EXECUTIVE INSIGHTS

Aligning Aseptic Fill/Finish Operations With Global Pharmaceutical Demand

Aseptic fill/finish (AF/F), one of the final steps of the pharmaceutical manufacturing process, is a vital step in ensuring consumers have timely access to safe, effective medications. This market is extremely dynamic, leading to challenges with ensuring enough capacity as well as putting existing capacity to optimal use.

There are many factors influencing capacity usage. Fluctuating and dynamic demand can create short-term supply imbalances, while long lead times for new machines often keep supply lagging aggregate demand. Additionally, it can be challenging to precisely and efficiently pair suppliers and customers, which can leave capacity sitting open while creating the perception that none is available.

More AF/F capacity, as well as a different footprint of capacity, is needed as demand continues to grow, making this a highly competitive market with lots of recent investment activity from dozens of key players. In the meantime, precise matchmaking is required to connect customers with suppliers that can accommodate their manufacturing demands. More flexibility is also critical to allow for quicker shifts between different drugs, containers and dosages. This adaptability will be key as demand continues to shift toward biologics and injectables.

Despite its challenges, AF/F represents a robust investment opportunity for several years to come, as customers look for more flexible, moderate-to-high throughput capacity in more ready-to-use formats.

AF/F at a glance

AF/F, one of the final steps of the pharmaceutical manufacturing process, is the transfer of a sterile drug product to a sterile container. Conducted by specialized firms or divisions within firms, AF/F is used for a broad range of pharmaceutical containment formats including basic vials, prefilled syringes, cartridges (such as autoinjectors), ampoules and prefilled bags used for infusions. Once the AF/F process is complete, the product is closed before being prepared for packaging and distribution.

Driving industry dynamics

There are multiple factors specific to the AF/F industry that cause demand churn, often meaning the supply side of the market has a significant lag in responding to increases and/or shifts in demand.

- **Pricey capital expenditures and long build times**
  Due to strict regulatory requirements and the high level of expertise required to bring a new AF/F facility online, significant capital expenditures and long build times come with any new capacity development. Machine manufacturing is often the biggest bottleneck; these intricate pieces of equipment are hand-tooled, making it impossible to scale production.
- **Limited space turnover**
  Pharmaceutical products typically stay on the market for many decades, either in their original branded form or by being transitioned to a generic/biosimilar version. There is a limited cycle of capacity being reallocated after products on the market recede or fail, which means demand must be met by new construction.
- **Increased AF/F demand and demand fragmentation**
  The demand for AF/F has increased, as the market must accommodate oral medications as well as other treatments that rely on AF/F, including many biologics that must be delivered via various injectable methods. This acceleration in demand has further increased the burden on existing supply, putting pressure on the ability of current AF/F players to scale supply quickly. Additionally, as products go off-patent, suppliers may find themselves filling requests for generics from many smaller customers instead of working with one larger client.

- **Regulatory and legislative changes**
  Government regulations and policy is another key dynamic that is impacting AF/F capacity. For example, the Inflation Reduction Act of 2022 incentivizes manufacturers to favor the development of biologics instead of small molecules, shifting the demand placed on AF/F facilities. More regulatory changes are on the horizon with the potential passage of the Biosecure Act, which would limit the ability of certain producers to use China-based contract development and manufacturing organizations (CDMOs) and put further pressure on domestic demand. Annex 1 provisions in the EU could make some older AF/F lines non-compliant with respect to modern isolator requirements.

A persistent lag

Demand continues to build and add stress to an already oversaturated industry, spurred by a variety of exogenous shocks that have accelerated demand far in excess of what supply can respond to in a limited time frame. It seems as though as soon as the industry adjusts to one shock, another is just behind it.

One factor that has driven demand over the past decade is the unexpected success of new blockbuster drugs, which far exceeded original forecasts and created a constant pressure on AF/F facilities to catch up with demand.

Then, as demand started to equilibrate and supply began to catch up to the new level of need, COVID-19 rocked the global pharmaceutical landscape. The quick development of COVID-19 vaccines that immediately needed to be broadly rolled out jolted manufacturing priorities and put acute pressure on supply. AF/F services worldwide pivoted to meet this high-priority need, scrambling to provide the billions of doses that were required.

Once again, as the market adjusted to the manufacturing requirements of the COVID-19 vaccines and supply started to catch up, another shock was right around the corner. The explosion of manufacturing demand associated with glucagon-like peptide-1 agonists, or GLP-1 agonists (known for their efficacy in treating diabetes and now being applied to weight management), delivered with autoinjector technology, again put acute pressure on the system and introduced another steep learning curve. GLP-1s are projected to be a $130+ billion market by 2033, and we can expect this growth to drive continuous pressure on AF/F capacity.

Connecting customers with existing supply

Despite the short-term dislocation in the AF/F industry that impacts capacity, there are AF/F facilities that are either sitting idle or can take on additional work. Often, the challenge boils down to precise matchmaking to pair customers that are currently shopping with available suppliers that can meet their manufacturing needs.

There are many factors that must be considered when vetting suppliers to make sure the company is an appropriate fit.

- **Throughput:** The supplier must be able to meet the output volume that the customer's application requires.
- **Format:** Dosing mechanisms such as prefilled syringes and cartridges require specialized equipment that may not be present in all AF/F manufacturing setups. To meet this shift, more suppliers are investing in flexible lines that can accommodate more needs.
- **Handling:** Pharmaceutical products require precise handling, and the exact requirements often vary by application. For instance, some require a cold chain throughout the manufacturing process while others may require procedures that keep operators from coming in contact with them. To protect the supply chain as well as those involved in it, it's important that products are manufactured at facilities that can accommodate specific handling requirements.

By understanding these customer needs and marketing their services to the right clientele, facilities with available supply can fill a vital hole in the AF/F industry by ensuring that all existing capacity is being utilized.

Responding with investment

Recognizing the urgent need for increased capacity to meet demand, investment is pouring into the AF/F market, with some investments as high as $285 million (see Figure 1). Many expansions are scheduled to come online by the end of 2025, and there is a significant focus on expanding prefilled syringe capacity and flexible fill/finish facilities that can more easily switch between different drug formats and volumes. Additionally, there are a number of CDMOs with AF/F capabilities, representing a large list of credible suppliers.

Figure 1
Companies are investing heavily to meet the expected AF/F demand spike

Company	Investment	Square feet*	Year online	Line speed/ TP^	Vials	PFS	Cart.	Specialty focus	Lyo	Player archetype
Jubilant HollisterStier	~$285M**	~200K**	2024-2025**	High	X			Vaccines	X	DP
Simtra BioPharma Solutions	~$250M	~150K	2025	High	X	X		GLP-1	X	DP
Vetter	~$240M	~300K	2024	High	Specific formats not disclosed					DP
Resilience	~$225M	Undisclosed	2025	High		X	X	GLP-1		DS & DP
Grand River Aseptic Manufacturing	~$160M	~150K	2026	High	X	X	X	Vaccines	X	DP
Kindeva Drug Delivery	~$150M	~150K	2024	High; low	X	X	X			Medical device manufacturing
Selkirk	~$90M	~115K	2026	Moderate	X	X				DP
INCOG BioPharma Services	~$75M	Undisclosed	2025	High	X	X	X			DP
august Biosciences	~$65M	~60K	2024-2025	High	X	X				DP
pci Pharma Services	~$50M	~200K	2024	High	X	X	X	GLP-1	X	DS & DP
Pyramid Labs	Undisclosed	~90K	2024	Undisclosed	X	X		Oligos, proteins, peptides	X	DP
SMC Ltd.	Undisclosed	Undisclosed	2024	High	X	X	X			Medical device manufacturing
Argonaut Manufacturing Services	Undisclosed	Undisclosed	2025	High	X	X	X	Vaccines		DP
Quotient Sciences	Undisclosed	Undisclosed	Undisclosed	High	Specific formats not disclosed			Radiolabeled; cytotoxic		DS & DP
DALTON Pharma Services	Undisclosed	Undisclosed	Undisclosed	Moderate	X	X	X		X	DS & DP
alcami	Undisclosed	Undisclosed	Undisclosed	Undisclosed	X				X	DP

*Area of facility expansion may include additional capacity beyond fill/finish lines (e.g., cold storage capacity)
**Data for Jubilant third and fourth line expansions at Spokane, WA, site — additional 40K square feet Montreal expansion expected to come online in 2027 for vial, PFS and cartridge capacity (~$75M investment supported by Canadian government)
^Speed/throughput listed in press release (high-speed/high-throughput line corresponds to >50K units/batch or large-scale manufacturing)
Note: AF/F=aseptic fill/finish; TP=throughput; PFS=prefilled syringe; GLP-1=glucagon-like peptide-1
Source: Company websites; Contract Pharma; Pharmaceutical Technology; BioSpace; PR Newswire; Fierce Pharma; L.E.K. research and analysis

While current investments aim to tackle capacity constraints and demonstrate tangible progress, they haven't yet alleviated the shortfall, prompting the search for additional solutions. In addition to new construction, players are exploring automation and advanced technologies to shorten the AF/F process time and improve output. Some large pharmaceutical firms are also partnering with CDMOs to handle the overflow of demand for biologic drugs, shifting away from internal manufacturing.

Flexibility is emerging as a key differentiator for companies investing in the AF/F space. As the demand for biologics and injectables grows, so too does the need for multipurpose facilities that can quickly adjust to evolving market needs.

A significant investment opportunity

The AF/F market represents a significant investment opportunity because demand is stable and capacity evolution is likely to persist for the next five to 10 years (see Figure 2).

With GLP-1 drugs alone projected to drive billions of units in demand and an increasing regulatory pressure to produce domestically, investors have an opportunity to capitalize on a sector that shows no signs of slowing. AF/F CDMOs will also benefit from making informed investments in the right segments of the market. Changes in internal capacity or manufacturing partners for large players are also likely to have a cascading impact benefiting small to medium-sized AF/F CDMOs as vendor relationships are redistributed. The future of fill/finish will be shaped by those that can adapt quickly to these evolving market conditions.

Flexible line capacity, automation and technology-driven improvements will continue to play a role in increasing efficiency and scaling production, providing opportunities for both new entrants and established players to expand their operations.

Figure 2
The shape of future customer capacity needs versus past capacity needs in the AF/F industry

	Historic AF/F needs	Current and future AF/F requirements
Throughput	• High throughput	• Moderate-to-high throughput
Packaging	• Heavily multidose vial	• Heavily ready-to-use formats (e.g., prefilled syringe, cartridge)
Flexibility	• More consistent throughput and packaging	• Higher degree of variability (throughput, packaging)

Note: AF/F=aseptic fill/finish
Source: L.E.K. interviews, research and analysis

Conclusion

To be reliable manufacturers and serve clients, it's imperative that AF/F companies strategically plan how they will secure supply. For those that rely on AF/F operations as part of their supply chain, it is a time to plan ahead and secure AF/F capacity early as it's getting harder and harder to guarantee supply in this dynamic market.

The AF/F market is at a pivotal moment as growing demand and a shifting pharmaceutical market create significant demand churn. The upside is that this creates a prime opportunity for investment, particularly as the demand for biologics and injectables rises. Companies that invest in expanding capacity, automation and flexibility will be best positioned to meet the future needs of the pharmaceutical industry. In particular, those with moderate-to-high throughput capacity that is flexible and capable of handling ready-to-use formats (like prefilled syringes and cartridges) are increasing their share of the demand.

If your organization is evaluating its ability to secure AF/F capacity, shore up potential supply chain vulnerabilities or make strategic investments, consider the four questions below. If you have a clear answer to most of these questions, you are probably in a great place to focus on other strategic initiatives. If you find that you are unsure or unable to answer some of them, it would be an excellent idea to conduct a more thorough diagnostic to understand current pain points and potential solutions.

1. How are your AF/F requirements likely to change over the next five to 10 years?
2. What supply chain vulnerabilities are you most concerned about, and what steps can you take to address those vulnerabilities?
3. If you needed to access AF/F capacity quickly, what levers could you pull?
4. Where are you prepared to invest or to outsource to ensure a more predictable AF/F situation?

As you assess your capabilities or weigh different growth strategies, please contact us for an informal discussion about your situation with a holistic, structured approach.

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