Compounding Outsourcing Facilities Annual Study

Executive Summary

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The U.S. Food and Drug Administration (FDA) established a Compounding Quality Center of Excellence to focus on improving the quality of compounded drugs, primarily those produced in outsourcing facilities. The Center of Excellence intends to build the capacity of the outsourcing facility market to improve the quality of compounded drugs and to meet provider needs for high-quality compounded drugs. An outside consultant, working closely with an FDA working group comprising representatives from across FDA, conducted research to provide insight into the dynamics and behaviors of the outsourcing facility market. The information provided is based both on quantitative data and qualitative conversations with outsourcing facilities and other stakeholders. Industry perspectives described in this report might not always align with FDA's position or understanding. Insights from this report will allow FDA to design targeted initiatives to support the production of high-quality drugs and improve engagement with the outsourcing facility industry. The observations included in this report represent the views and opinions of outsourcing facilities and associated stakeholders, which have not been assessed by FDA. The information in this report may require further investigation and validation. The views and opinions in this report do not necessarily represent those of FDA or the Compounding Quality Center of Excellence.

Data and Methodology

This study included two major components, market research and field research, to collect quantitative and qualitative data on the outsourcing facility market, business models and behaviors, and ecosystem. Market research included an analysis of existing data sources, including publicly available information and FDA data collected from outsourcing facilities. Field research included (1) an analysis of the input received from open-ended, voluntary conversations with outsourcing facilities and other relevant stakeholders and (2) a survey of currently registered outsourcing facilities.

Understanding the Outsourcing Facility Market

A better understanding of outsourcing facilities involves understanding the dynamics of the market, including size, growth potential, challenges, and barriers to entry. The outsourcing facility market has an estimated size of $2.3 to $4.6 billion, compared with the total U.S. pharmaceutical drug market revenue of $507 billion. The market is experiencing modest annual growth estimated at 2 to 5 percent. However, the total number of registered outsourcing facilities has remained stagnant since 2017, hovering at approximately 70–80. Outsourcing facilities continue to adapt their business models to try to balance profitability with the need for quality. They still broadly struggle to comply with regulatory requirements, including Current Good Manufacturing Practice (CGMP) compliance, and experience low profit margins. Market trends indicate high demand and growth potential for the outsourcing facility market, but stakeholders report that certain financial and regulatory challenges may prevent market entrants and growth for existing facilities. This may keep the outsourcing facility market from fully satisfying demand for compounded drugs.

Understanding Outsourcing Facilities

To support the outsourcing facility market in providing quality compounded drugs and meeting provider needs, FDA needs more insight into the production and compliance behaviors of these facilities. For example, production volume is highly concentrated in certain high-volume products made by larger outsourcing facilities. Smaller outsourcing facilities with pharmacy backgrounds tend to have more overall challenges complying with regulations and implementing recommendations in FDA guidance. However, most outsourcing facilities tend to struggle consistently with CGMP compliance in two categories: (1) production and process controls and (2)

control systems and procedures for maintaining suitable facilities. The primary factors that play a role in noncompliance are related to understanding quality issues and the knowledge and financial requirements of CGMP compliance, as well as engagement with FDA.

Understanding the Larger Outsourcing Facility Network

Outsourcing facilities interact with various partners, including buyers and suppliers, that affect their behaviors. Buyers of products want on-demand ordering for compounded drugs tailored to their specific needs, which can create differing expectations between outsourcing facilities and buyers and cause challenges in meeting demand. Outsourcing facilities also report that challenges with suppliers (e.g. active pharmaceutical ingredients [APIs], vials, components), including inconsistent supply and high input costs. Most outsourcing facilities report that they must rely on expensive consultants and outside testing facilities because they are unable to implement portions of CGMP regulations on their own. The breadth and variance of state regulations is another reported challenge for outsourcing facilities. Several struggle to register across states and have difficulty managing differing oversight and regulation requirements. Finally, given the struggles that some outsourcing facilities report with interpreting FDA guidance and regulation, improving communication between outsourcing facilities and FDA could help improve operations and quality in the market.

Key Challenges

Compliance issues are broad and persistent. Compliance data are one indicator of the level of quality drug production for the outsourcing facility market. Challenges with compliance are indicative of potential quality issues. The compounding outsourcing facility market is still working toward achieving an overall culture of quality that ensures compliance with CGMP requirements and production of high-quality compounded drugs that keep patients safe.

Despite high demand for products from outsourcing facilities, the market is showing limited growth. Outsourcing facilities need help navigating the realities of scaling production within CGMP and other industry requirements (both state and federal). Both are reported challenges for outsourcing facility production and might affect production decisions. The inability of facilities to satisfy demand can create difficulties in access to compounded drugs when they are needed for patient care.

Considerations for FDA

Outsourcing facilities are still making adjustments as they try to understand how to balance regulations with profitable and sustainable business models. They need consistent and constructive communication with FDA that is sensitive to the challenges and opportunities of the outsourcing facility market.

Integration into the Compounding Quality Center of Excellence

The data and findings from this report were directly used to guide the goals of the Center of Excellence: (1) to build the capacity of the outsourcing facility market to improve the quality of compounded drugs and (2) to build the capacity of the outsourcing facility market to meet provider needs for quality compounded drugs. A better understanding of the outsourcing facilities market and their challenges and opportunities will continue to guide the capabilities and initiatives of the Compounding Quality Center of Excellence.