an excellent example of the competitive forces that Porter laid out and its unique characteristics will be described in the next section. Internal uncertainties can include the risk of failure of R&D activities, among them unforeseen technical challenges, and manufacturing deviations resulting from variations in raw materials, process control failures or human errors in execution.

The increased availability of enterprise information and rapid escalation in computing power have made it possible to deploy decision support tools, including models, simulations and optimization frameworks which can facilitate informed decisions that take into account the interdependencies among the functional units and the necessary integration of decision levels. (Grossmann, 2005; Varma, Reklaitis, Blau, & Pekny, 2007). However, in spite of the concerted efforts of the information technology, operations research, and process systems engineering (PSE) communities it is still not possible to address decisions spanning the entire enterprise and its product life cycle. Rather, a series of enterprise modeling,

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