Introduction

1

Pharmaceutical development

Pharmaceutical development departments are often labeled as "Formulation," and while this is certainly an important part of creating a pharmaceutical, in reality it is only part of the whole process where the active pharmaceutical ingredient often referred to as the "API" is made into a pharmaceutical. Creation of a robust formulation is critical for the ultimate success of the product. This generally means that the API is formulated in the presence of buffers, excipients, and stabilizers to ensure its physical, chemical, and biological stability over its entire shelf life. However, if the formulation process is done just to achieve the greatest stability possible that may not lead to a successful development of the API into a pharmaceutical. Essentially the formulation, in addition to being stable and maintaining product quality, must be safe, easy to administer, easy and economical to manufacture, convenient for the end users, and ultimately marketable. Development to attain all these qualities requires an interface of many disciplines as well as focus areas. Thus, pharmaceutical development can be envisioned as a Venn diagram (Figure 1.1) where within each focus area there are many possibilities that can lead to a successful outcome for that particular attribute. The challenge is to interface all of these attributes to lead to a pharmaceutical target whereby the key elements from all of the areas meet the needs for the pharmaceutical. In order to successfully "hit" such a target requires a clear understanding of the needs for the pharmaceutical for the chosen indication by all the relevant functional areas in development. Such a document or agreement is often referred to as the target product profile (TPP).

The role of the TPP is to create a clear set of target goals that require input from all functional groups that contribute to the development of an API into the final drug product. Often the TPP is considered a document that meets directly the clinical and marketing needs, but it is important to also include manufacturing requirements. Development of a laboratory-derived successful formulation that is stable, safe, and easy to deliver can become very problematic if an efficient, easy, and economical manufacturing scale-up is not possible. Some of the key challenges in each of the development areas highlighted in Figure 1.1 will be discussed in the following subsections. Although the TPP applies to goals in general for pharmaceutics, much of the discussion will concentrate on the development of biotherapeutics manufactured by recombinant DNA technology, and in particular monoclonal antibodies.

Monoclonal Antibodies. http://dx.doi.org/10.1016/B978-0-08-100296-4.00001-4