STATE OF OUTSOURCING FACILITY SECTOR AND POSSIBILITIES FOR THE FUTURE

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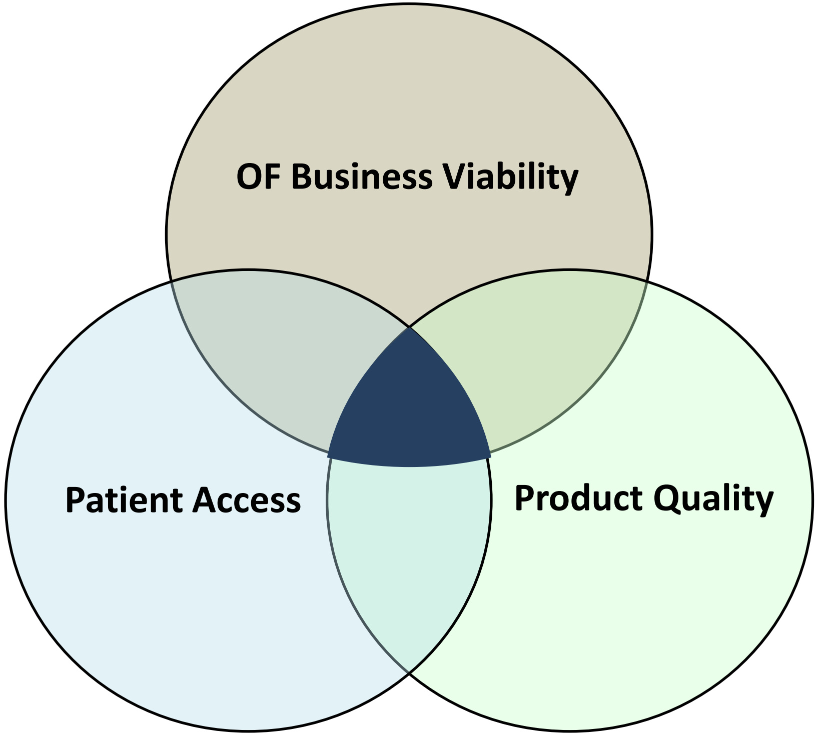
Background

- The outsourcing facility (OF) sector has been regulated under Section 503B of the Act since 2013
- While a few firms have been operating for several years, most of the sector is comprised of relatively young companies
- As a young sector, outsourcing facilities face struggles with identity and regulatory compliance
- Outsourcing facilities serve important patient needs and this necessitates forging a clear path forward

A Simple Framework

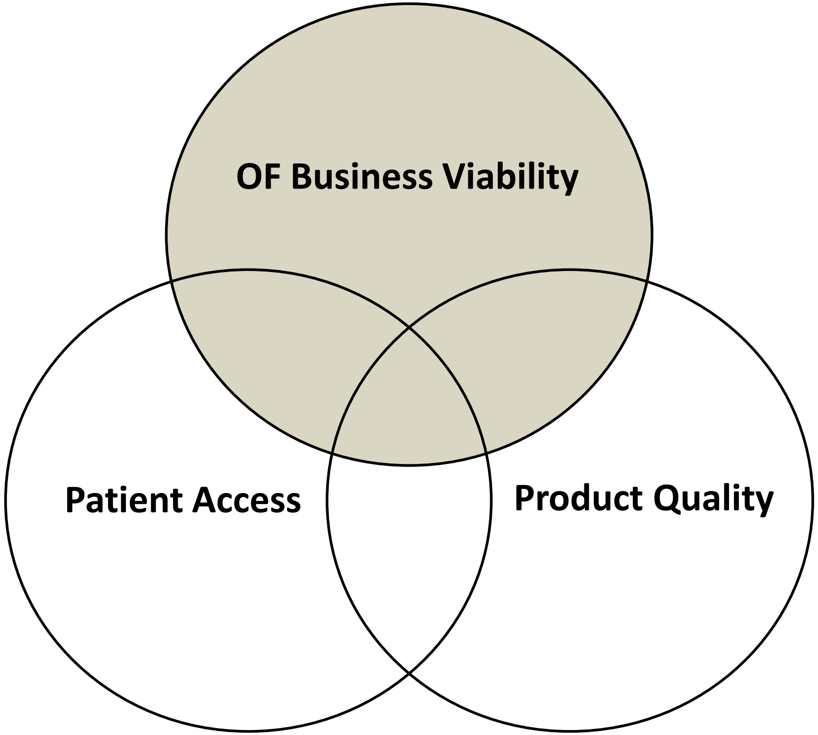


Sources of Information for this Presentation

- The Compounding Quality Center of Excellence Landscape Study
  - Analysis of data
  - Annual surveys of OFs
  - Deloitte's conversations with OFs and other stakeholders

- Listening sessions

OF Business Viability

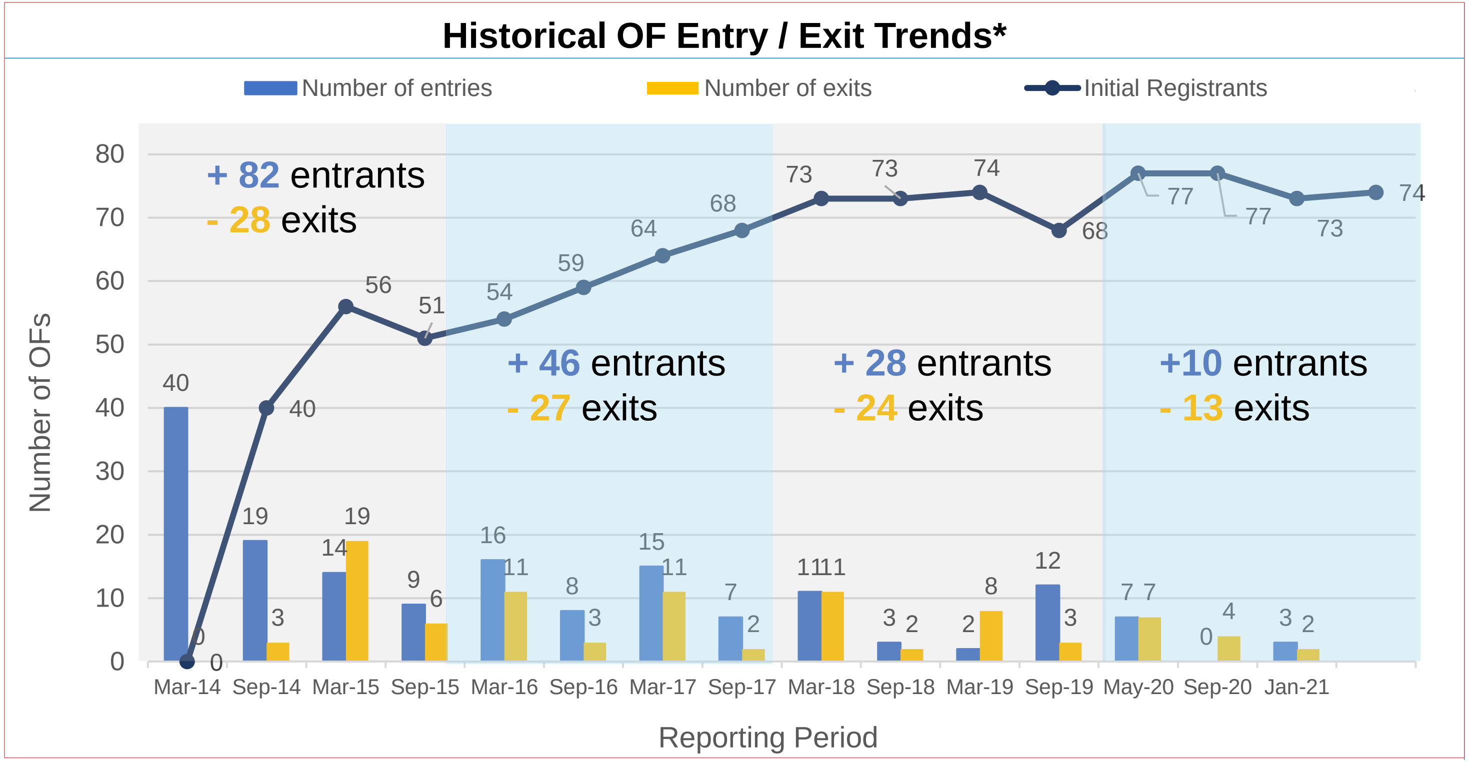


The Market

By the Numbers: Compounding OF Market			
76	23	$2.3 - $4.6B	2% - 4%
Number of Registered OF Facilities *(As of December 2019)*	States with OFs	*Size of the 503B Market	**Compounding Market Growth *(503A and 503B)*

**Methodology: CMS spending data indicate Medicare Part D spending on compounded drugs. Medicare Part D spending averages 30% of total prescription drug spending, which is the ratio applied to estimate total compounded drug spending. The GMI market report estimates 503B compounding holds a 52% market share. This is then applied to the total compounding market revenue to estimate the size of the 503B market; **Source: IBIS Report (2%), GMI Report (4%)*

Slowly Stabilizing, but Still in Flux



Reasons for OF Market Entry

- Good fit with business model
- Shortage drugs
- Meet customer demand/strategic partnerships

Why Do Outsourcing Facilities Exit the Market?

- Compliance issues
- Difficulties in getting established
- Outsourcing facility operations not the primary business model
- Operating as 503A

Top Business Challenges Identified by OFs

- Costs of maintaining and operating facilities, testing drug products, acquiring equipment, etc.
- Maintaining compliance with CGMP
- Recruiting skilled staff
- Keeping up with changing demand (either increases or inconsistencies)
- Availability of API and drug inputs

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Challenges in Identifying/Acquiring API Supply

- Because most OFs are not high-volume purchasers, many must depend upon brokers for API sourcing.
- Brokers vary in quality practices and reputability. Some brokers lack transparency regarding sourcing of APIs, although this appears to be improving.
- Supply chain concerns due to high overseas production and difficulties in characterizing chain of custody.
- Resource intensive to qualify suppliers, especially when multiple suppliers are needed.

Challenges With API Suppliers

Top Growth Opportunities Identified by OFs

- Competitive pricing
- Increasing demand
- Building and maintaining relationships with buyers
- Responding to drug shortages
- Using automation or technology

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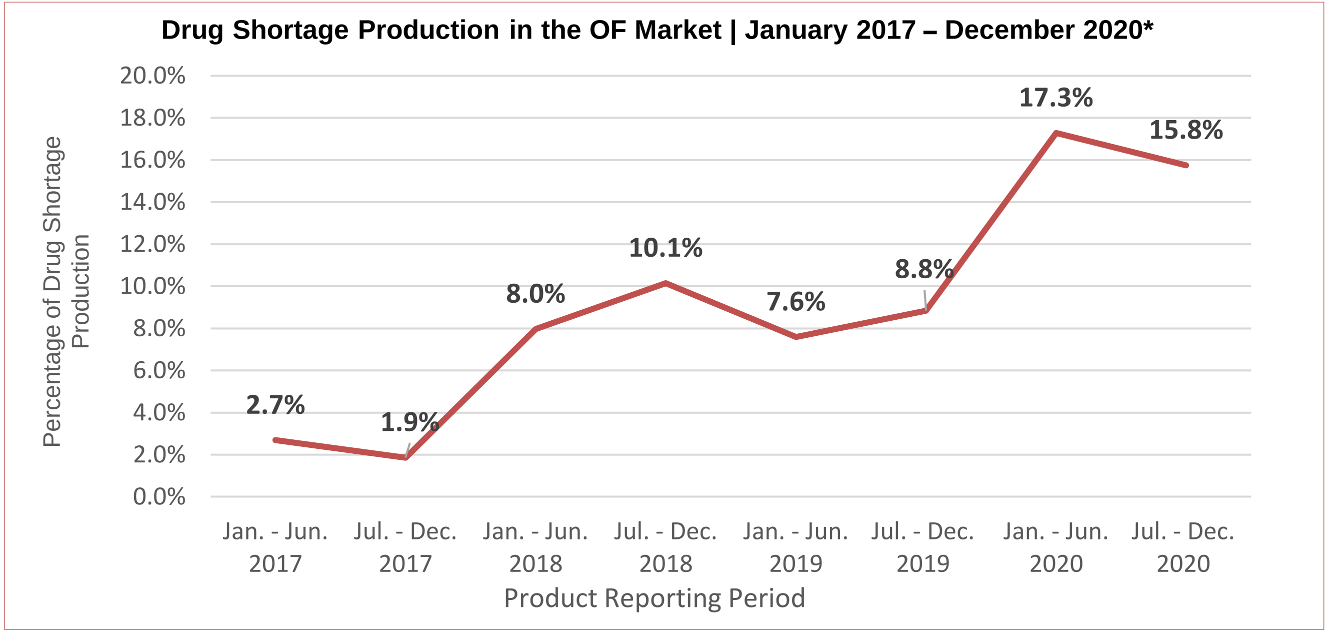
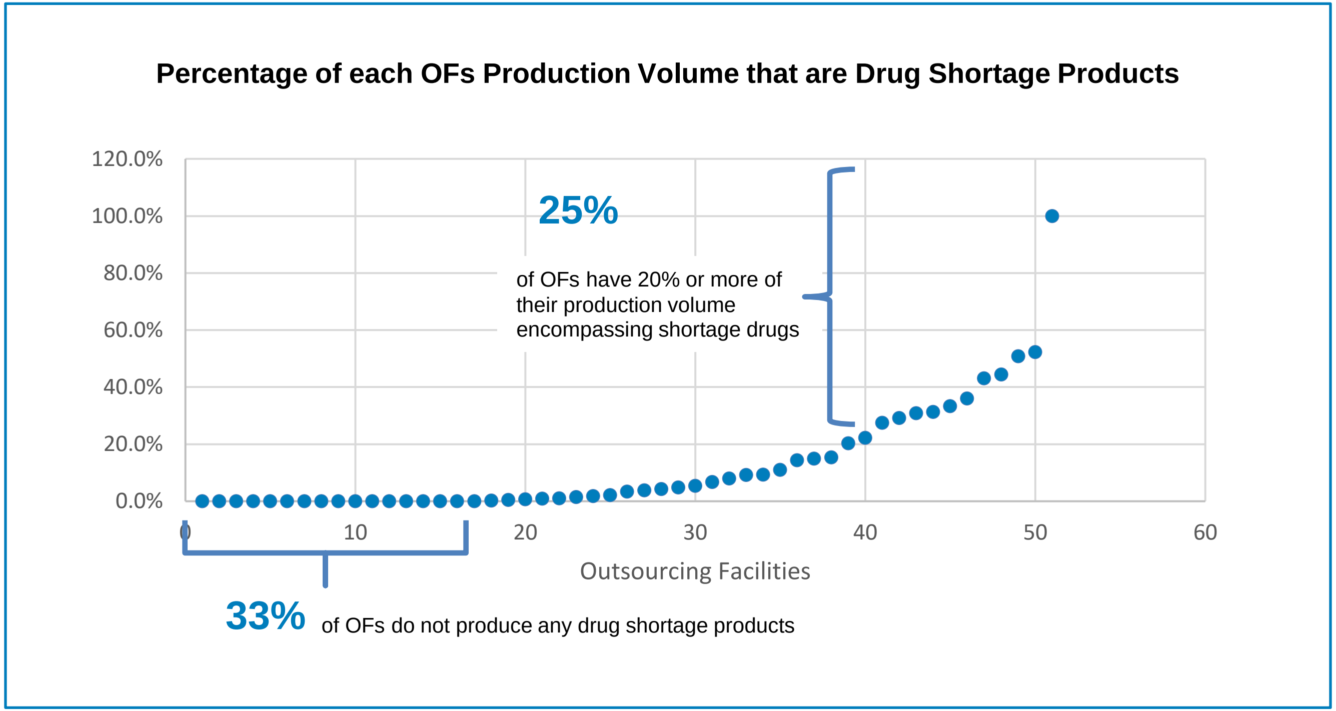
Trends in OF Shortage Production



Shortage Production Varies Across Firms



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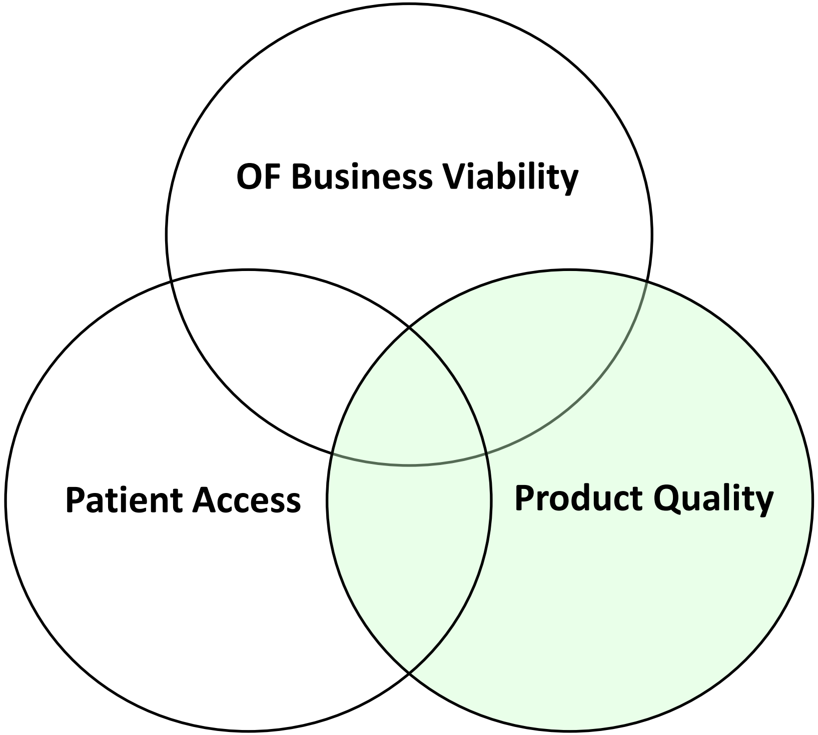
Automation Technology

- Approximately 60% of OFs claim to utilize automation technologies(based on survey data)
- Most technologies center around filling and packaging/labeling
- Firms not utilizing automation technology cite cost and lack of scale

Impact of Regulation

- All regulated industries are impacted by regulation—financially and otherwise.
- As a newly regulated industry, there is greater policy flux than with established industries as FDA continues to develop new policies.
- OFs are a young industry with mostly smaller companies. Firms can be more heavily influenced by policy changes due to being smaller in size.
- While public health and patient safety are always our foremost priorities, FDA is also mindful of the interplay between policy development and OF sector operations.
- OFs also cite that the differing regulatory models among states continue to be a challenge.

Product Quality



Quality—Motivating Factors

- In general, OFs are motivated to include quality practices/quality culture within their firms
- In addition to patient safety, OFs cite standardization, reliability, and customer satisfaction as motivators
- OFs also cite that purchasers tend to place more value on OFs that have more robust quality practices
- Risks of reputational harm and regulatory consequences also cited as motivators

Quality—Challenges

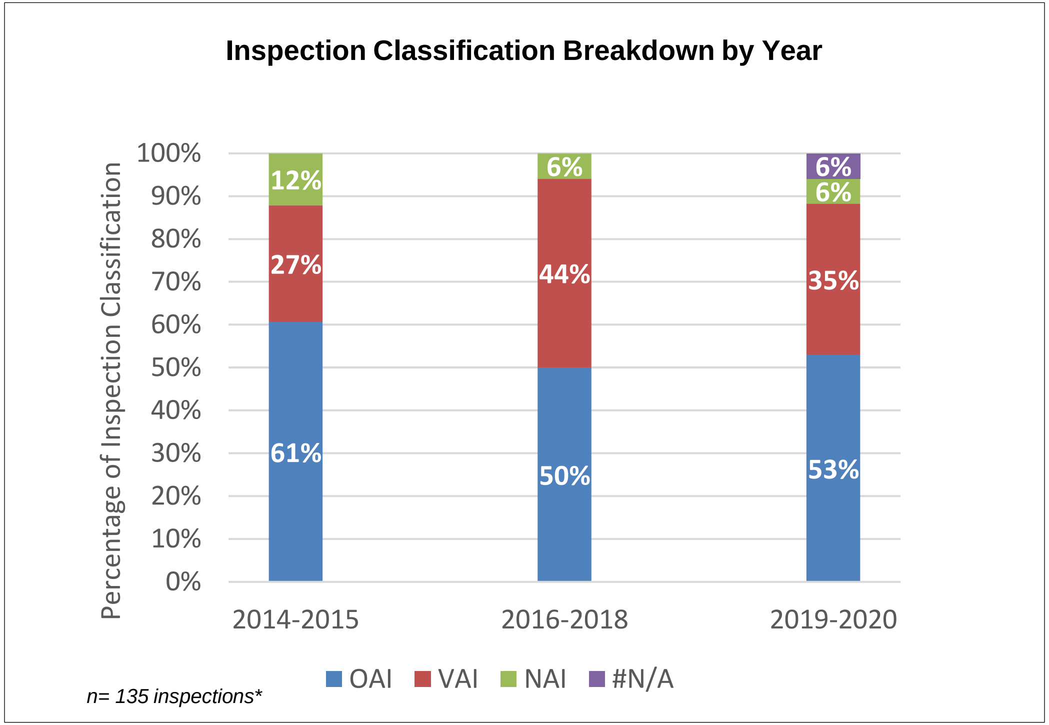
- Broad variability among OFs regarding quality practices and level of implementation

- Based on survey, 60% of OFs referenced utilization of SOPs to deal with quality failures, and 33% indicated use of a quality unit

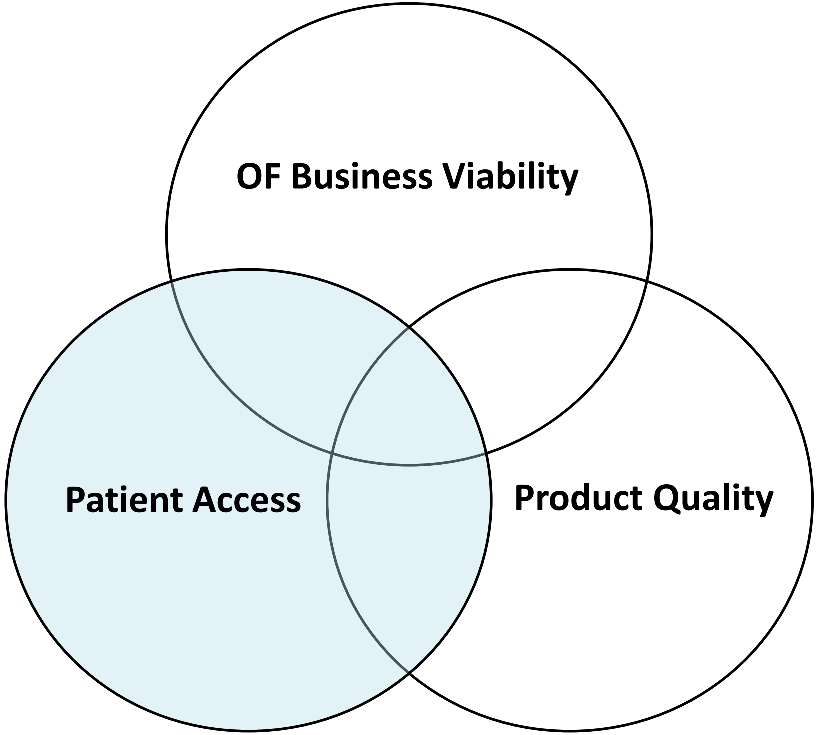
Compliance Challenges

- Compliance is an ongoing challenge, especially within the realm of CGMP
- Some OFs express a lack of clarity in reference to FDA expectations regarding 483 and Warning Letter responses
- OFs indicate FDA delays in timeliness of inspection closeouts, responses to submissions (e.g., 483 responses, Warning Letter responses)
- Some OFs indicate difficulties with understanding areas of FDA policy

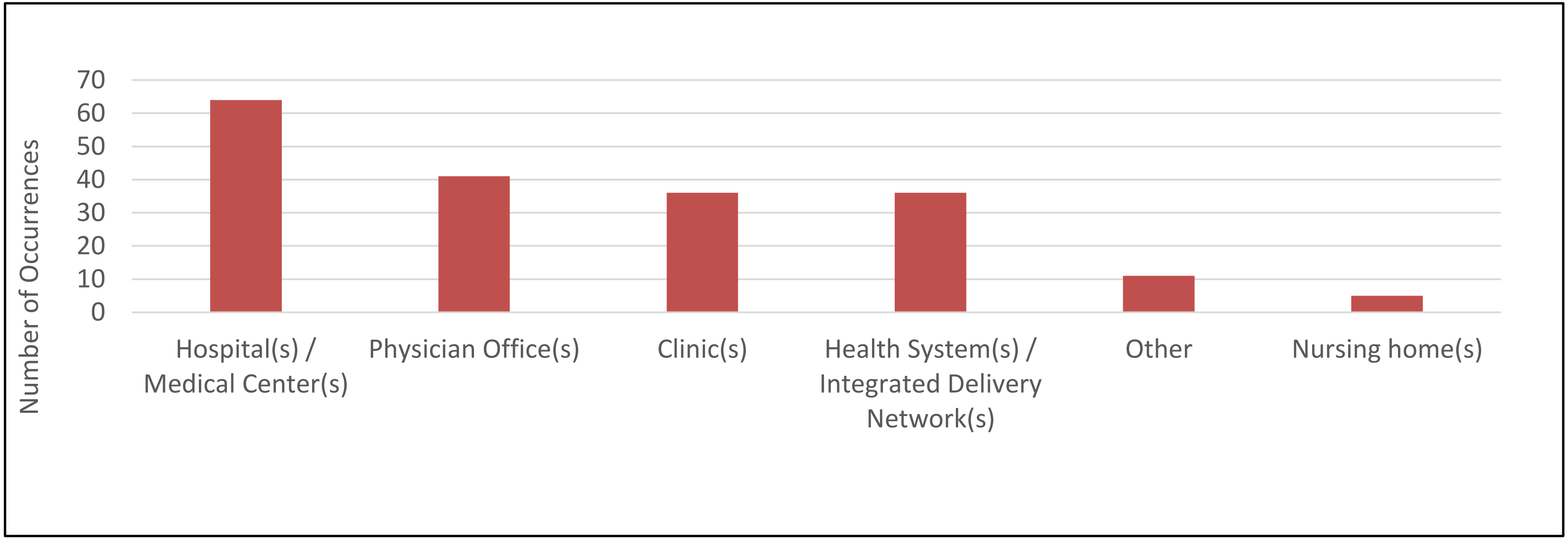
A Glimmer of Improvement



Patient Access



Who are the Customers?



Hospital Systems

- Large batch, standardized products (especially true for larger hospitals/hospital systems)

- Products that are beyond the compounding/production capabilities of in-house pharmacies

- Longer beyond use dates for products compared to in-house or 503A pharmacy

Physician’s Offices/Clinics

- Smaller portfolio of specialized products
- Office stock
- Niche products for specialized use (ophthalmology, dermatology)

Are GPOs Involved?

- Up to 45% of OFs (per survey) work with GPOs
- Typically true of larger OFs
- Hospitals and health systems utilize GPOs to assist in vetting OFs

Potential Product-Specific Areas of Demand Per Hospitals and Providers

- Shortage drugs
- Ready to use formulations
- Small-batch, niche products

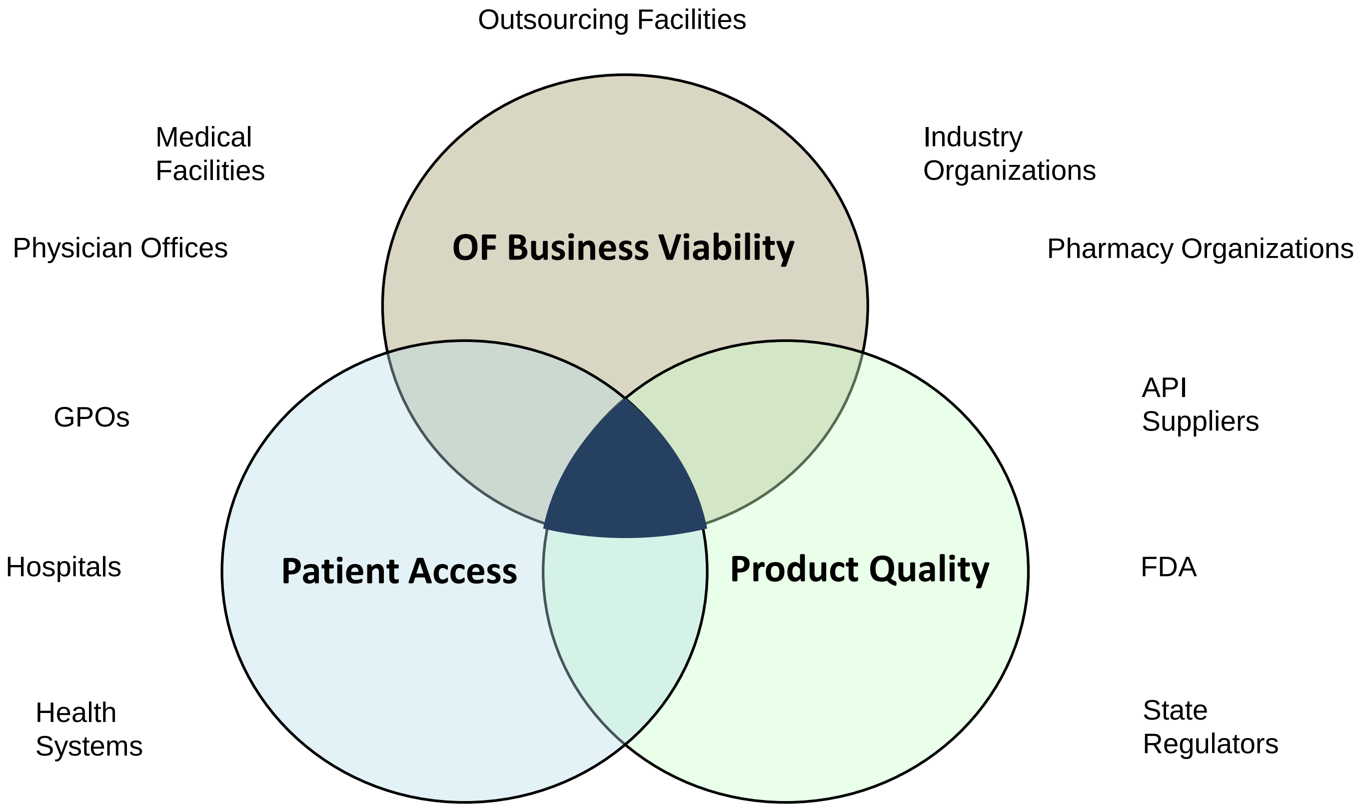
Key Takeaways

- OFs are young but growing and while there are difficulties, there are viable areas for business growth.

- Quality/compliance continues to be a pain point, but is showing signs of slight improvement and firms are motivated to improve quality.

- There is demand for OF products from diverse areas, most of which should be viable in the long-term. OFs indicate demand is growing.

The Future Involves All Stakeholders



How Do We Get to the Center?