



**Compounding Outsourcing Facilities
Annual Study**

Executive Summary

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In 2019, the U.S. Food and Drug Administration (FDA) designed and operationalized the Compounding Quality Center of Excellence to improve the quality of drugs produced in compounding outsourcing facilities. To strengthen understanding of industry dynamics, challenges, and opportunities present within the outsourcing facility ecosystem, FDA engaged an outside consultant to conduct the 2021–2022 Compounding Outsourcing Facilities Annual Study. This document provides an overview of key insights obtained from analyses from both quantitative and qualitative data, including conversations with outsourcing facilities and other relevant stakeholders, analysis of 2022 outsourcing facility survey responses, as well as an analysis of existing data sources. The 2021–2022 annual study final report is a snapshot in time created to support FDA’s continued development of the Center of Excellence and serve as a basis for strengthening the working relationship between FDA and outsourcing facilities. The information described herein represents the opinions and experiences from a variety of stakeholders in the outsourcing facility ecosystem to bring further context and understanding of outsourcing facilities and the market in which they operate, and do not necessarily represent the views of FDA or the Compounding Quality Center of Excellence.

An Evolving, But Durable, Outsourcing Facility Market

Quantitative and qualitative analyses of market data suggest that the outsourcing facility market is durable — and changing. Although providers report that outsourcing facility products account for a small percentage of total drugs purchased, customers also report that outsourcing facility compounded products are indispensable. These providers cite that access to ready-to-use, high-quality products with extended beyond-use dating are necessary for patient care. An analysis of market size (i.e., number of registered outsourcing facilities), value, and historical entry/exit trends suggests that the outsourcing facility market is durable and diverse. While the number of registered outsourcing facilities remains relatively stable since 2019, approximately 75 outsourcing facilities, this year’s market analyses suggest that there is an emerging stratification in the industry.

The industry may be “stratifying” across elements that include current good manufacturing practice (CGMP) expertise, resources (i.e., human capital, financial), and ability to grow customer bases as suggested by qualitative and quantitative analysis. Research suggests that production capacities and compliance with CGMP requirements may vary between outsourcing facilities. Further observations from conversations with outsourcing facilities and other relevant stakeholders suggest that stratification also occurs across a variety of other factors, including outsourcing facility reputation (e.g., ability to gain traction with new customers), stable supply lines, and resources (e.g., finances, funding development costs, funding quality-related activities).

A combination of the aforementioned factors may position some outsourcing facilities to have more market success (e.g., share of market, stability in customer base, anecdotal reports of growth) than others. For example, many facilities that are better resourced can extend focus beyond baseline CGMP compliance to other market attributes, such as dedicating resources into various areas, ranging from new facilities to automation. Many outsourcing facilities made these investments based on the rationale that they would better meet customer demand, improve customer relationships, or differentiate themselves to customers from other outsourcing facilities. Thus, this industry may be showing signs that are typical of a more advancing industry, including differentiation on customer relationships/service and some companies reaching economies of scale.¹

¹ Harvard Business Review’s article: [Exploit the Product Life Cycle](#), outlines characteristics of the maturity stage of an industry. These characteristics include “evidence of market saturation ... competitive attempts to achieve and hold brand preference” which can involve “finer differentiations in the product, in customer services, and in the promotional practices and claims made for the product.”

Emergence of Customers' Roles

Based on observations both from customers and outsourcing facilities, the facilities may be increasingly focused on customer's needs and customer experience. Research suggests that customers fall into four categories: Acute and Ambulatory Care Centers, Therapeutic Specialty Areas, Alternative Areas (i.e., veterinary, wellness), and Insurance/Procurement. There are global drivers, shared across customer profiles, necessitating the need for outsourcing facility products such as offsetting labor needed for in-house compounding and procuring products produced under CGMP requirements (which are perceived to be of higher quality, or held to more rigorous quality standards, than USP 797). Customers report the need for reliable delivery and communication around supply delays, as well as more specific requests such as distinguishable labeling. Customers also report a level of selectivity when choosing to engage with outsourcing facilities, opting for consistent and responsive facilities.

Conversations with outsourcing facilities suggest that customer needs may be influencing outsourcing facility business operations, where they are making investments, changing processes, and focusing on customer demand. Challenges faced by customers and unmet demand may be influencing new actors to step in to address areas of need. Several instances of nontraditional actors entering the stakeholder ecosystem include previously external parties working toward funding development costs in order to access critical products, analyzing hospital data to advance standardization and reduce waste, and streamlining supply chains.

Role of FDA

In the future, various stratifications/factors in the market may necessitate a change in the way the Center of Excellence engages with different stakeholders. Moving forward, outsourcing facilities may benefit from different types of Center of Excellence engagement, such as differing levels of training or engaging in discussion topics (e.g., CGMP basics vs. advanced topics) to ensure engagement is relevant and continues to be valuable for outsourcing facilities. Further, different business models may be faced with different challenges. Outsourcing facilities owned by hospital systems, for example, can be nonprofit and thus may have different incentives or drivers than commercial actors.

Across the industry, outsourcing facilities continue to express a desire for connection, both with industry colleagues and stakeholders in the broader ecosystem. Providing opportunities for outsourcing facilities to build a network may introduce a way that outsourcing facilities can share ideas and solutions to mutual operational challenges. Fostering connection in the broader ecosystem may raise awareness of the outsourcing facility industry for providers, better align outsourcing facilities to their customer's requests, and ultimately position the industry to better fill areas of need. Finally, a universal desire for two-way engagement persists among stakeholders. Without a clear sense of a return on engagement investment, outsourcing facilities may be more reluctant to engage with the Compounding Quality Center of Excellence in the future, as suggested in field research conversations. In conversations, outsourcing facilities provided a few suggestions to improve two-way engagement including organizational charts, brown bag conversations, focus groups, and hotlines. However, outsourcing facilities also requested outputs that may not be under the purview of the Center of Excellence (e.g., changes to guidance documents). In order to set expectations and improve satisfaction with engagement, the Center of Excellence may benefit from clear communication on its role in the industry and its goals for outsourcing facility engagement.