SINCHRONIZING NEW PRODUCT DEVELOPMENT PROJECTS AND SUPPLY CHAIN RETROFITTING FOR FINANCIAL SUSTAINABILITY IN THE PHARMACEUTICAL INDUSTRY

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Abstract: In today's highly competitive marketplace, supply chain and product development activities should be coordinated and synchronized so that market demand, product release and capacity requirements are matched in a financially sustainable fashion. In this work an integrated model is developed which incorporates simultaneous treatment of supply chain design-planning and R&D decisions in the pharmaceutical industry. Moreover, the aforementioned cross-functional model embeds a capital budgeting formulation enabling the quantitative assessment of the firms’ value. The model also considers the endogenous uncertainty associated with product test outcomes during the development process. To tackle this problem, a scenario based multi-stage stochastic mixed integer linear programming formulation is proposed. This model includes risk constraints which allow finding optimal solutions within accepted risk levels. A decomposition technique is applied in order to reduce the computational effort required for the solution of the monolithic model, thus facilitating the solution of realistic industrial problems of moderate scale.

Keywords: R&D pipeline management, supply chain management, enterprise wide optimization, financial modeling

1. INTRODUCTION

Many proposals have emerged from the chemical industry for Supply Chain (SC) improvement. One of the themes is the need for increasing the degree of functional coordination. It has been noticed that closer coordination between logistics and other functional units can improve overall business performance. From another stand point, the Process System Engineering (PSE) community is increasingly expanding its research scope to issues spanning the product and processes life cycles (see Fig. 1) which has led to recognize that the optimum management of the whole chemical SC and R&D activities offer key opportunities for preserving and improving the firm’s value (Grossmann, 2004). Moreover, Enterprise-Wide Modeling and Optimization (EWMO) has emerged recently as a new promising research challenge. One of the key features in EWMO is the integration of the information and decision making among the various functions that comprise the SC of a company. The research goal posed in the PSE community is to integrate these decisions into one monolithic algorithm architecture.

As indicated by Varma et al. (2007) there is a need to model financial planning decisions, R&D resource allocation as well as capacity expansion decisions within an integrated model, so that capital and capacity allocation can be performed simultaneously with R&D projects selection and prioritization in order to enhance value generation. Certainly, R&D decisions impact the normal activities of production echelons. Thus, such operational impact should be considered and assessed when making R&D decisions.
Planning of new product development activities has been an active research topic in last decades. Schmidt and Grossmann (1996) address the optimal scheduling of testing tasks in the new product development process. They do not take into account the interaction with production capacity in their model. Maravelias and Grossmann (2001) consider the simultaneous optimization of resource-constrained scheduling of testing tasks in new product development and design/planning of batch manufacturing facilities. The authors adopt a two-stage stochastic optimization approach to account for the uncertainty in the outcome of the tests. Levis and Papageorgiou (2004) determine the product portfolio and the multi-site capacity planning in the face of uncertain clinical trials outcomes while taking into account the trading structure of the company. Recently, Colvin and Maravelias (2008) use a multistage stochastic approach to deal with the pharmaceutical R&D pipeline, accounting for the endogenous uncertainty of clinical trial outcomes. The above described approaches incorporate as objective function NPV and they do not account for financial issues nor do they incorporate capacity expansion decisions.

In this work an integrated model is developed which incorporates simultaneous treatment of the SC design-planning and R&D issues in pharmaceutical industries. Moreover, the aforementioned cross-functional model embeds a risk management and capital budgeting formulation enabling the quantitative assessment of the firm’s value.

### 2. PROBLEM STATEMENT

One of the industries for which R&D pipeline management is particularly significant is pharmaceuticals. No pharmaceutical product can be placed on the market without receiving prior authorization from the relevant public health agencies. For this type of businesses in which 50% of new product development resources are spent on failed or cancelled products, solutions from holistic approaches are a necessity in order to support strategic decision allowing financial sustainability to be achieved.

New products in the development phase are required to go through strict tests. Generally, tests can be classified into pre-clinical tests; clinical trials (this stage is comprised of three phases); and regulatory approval. This study is focused on the clinical trials stage. Failure to pass any clinical trial implies termination of the R&D project. Each new product trial has a probability of success, an associated duration and cost. Once new products are approved, they compete for SC capacity which may be shared with ongoing products as well. Therefore, SC decisions on capacity expansion and planning must be made in tandem with new product projects so that target market demand is adequately fulfilled. In our model, it is assumed that various items of technological equipment are available to be installed in existing and potential facility sites.

Regarding the financial area, the formulation endeavors to model cash management and value creation. The model presented in Laínez et al. (2007) is followed and extended to a stochastic formulation. This model takes into account the assets associated to the net working capital (NWC). The NWC dependence on inventories, accounts receivable
and accounts payable is modeled for each planning period throughout the planning horizon. A risk management formulation is also included to constraint the risk of obtaining Corporate Value (CV) less than a minimum desired level.

Finally, the Optimal Condition Decomposition (OCD), which is a particular case of the langrangean relaxation procedure, is applied to overcome the computational cost of solving the monolithic problem. One of its advantages is that it provides information to update multiplier estimates in each subproblem iteration (Conejo et al., 2002). As it is shown, significant CPU time reductions may be achieved by using the OCD.

To sum up, the proposed holistic model offers robust decision support to business managers; it determines the most appropriate subset of potential products to be launched, capacity expansion of production processes, and production profiles for each possible scenario so as to optimize the expected CV. Performance comparison with the traditional sequential decision approach is made in order to demonstrate the significant economic benefits of using holistic approaches.

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