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COMMUNITY BLOG

## THE EVOLUTION OF BIOPHARMA INNOVATION IN CHINA

The drug development and manufacturing industry in China has historically focused on generic drugs and Chinese CROs have heavily depended on drug development business from Western countries. However, these trends have changed significantly in the past several years, and it is becoming clear that the biopharma sector in China is growing rapidly with a focus on technology innovation and first-in-class drugs. This change started in 2015, when China's regulatory agency, the National Medical Products Administration (NMPA), started a series of reforms and changes to accelerate in-country drug development and expand clinical trials[1]. One of the key reforms was the decoupling of drug development and production where the drug developer does not have to be the drug manufacturer[2]. This decoupling allows companies to focus on innovative drug discovery without the need to divert resources to process development, scale up manufacturing, quality control and lot release of the drug product. Secondly, the Center for Drug Evaluation (CDE) issued guidelines for conducting clinical trials across multiple therapeutic areas including oncology and rare diseases[2], thus encouraging more in-country trials of novel therapies. Additionally, the funding environment to support Chinese biopharma companies has grown significantly in the past several years. There has been a rapid increase of available capital through VC firms and more relaxed regulations for companies to go public including the formation of the STAR Board[3] in Shanghai.

Notably, in 2023 there have been several licensing deals where Chinese biotech companies have developed and licensed drug assets to big pharma and conversely, have in-licensed several drug assets[4]. This bidirectional licensing activities suggests that Chinese biopharma companies have gained traction on the world stage as developers of high-quality therapeutic assets. Licensees include top pharma companies such as GSK, Takeda and AstraZeneca and the total value of the top 10 licensing deals range from $2 billion to $700 million[4]. However, the deals where Chinese biotech are the licensees tend to have a lower total value and range across multiple disease areas including oncology, infectious disease and liver disease[4]. Unsurprisingly, as the number of biotechs developing licensable assets increases, China based CROs are also growing likely to accommodate the increased outsourcing needs.

The 2022 top global CROs list includes 3 Chinese companies - Wuxi AppTec, Pharmaron, and AsymChem[5]. The revenue growth projections of China based CROs continues to be strong with an anticipated market growth 13% in 2021 to 19% in 20245. While China based CROs have always been known to have deep expertise in chemistry and small molecule drug development, in the past few years there has been a rapid growth in advanced modalities including monoclonal antibody-based therapies. Importantly, the CROs are no longer dependent on business from North America and Europe since Chinese biopharma companies are outsourcing to in-country CROs. This trend likely started during the COVID-19 pandemic but has continued to hold strong as Chinese CROs have developed impressive end-to-end capabilities across the drug discovery continuum. It is estimated that about 40% of WuXi Biologics, a leading Chinese CRO, client base is in country[6]. Another key development has been that China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use in 2017, allowing the use of data from clinical trials run in China to be used in filings to multiple regulatory agencies[6]. Since this development, the clinical CROs based in China can compete with global clinical CROs as they can generate usable data at a more economical price tag compared to several North American and European CROs[6].

It is clear that China continues to be a competitive player in the preclinical and clinical drug development sector and is expected to grow at a significant pace. This growth is fueled by available capital, supportive government regulations, lucrative licensing deals and an aggressive strategy from Chinese CROs to support domestic biopharma companies while penetrating Western markets.

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