



CDMOs Play a Critical Role in the Biopharmaceutical Ecosystem

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Biopharmaceutical industries have advanced significantly after the millennium. Novel biopharmaceuticals have been developed one after another, and blockbuster drugs have been produced. Accompanying the increase in the demand for biopharmaceuticals, a business model called “contract development manufacturing organization (CDMO)” has emerged. A CDMO is entrusted with the development and manufacturing of production processes from pharmaceutical companies. In this review, we identify the success factors of the biopharmaceutical CDMO by analyzing the foundry business for the semiconductor industry. Furthermore, we also review monoclonal antibody production platforms and new technologies that are critical aspects of differentiation strategies in the biopharmaceutical CDMO.

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INTRODUCTION

Biopharmaceutical drugs or biologics is a general term for drugs manufactured using biotechnology. Unlike small-molecule drugs that are chemically manufactured, biologics are complex molecules, such as proteins, or cells that are used as medicinal ingredients. Protein therapeutics was a niche market in the 20th century, but it has dramatically changed with the advent of antibody drugs in the 21st century. Eventually, protein therapeutics dominated the sales of new drugs in the pharmaceutical industry, resulting in paradigm shift (Ecker et al., 2015). The share of biologics in the total sales of the top 100 drugs was more than 16% in 2012 and expected to reach 55% by 2026. Global sales of biologics in prescription medicines continue to grow rapidly with an annual average growth rate of 9.6% from 2019 to 2026 (Evaluate Pharma World Preview 2020, 2021). Furthermore, new modalities, such as gene therapy drugs, have been developed to treat unmet medical needs.

While the biopharmaceutical industry has made remarkable progress, the contract manufacturing and development organization (CDMO), which performs the development and manufacturing of drug substances in contract with biopharmaceutical companies, has grown simultaneously (Lakshmikanthan, 2007). **Figure 1** shows an ecosystem of the pharmaceutical industry that is a horizontal division model of drug discovery by biotech and pharmaceutical companies as well as drug manufacture by CDMOs. The market size of the biopharmaceutical CDMO industry exceeded 10 billion US dollars in 2018. In addition to the continuous development of antibody drugs, various new biologics have emerged, expanding the biopharmaceutical CDMO market. The average annual growth rate is expected to be 10.2% from 2020 to 2025, which is higher than the small molecule drug market (8.0%) (BCC Research, 2020).

Prior to the biopharmaceutical industry, the semiconductor industry established a horizontal division model in the 1980s. There are three divisions in the semiconductor ecosystem as follows: fabless, foundries that manufacture microchips for other companies, and integrated device manufacturers (IDMs) (Anzenbacher and Wagner, 2020). **Figure 2** shows a comparison of the