

Center of Excellence Areas of Customer Need for Outsourcing Facility Products

Meghan Murphy, PhD

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Information Sources for Today's Talk



- The Compounding Quality Center of Excellence Landscape Study
 - Analysis of data
 - Annual surveys of outsourcing facilities
 - The contractor's conversations with outsourcing facilities and other stakeholders
- Listening sessions and other conversations
- All research in the Landscape Study is conducted by a contractor through their direct engagement with outsourcing facilities and other stakeholders. The results are reported to FDA by the contractor in an anonymized manner. The research results reflect only the views of the research participants.
- The information in this presentation describes perspectives shared by stakeholders. This is a reporting of information from the stakeholders and does not necessarily represent FDA's opinions nor has FDA independently verified the accuracy of the information.

Background

- The outsourcing facility industry is still relatively young and evolving and, as such, serves a wide variety of customers
- Customer needs range broadly in terms of individual products and product volume
- Customers and outsourcing facilities often work together in an effort to match customer need with outsourcing facility capabilities

Overview

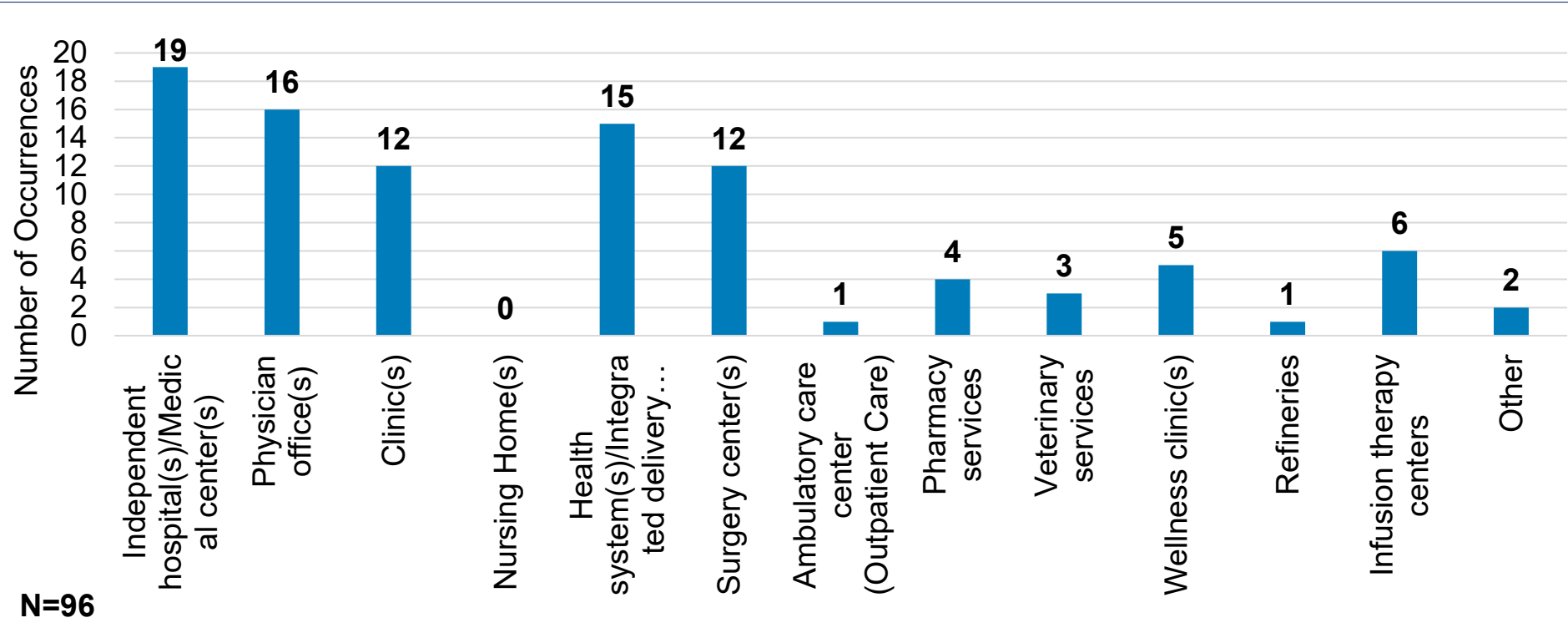


- Major customer areas and product needs reported for each
- Products most frequently produced by outsourcing facilities
- Challenges faced by customers
- Challenges faced by outsourcing facilities

Cross-Section of Outsourcing Facility Customers



Q: What types of practice settings receive your 503B compounded products?
(From 2022 Landscape Study Survey)





Major Customer Areas

- Hospital and Health Systems
- Clinics
 - Ophthalmology
 - Dermatology
- Surgery Centers
- Infusion Centers

Hospitals and Health Systems



- Need for sterile products beyond the compounding/production capabilities of in-house pharmacies
- Generally need high volume of products
- Desire to utilize longer beyond use dates for outsourcing facility products compared to in-house or 503A pharmacy
- Example products: sterile operating room syringes, sedatives, paralytics, narcotics, antibiotics, total parental nutrition, and epidurals

Hospitals and Health Systems— Special Cases



- GPOs utilize outsourcing facilities for various products to broaden their portfolios
- Children's hospitals have product needs centered on specialized dosing for pediatric patients

Clinics—Ophthalmology Products



- Specialized sterile formulations, most often topical drops but can also include injectable formulations
- Formulation preferences can vary between individual ophthalmology practices and individual ophthalmologists, lending to small batch sizes/volume of product
- Products commonly utilized include antibiotics for ocular use and repackaged bevacizumab (Avastin)



Clinics—Dermatology Products

- Specialized formulations of non-sterile, topical products (creams, gels, etc.)
- Generally small batch sizes and low product volume
- Formulation preferences can vary among physician practices and individual physicians
- Example product: topical local anesthetic preparations

Surgery Centers

- Often lack equipment for sterile compounding
- Need moderate to large volume of products
- Example products: sterile operating room syringes and/or sterile injectables for anesthesia, narcotics, antibiotics

Infusion Centers

- Serve outpatient or home settings by providing IV products
- Require very high product volumes
- Example products: electrolytes for total parental nutrition, antibiotics, antivirals, chemotherapy

Overall Heterogeneity of Product Needs



- Need for product volume varies widely from very high volume (infusion centers, health systems) to low volume (ophthalmology and dermatology specialty products)
- Broad diversity in product needs ranging from standard therapeutics (anesthetics, narcotics, antibiotics) in hospital and ambulatory settings to highly specialized products for individual physician practices

What are Outsourcing Facilities Supplying?



Cardiovascular	Anesthesia	Reproductive	Analgesia	Ophthalmology
Phenylephrine Hydrochloride Norepinephrine Bitartrate	Rocuronium Bromide Lidocaine Hydrochloride	Oxytocin Testosterone	Fentanyl Citrate Hydromorphone Hydrochloride	Bevacizumab Moxifloxacin Hydrochloride

- Based on product data reported to the Agency
- Top 5 therapy areas comprise approximately 70% of reported product volume
- Aligns with reported needs of customers that utilize higher volume of products

Challenges Faced by Customers



- Small volume products—less often supplied
- Not many outsourcing facilities specialize in dermatology products because they are typically nonsterile preparations

Challenges Faced by Customers



- Individual customers often utilize multiple outsourcing facilities to meet product needs
 - Needs for high volume products outstrip the production capacity of an individual outsourcing facility
 - No single outsourcing facility has a sufficiently broad product portfolio to provide all needed drugs
 - Supply from outsourcing facilities can be inconsistent at times, necessitating “back up” to ensure constant supply

Outsourcing Facility Challenges



- Lack of standardization of products between customers. Different hospitals/health systems/clinics have different preferred formulations of similar drugs compelling outsourcing facilities to tailor products to individual customers.
- Outsourcing facilities find it difficult to justify the production costs of specialty products (e.g., ophthalmics) due to small batch sizes
- Sensitive to supply chain disruptions for APIs, vials, and other supplies that can cause production inconsistencies.
- Continued “growing pains” regarding quality and CGMP compliance can cause disruptions in supply

Summary

- Outsourcing facilities serve a broad range of diverse customers, each with specific needs
- Customers utilize outsourcing facilities to meet needs and fill gaps that cannot be served either internally or by commercial products
- While there is often a good match between customer need and outsourcing facility supply, both parties face challenges

