

INDUSTRY OVERVIEW REPORT

Pharmaceutical Drug Discovery & Development

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Executive Summary

Drug discovery and development involves a complex series of processes occurring in a highly regulated environment. The process begins with the drug discovery phase, where pharmaceutical companies use drug identification processes to narrow an average of one million potential drug targets down to a handful of lead targets. Thereafter, the pre-clinical processes narrow the lead targets down to one or two drug candidates, which are moved into the drug development phase. During drug development, the drug candidate(s) pass through the clinical trials phases, which can ultimately result in the drug being approved for sale and use in the United States. On average, it takes nearly 10 years to bring a new drug to the U.S. pharmaceutical market, at a cost of around \$1 billion.

Introduction

The overall pharmaceutical drug value chain consists of three major components: Generation, Manufacturing and Conveyance (Figure 1.). The Generation component consists of two phases: discovery and development. Phases for the Conveyance component consist of marketing, distribution and delivery to the consumer. Manufacturing links the Generation and Conveyance components.

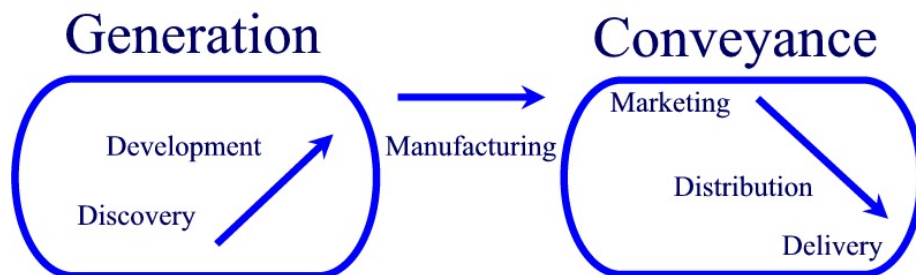


Figure 1 – Major components of the pharmaceutical value chain.

This paper focuses on the Generation component of the pharmaceutical drug value chain, evaluating the processes involved in bringing a drug target through discovery and development, to FDA approval.

Discovery Phase

The discovery phase consists of two major processes, target identification and pre-clinical testing (Figure 2). In the target identification process, new targets are identified, validated and optimized. Thereafter, targets pass into the pre-clinical processes where their chemical and physical properties are tested and developed.

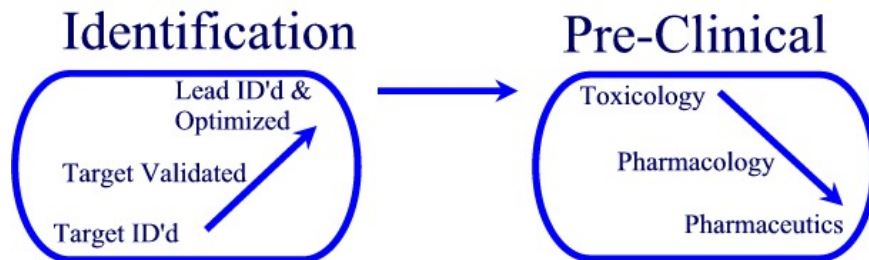


Figure 2 – Major processes in the discovery phase of drug generation.

Identification Processes

Target Identification

The drug discovery process begins when researchers attempt to identify compounds that have therapeutic value, a process called target identification. Traditionally, the process of target identification consists of research chemists manually mixing biochemical compounds and testing the result for a reaction. To identify the batch of targets, an average of one million separate reaction mixtures are conducted, generating a significant paper trail that must be tracked and shared along the value chain.

Although the researchers work from a library of known compounds, the traditional discovery process is essentially random; a fact demonstrated by the attrition statistics. An article on drug attrition reported that between 1991 and 2000, target attrition rates approached 90%:

- 38% of drug targets failed in phase I testing
- 60% of the remaining drug targets failed in phase II testing
- 40% of the remaining drug targets failed in phase III testing
- 23% of those that passed phase III, were not approved by the FDA

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