Product Development

What is Product Development?

Product Development (PD) encompasses the second component of ‘research & development’, namely development. PD is a main factor that differentiates the pharmaceutical and biopharmaceuticals industry from all other industries. Drugs, because of their direct influence on human health, are heavily regulated so as to ensure safety for consumption. For every 10,000 compounds screened in the laboratory, approximately 250 make it to pre-clinical stage. Of those, perhaps 5 reach Phase I clinical studies and advance into Phase III clinical studies. The pre-clinical stage involves extensive toxicology tests on the promising compounds. These experiments are performed in vitro and in animal models. The usual time span is 1-1.5 years, and the estimated cost US$70-90 million, or 10% of the development cost. Clinical testing involves 3 phases. The total time span is 4-7 years and the estimated cost US$100-150 million, or 16% of the development cost. It involves testing for human subjects, in increasing larger sample sizes. After the clinical trials are completed, the firm submits a New Drug Application (NDA) request to the FDA for approval to market the drug. Further studies may be performed in Phase IV to further explore the drug’s capabilities. PD straddles both the pharmaceutical and biopharmaceutical sectors, as both types of drugs are subject to the same regulatory scrutiny and requirements.

Trends in PD

Although seeking the NDA approval by the FDA in the United States is the key objective in the PD stage, firms have been increasingly opting to conduct longer and more extensive clinical trials in order to differentiate their drug in their respective markets. This is in part a result of past legislation that legalized the production of generic drugs after patent rights expire. PD is important to prove the efficacy of a slightly differentiated drug over its competitors. Such a drug could reap large profit margins for its developer, as studies have shown that first-mover advantage is not a key factor to success in drug markets. Whereas the bottleneck in the idea-to-drug process used to lie in the identification of targets, it has shifted to the PD stage, as trial candidates are increasingly difficult to source for. This has led to the development of overseas markets for such trials, where candidates are willing to accept lower payment and are more plentiful in supply.

PD and North Carolina

The PD presence is large in North Carolina. Contract Research Organizations (CROs) are the most common for of firms that perform this function; few firms conduct the process in-house due to the cost and effort. The 74 odd CROs in North Carolina employ 16,000 people. This list includes big global players such as Cato and Quintiles.