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Bridging
Creative Science
with
Business Strategies

Challenges and Opportunities in the Pharmaceutical Pipeline

By

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Forward

As medicine moves into the 21st Century, life saving therapies will move from inception into medical products faster if there is a better synergy between science and business. Medicine appears to have 50-year innovative cycles of education and scientific discoveries. In the 1880's, the chemical industry in Germany was faced with the dilemma of modernization to exploit the new scientific discoveries. The solution was the spawning of novel technical colleges for training in these new chemical industries. The impact of those new employees and their groundbreaking compounds had a profound influence on medicine and medical education in Germany between 1880-1930. Germany dominated international science during this period and was a training center for scientists worldwide. This model of synergy between education and business was envied and admired in Europe, Asia and America. British science soon after evolved to dominate the field of science during the prewar and post World War (1930's-1970's) because the German scientists fled Hitler's government. These expatriated scientists had a profound influence on the teaching and training of British scientists, which lead to advances in medicine such as antibiotics (see Chapter 1). After the Second World War, the US government wisely funded the development of the medical infrastructure that we see today. British and German scientists in medicine moved to America because of this bountiful funding for their research. These expatriated scientists helped drive these medical advances into commercialized products by the 1980's. America has been the center of medical education and advances of biotechnology but will it continue? International scientists trained in America have returned to Europe and Asia for the past 30 years. These American-trained scientists and their governments are very aware of the commercial potential of biotechnology. Those governments are now more prepared to play an active role this new science. Germany, Ireland, Britain, Singapore, Taiwan and Israel are such examples of this government support for biotechnology in the 21st century. Will the US continue to maintain its domination of biotechnology in this century? Will the US continue to be the first destination for young international scientists? Will the US education system adjust to the new dynamic of synergistic relationships between the education system, industry and government? Or will the US scientists leave their laboratories for Europe and Asia to have more opportunities to do their medical research? This book will try to address these questions but also will help the reader understand who will emerge by 2030(?) as the leader in science and education.

The goal of this book is facilitate an understanding of the pharmaceutical industry by learning the process of developing a medical product. The strategy is to define the vocabulary and organizational structure of each segment of the pharmaceutical pipeline: the science, the clinical development and the management. The evolution of a medical concept into a product requires an appreciation of challenges at each step in the pipeline. Medical products are defined as any new molecular (biological or chemical) entities, diagnostic for *in vivo* or *in vitro* use and any medical device that fulfills an unmet medical need. Each type of medical product has a different process through the pipeline requiring an understanding of the managers needs of each

segment and the company's culture. The drug development process will be compared to Odysseus and his ten-year quest to reach his home in Ithaca.

This endeavor should help the reader integrate a myriad of components into a manageable and coherent framework from which they can understand how successful products can be made faster, cheaper and better for their company. We will start with a survey the Health Care System in the United States, and then focus on how this industry transforms innovative concepts to a medical products. The stages of the product's development will be from preclinical validation, clinical development/FDA to management issues. The challenges and the opportunities for successfully bring a product to market are constantly evolving in this industry with many sectors of the health care industry impacting the success or failure these medical products. Case studies of specific medical products will be evaluated and the company strategy for bringing the product into the market will be discussed. This project will attempt to address several important questions: What are the critical stages of developing a new medical product? What is the organizational structure of the pharmaceutical industry: globally, nationally and locally? What is the industry's relationship between the biotechnology sector, the government and academics? What are the goals of each segment of the pharmaceutical pipeline? How to defining what an unmet medical need is scientifically, clinically and ethically. What are the emerging markets for new medical products? Where will the industry be in the next five years (~2010)? What role will Biotechnology Centers play in facilitating the collaboration between academics, entrepreneurs, venture capitalists, the pharmaceutical industry and the government?

Historically, the pharmaceutical industry had its origins in the mid-19th century in Europe. This was due to two events: the development of the medical products from the petroleum-chemical industry and the rise of the science and technical colleges. Concurrently, there was a revival of classical education at the universities due to the discovery of the historical site of Homer's Troy. It is my opinion; these two events lead to the business culture of the pharmaceutical industry leaders today. Thus by understanding the culture of the Greek warriors on the Scamandian plain, we may understand these players and facilitate medical products through the pipeline today. After reading this book, the reader should be able to enter the industry with a sensitivity and awareness of how to be successful. The reader will have a better understanding of how to work within the organizational structure: the scientific principles, the clinical realities and management issues. The outcome of this book will be to facilitate the unmet medical needs of society with novel medical products in the 21st century.

A. Introduction

Chapter 1. The Development of Medical Products

B. Science/Technology:

Chapter 2. The Chief Scientific Officer (CSO);
Drug Discovery and Preclinical Development of Medical Products

C. Clinical Development:

Chapter 3. The Chief Medical Officer (CMO);
Clinical Development of Therapeutic Agents

Chapter 4. The FDA; Clinical and Regulatory Affairs

D. Management:

Chapter 5. The Chief Executive Officer (CEO);
The Management of Business.

Chapter 6. The Drug Companies;
From a concept to a multi-national pharmaceutical company.

Chapter 7. How to analyze a Biotechnology Company and its Medical Product.

Chapter 8. The role of Biotechnology Centers in medicine for the 21st century.

E. Biotechnology Company's Case Studies

Chapter 9. Onyx: A Gene Therapy Company or a NCE company?

Chapter 10. A merger of equals: IDEC and Biogen?

Chapter 11. Bristol Meyers Squibb and ImClone: meeting expectations?

F. Summary and Conclusions