

being rapidly advanced. In fact, after collaboration with experienced foreign biopharma companies, several Chinese biopharma companies have gained techniques and skills in development and commercial scale manufacturing of a number of therapeutic MABs and successfully launched several MAB drugs in the Chinese market.

In this Chapter, we are going to analyze and discuss both in detail and in depth the current state and capability of Chinese biopharma companies in developing and manufacturing novel biologic drugs.

2.2 R&D capability of Chinese biopharma companies

2.2.1 Barriers retarding Chinese biopharma companies to gain R&D capability in development of biologic drugs

In the past, although many Chinese biopharma companies claimed that they had R&D programs in house, majority of their programs was actually copying the manufacturing process of off-patented drugs developed by biopharma companies in other countries. To them, discovery and development of innovative biologic products used to be a brand new concept. However, in recent three to five years, a growing number of Chinese biopharma companies have attempted to enter the field. For example, as discussed earlier, the R&D capability of Chinese biopharma companies in developing new recombinant protein drugs has reached quite sophisticated level and almost close to their Western counterparts.

However, the R&D capability of Chinese companies in developing novel MAB-based drugs still falls far behind their Western counterparts. Currently, only a small number of them have R&D programs focusing on MABs for therapeutic use. But almost all their programs are in very early stages. Although several MAB drugs have been developed and marketed in China by Chinese companies, all of them are either off-patented or developed by biopharma companies in other countries and licensed in to China by Chinese companies (such as Nimotuzumab discussed earlier).

There are numerous factors that have retarded the Chinese biopharma companies to gain capability in developing therapeutic MABs. Figure 20 summarized those key barriers.

Figure 20.

Key barriers retarding Chinese biopharma companies to gain capability in developing therapeutic MABs

Key barriers retarding Chinese biopharma companies to gain capability in developing therapeutic MABs

- ◆ Lack of experience:

At present, although a number of Chinese research institutions possess the capability in MABs and other types of research such as genomics and proteomics, they have been focused on basic research with less capability and financial strength to develop them into drugs. On the other hand, the entire Chinese biopharma industry has been lacking of the knowledge, skills and experience to design new MABs, even in those relatively large and financially capable Chinese biopharma companies.

◆ Requirements of high techniques:

Even though some Chinese companies are interested in developing novel MAB drugs, their current technical capability are not ready yet. For example, developing a manufacturing process for a MAB drug involves the techniques and skills in both biology and molecular biology in addition to those in bioengineering. In the upstream process, such knowledge and skills are required as gene transfection, cell line development, optimization, detection (with high-throughput assay) and selection. In the downstream process, parameter optimization of a bio-production process and complete characterization of the final product are also critical as they affect the final yield and quality of a MAB product. All these are currently still new concepts to many Chinese biopharma companies.

◆ High cost of the whole development process:

It is reported that, in general, it takes 2 – 3 years to develop a feasible process for manufacturing of a MAB drug on large scale; whereas it could take almost the same time to scale up the process to commercial scale (so, in total, it could take 4 – 5 years to develop and commercialize a production process for a MAB drug). The financial cost to conduct such a type of research is a significant barrier to many Chinese biopharma companies both in the past and at present, not to mention that most of them do not possess the required skills.

◆ High price of MAB drugs:

As the entire development process takes enormous time and manpower, the final drug products could become expensive to most Chinese patients even though they are developed and manufactured in China with low cost Chinese labor and materials. Although the population of the middle class Chinese that could afford high-end biologic drugs is growing rapidly, still very few of them are able to afford brand new MAB drugs at a price close to that in the West. There have thus not been compelling motivations in the past for Chinese biopharma companies to be embarked on the development of innovative MAB drugs.