Compounding Outsourcing Facilities Annual Study

Executive Summary

September 21, 2021

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The U.S. Food and Drug Administration (FDA) established the Compounding Quality Center of Excellence in 2019 to improve the quality of compounded drugs, primarily those produced in compounding outsourcing facilities (also referred to as 503B facilities). With support from members of the Center of Excellence, which includes representatives from across FDA, Deloitte Consulting conducted the 2020–2021 Compounding Outsourcing Facilities Annual Study to strengthen understanding of industry dynamics, challenges, and opportunities related to the outsourcing facility market. The information is based on analyses using quantitative and qualitative data methodologies, including conversations with outsourcing facilities and other relevant stakeholders, as well as an analysis of existing data sources. This report describes the opinions and experiences of various stakeholders in the outsourcing facility ecosystem. The 2020–2021 study is a snapshot in time created to support FDA's continued development of the Center of Excellence and strengthen the working relationship between FDA and outsourcing facilities. 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 might 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

The 2020–2021 annual study included both market research and field research. Market research included analyzing existing data sources, as well as nonpublicly available data collected from outsourcing facilities, such as product reporting and inspection data. To maintain confidentiality of respondents, nonpublicly available data are presented in an aggregated form. Field research included gathering information from two sources: (1) open-ended, anonymous, voluntary conversations with outsourcing facilities and other related stakeholders and (2) responses from a survey distributed to currently registered outsourcing facilities. Market research and field research included both quantitative and qualitative data on the dynamics and behaviors of the outsourcing facility market to build on the findings of the initial 2019–2020 report.

State of the 503B Market During 2020 to 2021

Relative Market Stability

During 2020 to 2021, the market has remained stable in value and size, including during disruptions related to the COVID-19 pandemic in 2020. The current outsourcing facility market value is estimated to be $2.3 to $4.6 billion, reflecting the same value reported in the 2019–2020 report. Despite rapid growth in the early stages of development, the number of outsourcing facilities in the market has stabilized in recent years, with 72 currently registered outsourcing facilities as of June 7, 2021, although some fluctuation in exits and entrants is still occurring.

Industry Shifts

Relative stability in the number of outsourcing facilities and value of the market might also be evidence that the market incentivizes certain types of behavior, including the production of large-batch standardized products, and creates perceived business risk among stakeholders that might deter certain types of production. Moving forward, the role that outsourcing facilities can, and should, play remains a question. For example, outsourcing facilities are perceived to play a role in responding to drug shortages even though few are reportedly equipped to respond because of costs and regulatory safeguards. Thus, the expectation for outsourcing facilities to serve this purpose might be at odds with the market realities that drive most outsourcing facility business decisions.

Analyses suggest that outsourcing facilities continue to enter and exit the market. Smaller outsourcing facilities, outsourcing facilities that have other business operations (e.g., 503A facilities, testing laboratories, contract manufacturing) and outsourcing facilities that face challenges navigating state regulations represent the most common exits. Financial and regulatory realities, as well as inconsistent demand, may have contributed to these

market exits because they may present barriers to growth for currently registered outsourcing facilities. In addition, field research conversations with outsourcing facilities that recently left the market highlighted the challenges of working in a dual regulatory reality, adhering both to state and federal laws, as well as a perceived lack of harmonization between FDA and the states. Despite consistent challenges, the outsourcing facility market has exhibited durability, as evidenced by outsourcing facilities that continue to enter the market, particularly those focusing on automation and maintaining state-of-the-art facilities, as well as outsourcing facilities with other business operations, such as those related to research, analytical support, or specialty pharmaceuticals. Product demand also persists, especially for large-batch standardized products that yield more predictable profit.

Production and Compliance Challenges

The outsourcing facility market also continues to face challenges in producing high-quality compounded drugs. Outsourcing facility survey results for 2021 suggest that outsourcing facilities consider stability and expiration dating for compounded drugs, quality assurance activities, and the overall costs of CGMP compliance to be particularly challenging.

During 2020 to 2021, outsourcing facility production has declined. Although 2017 to 2019 production data highlighted a steady increase during 2017 to 2019, outsourcing facility production declined during 2019 to 2020 by 35.9 percent. Analysis suggests that a decrease in production occurred for the majority of products. Some of this loss of production might be due to challenges encountered because of the COVID-19 pandemic.

COVID-19 Disruptions

Disruptions brought on by the COVID-19 pandemic in 2020 highlight a case study for outsourcing facility resilience and production, including producing drugs in shortage. The production decline might also be linked to a reported reduction in elective surgeries during the COVID-19 pandemic, resulting in lower demand for products typically used in operating room procedures. Although outsourcing facilities and other stakeholders continually emphasized the production challenges brought on by COVID-19, some outsourcing facilities were able to adapt during this time—even experiencing growth in some instances—to respond to changing market realities. Overall, the pandemic revealed stratification in the market among facilities that experienced challenges, that demonstrated resiliency, that grew through the acquisition of new clients, or a combination of these.

Identifying Needs of Providers

To better understand the role 503B facilities play for providers (e.g., physicians, hospital systems, ambulatory care centers), the Deloitte team sought to establish a deeper understanding of the demand for 503B products during field research conversations. The researchers spoke with 19 individual providers to understand which factors motivate the use of 503B compounded products and what providers seek from the 503B industry (e.g., product needs, improvements to existing practices). Field research conversations with outsourcing facilities and other stakeholders suggest that outsourcing facilities could support unmet provider needs, particularly regarding drugs in shortage, small-batch products, or niche therapeutic areas, for market or regulatory reasons.

Anticipating New Roles in the 503B Market

Stakeholder expectations of the role of outsourcing facilities in the pharmaceutical supply chain (e.g., agility) can be at odds with the current value they deliver (e.g., large-batch standardized operating room products). In addition, policy changes might further change the system in which 503B facilities operate.

FDA Engagement and Implications for the Compounding Quality Center of Excellence

Market analysis suggests outsourcing facilities welcome FDA engagement and want more interactions in the future. For example, outsourcing facilities appreciate and have benefitted from training. In field research

conversations, outsourcing facilities also suggested new ways to improve or expand training. In addition, many outsourcing facilities desire improved two-way communication and collaboration channels with FDA (e.g., follow-up from listening sessions, Q&A forums directly with FDA directly to promote transparent communication regarding challenges faced by facilities). Many outsourcing facilities also seek additional transparency and guidance around inspections, particularly with Form 483 close-outs, suggesting an area for further FDA consideration and potential intervention.

Conclusion

As the outsourcing facility industry continues to evolve, the Center of Excellence offers FDA an important opportunity to engage with outsourcing facilities to support their efforts to deliver high-quality compounded drug products to consumers. The 2020–2021 study continues to establish an understanding of the market, suggesting that in the roughly 8 years since the industry was formalized, outsourcing facilities are becoming more stable, demand for compounded drugs among customers continues, and understanding of CGMP standards across the industry continues to improve. Existing financial and regulatory realities also continue to shape the industry. The Center of Excellence offers industry stakeholders and FDA a unique opportunity to enhance two-way engagement and enable industry improvements.