PHARMACEUTICAL SUPPLY CHAIN CHALLENGES & OPPORTUNITIES SURVEY REPORT

TriRx
PHARMACEUTICAL SERVICES

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PHARMACEUTICAL SUPPLY CHAIN CHALLENGES OPPORTUNITIES SURVEY REPORT

INTRODUCTION

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This survey was conducted in 2021 among pharmaceutical/ biopharmaceutical, generics, and OTC organizations, many of which outsource development and manufacturing services. The study's objectives were to gain insights into current product lifecycle supply chain challenges experienced by innovator and generics pharmaceutical organizations, disruptions caused by the COVID-19 pandemic, and future market directions.

Demographic

The study exclusively surveyed the North American markets. It reflects a mix of large, mid, and small-sized pharma/biopharma, generics, and Over-the-Counter (OTC) organizations, with some weighting towards mid-sized companies. Respondents mainly work in drug manufacturing, quality assurance/quality control, business development, and supply chain management roles. Over 95% are in C-suite or director-level positions. The study surveyed industry executives working with liquid and semi-solid, oral solid dose, injectable, and inhalant drug delivery formats.

88% of survey respondents outsource development and manufacturing services to Contract Manufacturing Organization (CMO) or Contract Development and Manufacturing Organization (CDMO) organizations. Additionally, a large percentage of respondents are part of the decision-making process and/ or oversight process for the organizations contracted by their companies. As a collective, survey respondents were well-positioned in terms of their roles and authority to provide insights into current supply chain challenges.

Trends: Unclear Market Demand, Pandemic Disruptions, Ongoing Serialization Challenges, and the Rise of Semi-solids

The results of this survey were an interesting window into both long-existing industry challenges, issues worsened by the volatility of the pandemic, and the evolutions of a changing market. It is little surprise that pandemic-related challenges like disruptions to transportation and operations and efficiency challenges due to the lack of in-person communications were top of mind. 93% of survey respondents indicated that predicting market demand has been highly challenging. A portion of this demand volatility can be attributed to the unique needs of the pandemic; however, will future demand patterns be just as difficult to predict?

Tracking suppliers' regulatory compliance throughout the supply chain and supply chain disruptions is increasingly motivating many pharmaceutical organizations to consolidate service providers to avoid supply chain gaps. Serialization challenges continue to vex organizations across the industry, and labeling issues have particularly challenged smaller pharmaceutical companies.

Interestingly, semi-solids (creams, lotions, and ointments) are on the rise. Survey respondents indicated that this dosage form is the most strategic based on sale volume — respondents also stated that it is the most difficult dosage form to develop and manufacture. Unsurprisingly, semi-solids are prevalent within the dermatology sector. But, this dosage form also has a sizable position in therapeutic areas like metabolic and endocrine, respiratory, cardiovascular, oncology, hematology, and several others.

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PHARMACEUTICAL SUPPLY CHAIN CHALLENGES OPPORTUNITIES SURVEY REPORT

DEMOGRAPHIC

DEMOGRAPHIC

1. Survey Respondent's Current Industry.

53%
Pharmaceutical / Biopharmaceuticals

47%
Generics / OTC

2. Size of Survey Respondent's Firm (Pharmaceutical).

35% **Large Pharma**
More than 2,500 employees

50% **Midsized Pharma**
500 to 2,500 employees

15% **Small Pharma**
Up to 500 employees

3. Survey Respondent's Type of Firm (Generics & OTC).

29% **Large Generic/OTC**
Revenue $1B and up

57% **Midsized Generic/OTC**
Revenue $250M - $1B

14% **Small Generic/OTC**
Revenue under $250M

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Base for infographic 2 is 40. Base for infographic 3 is 35.

4. Survey Respondent's Region.

100%
North America

5. Survey Respondent's Job Title.

56% Director/Senior Director

39% Executive (VP, President, CEO, CIO, CTO, COO, etc.)

5% Manager/Senior Manager

6. Survey Respondent's Department or Current Work Area.

Drug Production/ Manufacturing

31%

Quality Assurance/ Quality Control	20%
Business Development	19%
Purchasing/ Procurement	19%
Supply Chain	5%
External Manufacturing	4%
Formulation/ Analytical	3%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications.

7. Level of Outsourcing in Survey Respondent's Company.

88%

My company currently outsources services or operations to Contract Development & Manufacturing Organizations (CDMOs)

12%

My company does not currently outsource development / manufacturing services or operations, but is in the process of evaluating CDMOs – likely to need within the next 24 months

8. Survey Respondent's Role with Tasks Related to Outsourcing of Development / Manufacturing Services to CDMOs.

71% I am part of the decision-making unit that selects the CDMOs

16% I supervise or coordinate with CDMOs

13% I am part of a team that establishes criteria / makes recommendations on the selection of CDMOs

9. Survey Respondent's Years of Experience Within the Life Science Industry.

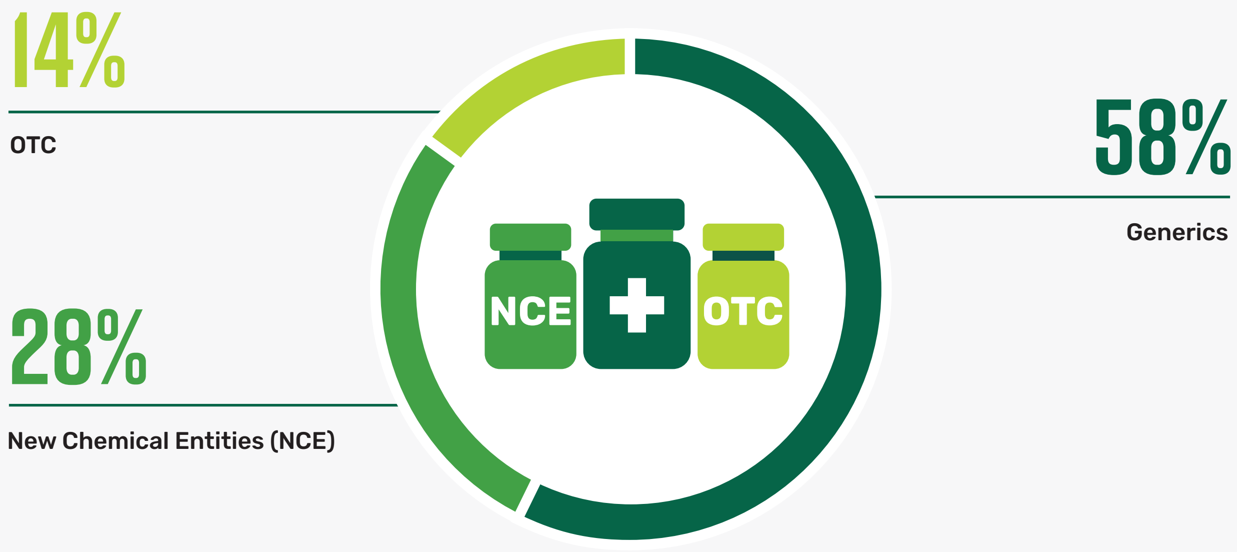
28%
3 – 5 years

48%
5 – 10 years

24%
More than 10 years

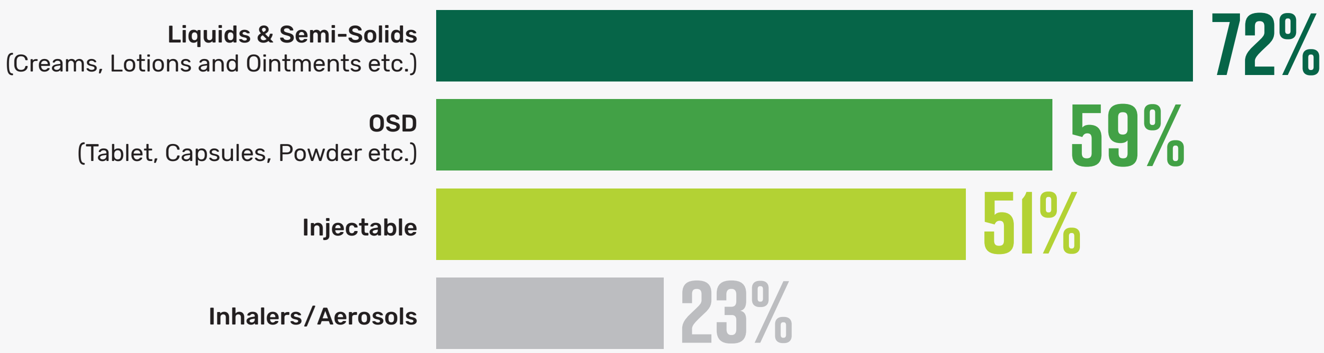
NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications.

10. Type of Molecules the Pharmaceutical Survey Respondent's Company Focuses on.*



Base: Pharmaceutical / Biopharmaceutical industry

11. Recent Types of Dosage Forms Survey Respondents Have Worked With.



NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications.

PRODUCT LIFECYCLE

SUPPLY CHAIN CHALLENGES

PRODUCT LIFECYCLE SUPPLY CHAIN CHALLENGES

12. Product Lifecycle Supply Chain Stage That Is Most Challenging to Survey Respondent's Organization.

Manufacturing/Packaging Stage
Manufacturing and packaging stage of the product

36%

Sourcing / Procurement Stage
Procurement of raw materials and other related resources required for developing / manufacturing the product

25%

Planning / Development Stage
Research, Development and Clinical stage

24%

Storage/Logistics Stage
Storage and transportation stage of the product

12%

Selling / Consumer Stage
Sell stage of the product to final consumer

3%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications.

13. Top 5 Most Challenging Issues at the Development Stage of the Product Lifecycle Supply Chain for Survey Respondent's Organization.

- Access to technically strong R&D/Clinical staff — 68%
- Identifying the right products/therapeutic areas for investments — 57%
- Developing innovator patent attack strategy* — 57%
- Compliance with additional regulatory framework around developing liquid/semi-solid dosage forms** — 56%
- Retaining R&D/Clinical/Formulation personnel — 55%
- Disrupted and unusual future product forecasting — 53%
- Partnering with the right CRO for clinical development and testing*** — 53%
- Designing optimal and efficient 'Time to Market' timeline — 52%
- Identifying comparator sourcing partner — 48%
- Access to technically strong formulation experts — 44%
- Developing IP/Patent protection strategy — 28%

**Base: Currently work in Generics / OTC industry*
***Base: Work with Liquids & Semi-Solids*
****Base: Currently work in Pharmaceutical / Biopharmaceuticals industry*

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Percentage indicates number of respondents that selected the option as a top 5 issue.

14. Top 5 Most Challenging Issues at the Sourcing / Procurement Stage of the Product Lifecycle Supply Chain for Survey Respondent's Organization.

Planning for large volumes of material and product needed for (liquid and semi-solid dosage form) development stage*	48%
Tracking compliance of suppliers with required regulatory standards	48%
Lack of transparency with internal stakeholders — sharing of information, vague requirements	44%
Establishing KPI for best practices (overall operations) — variety, velocity, visibility, and volume	43%
Identifying and sourcing reliable high quality raw material suppliers	43%
Access to trained procurement staff	41%
Identifying and sourcing niche excipients required for liquid and semi-solid dosage forms*	41%
Changing order scope or requirements for vendors	40%
Establishing reliable, interruption free, timely supply channels for materials	40%
Lack of transparency with vendors — unavailability of past evaluation metrics, vague specs	39%
Establishing QC and raw material testing practices	36%
Anticipating the need for material supply	33%
Navigating budget constraints and achieving low COGS without compromising quality	29%

**Base: Work with Liquids & Semi-Solids*

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Percentage indicates number of respondents that selected the option as a top 5 issue.

15. Top 5 Most Challenging Issues at the Manufacturing/Packaging Stage of the Product Lifecycle Supply Chain for the Survey Respondent's Organization.

Lack of Serialization	47%
Addressing IT security threats	45%
Establishing reliable, interruption free, timely manufacturing operations cycle	44%
Tracking compliance of CDMOs with required regulatory standards	43%
Clearly defining the project scope for outsourcing partners (CDMOs)	41%
Compliance with additional regulatory framework around manufacturing liquid/semi-solid dosage forms*	41%
Access to trained manufacturing staff	40%
Lack of smart packaging and labeling options	40%
Partnering with the right CDMOs for manufacturing and packaging	40%
Establishing robust data driven planning and scheduling strategies for manufacturing	39%
Limited choices of commercial scale contract outsourcing partners	35%
Scaling up from clinical/development phase to commercial phase	28%
Addressing counterfeiting threats	28%
Other	1%

**Base: Work with Liquids & Semi-Solids*

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Percentage indicates number of respondents that selected the option as a top 5 issue.

16. Top 5 Most Challenging Issues at the Storage/Logistics Stage of the Product Lifecycle Supply Chain for the Survey Respondent's Organization.

Establishing secure, temperature-controlled drug storage and distribution channels	57%
Tracking compliance of storage and logistics partners with required regulatory standards	55%
Understanding import/export requirements and navigating disruptions across global markets	53%
Limited choices of logistics outsourcing partners	53%
Global presence and reach — locations and shipping capability	51%
Establishing reliable, interruption free, timely storage and logistics channels for finished products	51%
Lack of an efficient returns and destruct capability	48%
Access to digital dashboards for tracking shipments	45%
Partnering with the right logistics partners for storage and distribution	43%
Last minute additional fees/penalties for changes in scope/requirements	43%
Other	1%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Percentage indicates number of respondents that selected the option as a top 5 issue.

17. Top 5 Most Challenging Issues at the Sell Stage of the Product Lifecycle Supply Chain for the Survey Respondent's Organization.

Predicting market demand to keep up with supply

93%

Establishing direct to consumer/patient/physician channels

91%

Establishing reliable PBM/wholesalers/pharmacies networks

89%

Negotiating with regulatory bodies and formularies for better tier/pricing

84%

Competing with other (potentially favorable) dosage forms e.g. OSD*

83%

Navigating pricing pressures and related restrictions

83%

**Base: Work with Liquids & Semi-Solids*

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Percentage indicates number of respondents that selected the option as a top 5 issue.

18. Top 5 Most Challenging Pandemic Related Issues Impacting Survey Respondent Organization's Product Lifecycle Supply Chain.

Disruptions in transportation and logistics

57%

Disruptions in commercial operations — manufacturing, packaging etc.

57%

Reduced workforce efficiency due to lack of in-person communication

55%

Delayed approvals of non-COVID related products

53%

Disrupted communications — Internal and external

53%

Supply shortages of APIs and other raw materials

52%

Disrupted data collection and analysis

48%

Disruptions in clinical trials

45%

Shift in resource allocation from non-COVID to COVID related products

41%

Disrupted access to high skilled workforce

37%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Percentage indicates number of respondents that selected the option as a top 5 issue.

19. Solutions Survey Respondent's Organization are Currently Implementing to Address Some of the Overall Supply Chain Challenges.

Digital platforms for clinical trials/ activities
43%

Working with one stop shop CDMO to eliminate supply chain gaps
40%

Digital platform for commercial activities
36%

Digitaltrans formation — e-signatures, virtual meetings
29%

Consolidating suppliers
29%

Renegotiating existing supply agreements
27%

Developing a sustainable serialization strategy
27%

Possible direct to patient initiatives/ strategies
25%

Documentations and paperwork via online portals
21%

Implementing blockchain technology
19%

End to end supply chain visibility
19%

Virtual on-site audits and videos
17%

Adopt new tech — IoT, Analytics, Machine Learning and Artificial Intelligence
17%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications.

20. Solutions Survey Respondent's Organization are Planning on Implementing Within the Next 24 Months to Address Some of the Overall Supply Chain Challenges.

Consolidating suppliers	36%
Developing a sustainable serialization strategy	32%
Digital platforms for clinical trials/ activities	32%
Digital platform for commercial activities	29%
Adopt new tech — IoT, Analytics, Machine Learning and Artificial Intelligence	29%
Working with one stop shop CDMO to eliminate supply chain gaps	28%
End to end supply chain visibility	27%
Documentations and paperwork via online portals	27%
Virtual on-site audits and videos	25%
Implementing blockchain technology	25%
Digital transformation — e-signatures, virtual meetings	24%
Renegotiating existing supply agreements	20%
Possible direct to patient initiatives/ strategies	19%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications.

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DOSAGE FORMS AND THERAPEUTIC AREA LANDSCAPE

DOSAGE FORMS AND THERAPEUTIC AREA LANDSCAPE

21. Based on Sales Volume, the Most Strategic Dosage Form of Survey Respondent's Products That Have Multiple Dosage Forms.

44% Semi-Solids (Creams, Lotions and Ointments etc.)

33% OSD (Tablet, Capsules, Powder etc.)

23% Injectable

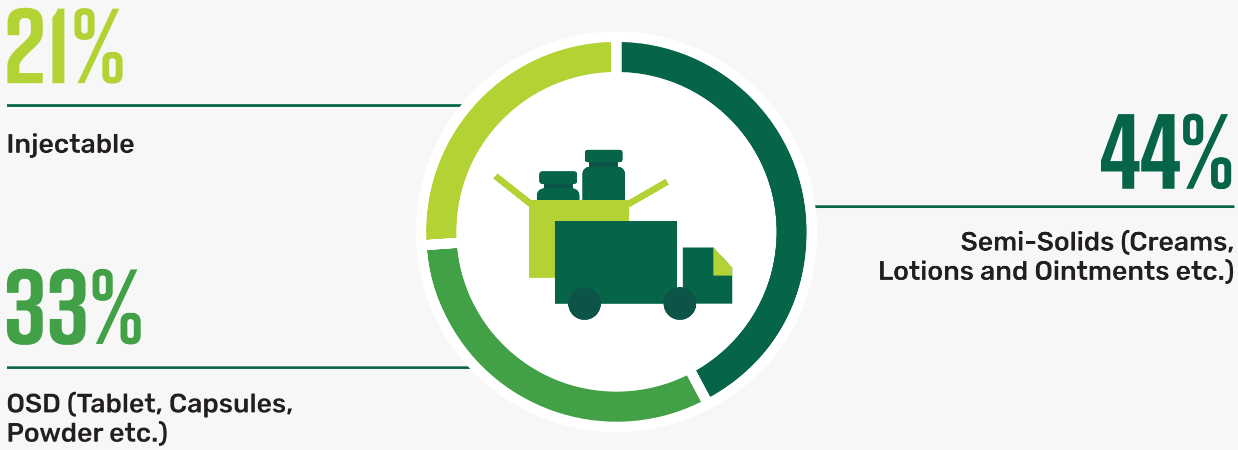
22. Important Drivers/Factors for Deciding on the Dosage Form for a Drug Product with Multiple Dosage Forms.

Driver/Factor	%
Ease of administration	17%
Formulation factors – solubility, bioavailability etc.	15%
Access and availability of excipients, raw materials etc.	15%
Supply chain logistics	13%
Time to market from development to commercial	13%
Regulatory framework	11%
Patient preferences	9%
Cost of manufacturing/ packaging	5%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Percentages for #22 indicates number of respondents that ranked the option as the first most important driver.

23. The Most Challenging Dosage Form to Develop / Manufacture.

24. Dosage Form Most Challenging to Package, Store, and Ship.



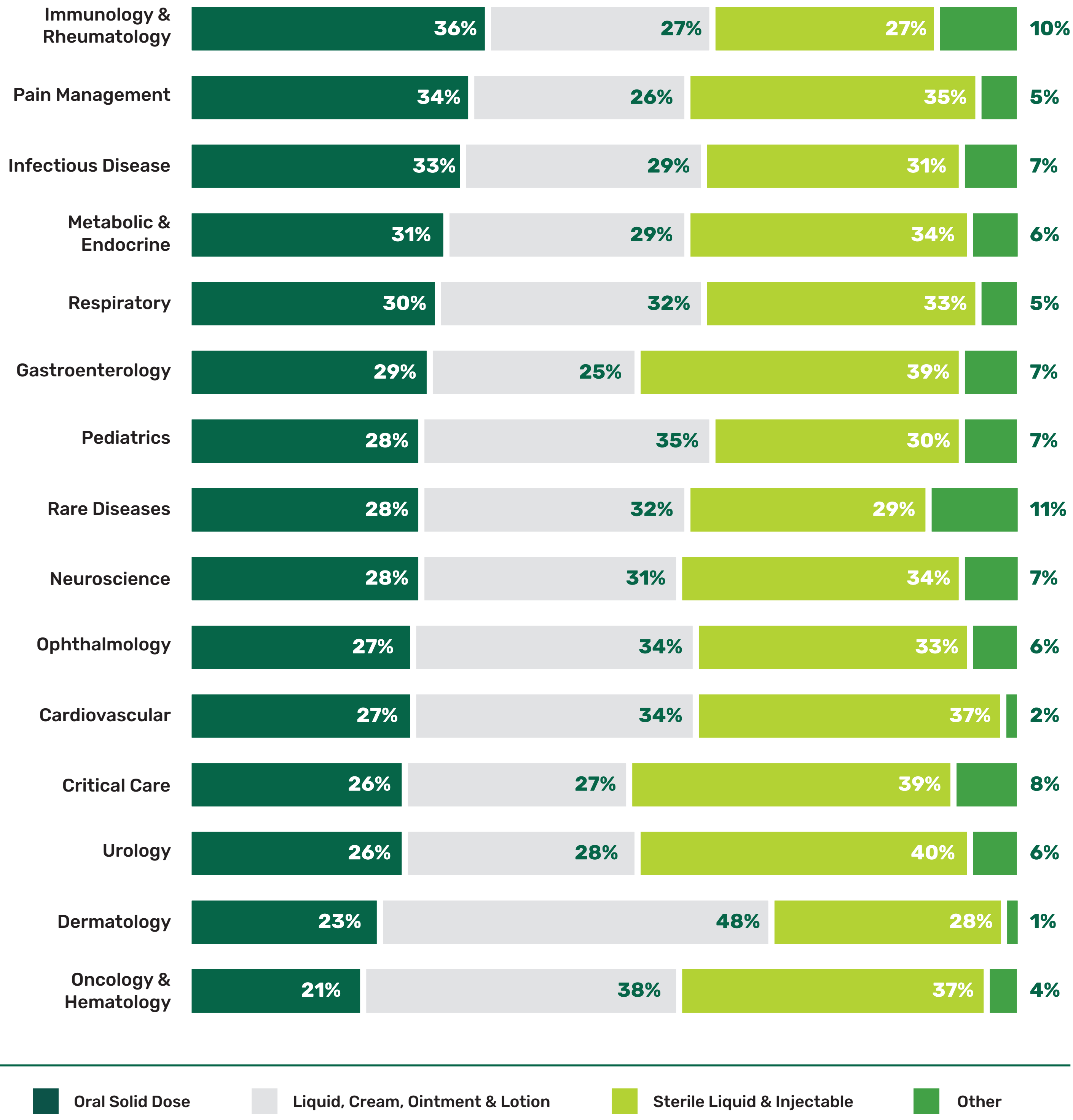
NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Percentages indicates number of respondents that ranked the option as the first most difficult dosage form.

25. Therapeutic Focus of Survey Respondent's Current Product Pipeline.

Therapeutic Area	%
Pain Management	32%
Infectious Disease	27%
Critical Care	23%
Gastroenterology	23%
Urology	19%
Metabolic & Endocrine	17%
Oncology & Hematology	17%
Respiratory	16%
Ophthalmology	16%
Pediatrics	15%
Immunology & Rheumatology	15%
Cardiovascular	15%
Neuroscience	13%
Dermatology	12%
Rare Diseases	12%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications.

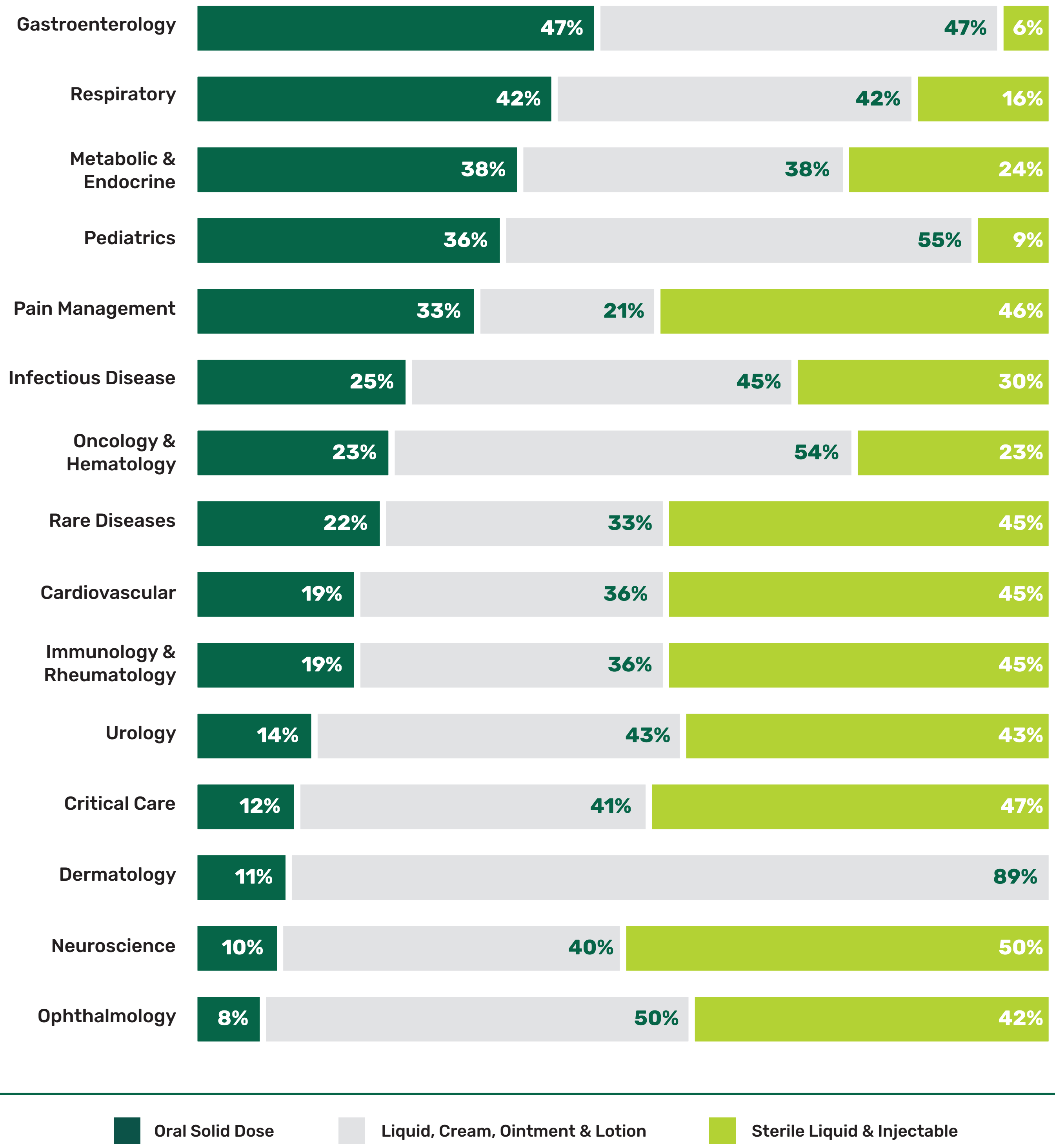
26. A Breakdown by Volume of the Survey Respondent's Current Products Based on the Therapeutic Areas and Dosage Forms.



Base for each answer varies depending on the therapeutic categories of the respondents' companies.

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications.

27. Commercially Preferred Dosage Form for Each Therapeutic Category for Which Survey Respondent's Organization Currently Provide Products.



Base: Total number per answer varies depending on the therapeutics categories of the respondents' companies.

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications.

28. Decision Drivers, Ranked Most to Least Important, When Selecting a CDMO Partner.

Quality
Mean Rank: 4.6
#1

Innovation
Mean Rank: 4.7
#2

Flexibility
Mean Rank: 5.2
#3

Cost
Mean Rank: 5.5
#4

Technical Competence
Mean Rank: 5.5
#5

Reliability
Mean Rank: 5.6
#6

Accessibility
Mean Rank: 5.7
#7

Regulatory Track Record
Mean Rank: 5.9
#8

Communication
Mean Rank: 6.1
#9

End to End Service
Mean Rank: 6.2
#10

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Scores indicates the mean rank of the decision driver. The lower the rank higher the importance.

29. Importance of the Following Attributes Factoring into Survey Respondent's Selection Process of CDMO(s) — Top 2 Box Scores.

Remote monitoring capability	80%
Access to CDMO's C-suite leadership	79%
Technical know-how and expertise	77%
Project fit (facility, capacity/ capability)	76%
Cultural fit with the CDMO	76%
Financial stability	76%
Therapeutic experience	75%
Regulatory compliance history	73%
Safe and secure IT infrastructure	72%
References from colleagues or co-workers	71%
CDMO is accessible and approachable	71%
Geographic convenience — CDMO location proximity	69%
CDMO brand's industry reputation	69%
Contractual approach — Assured IP protection	68%
Cost	68%
Global presence	67%
Enables speed to market	65%
Size and structure of CDMO	65%
Scale up and commercialization experience	63%
Risk mitigation capability	59%
One stop shop	57%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Percentages indicates 'Very Important / Somewhat Important' Top 2 Box scores by survey respondents for each option.

30. Importance of Performance Attributes When Evaluating CDMO(s), After Engaging for Product Manufacturing and Packaging — Top 2 Box Scores.

Attribute	Top 2 Box Score
Responsiveness in case of troubleshooting	79%
Meeting project deliverable requirements	77%
Account management	77%
Communication / Transparency	76%
CDMO staff knowledge / technical competence	76%
CDMO remains approachable and accessible	75%
On time delivery	75%
Quality compliance	75%
Billing Practices	75%
Resource management	71%
Willingness to go above and beyond the requirements	69%
Safety audits	68%
Flexibility with deviation from SOP	68%
Compliance audits	67%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Percentages indicates 'Very Important / Somewhat Important' Top 2 Box scores by survey respondents for each option.

31. Top 5 Biggest Frustrations of the Survey Respondent's Existing CDMO(s) for Product Manufacturing and Packaging.

Limited capabilities availability
53%

Limited capacities availability
52%

Unsatisfactory risk mitigation capability
47%

Lack of communication/ transparency
43%

Inefficient account management
40%

Lack of quality in deliverables
40%

Lack of on time delivery
40%

Inflexibility with changing needs
39%

Lack of security/ confidentiality
37%

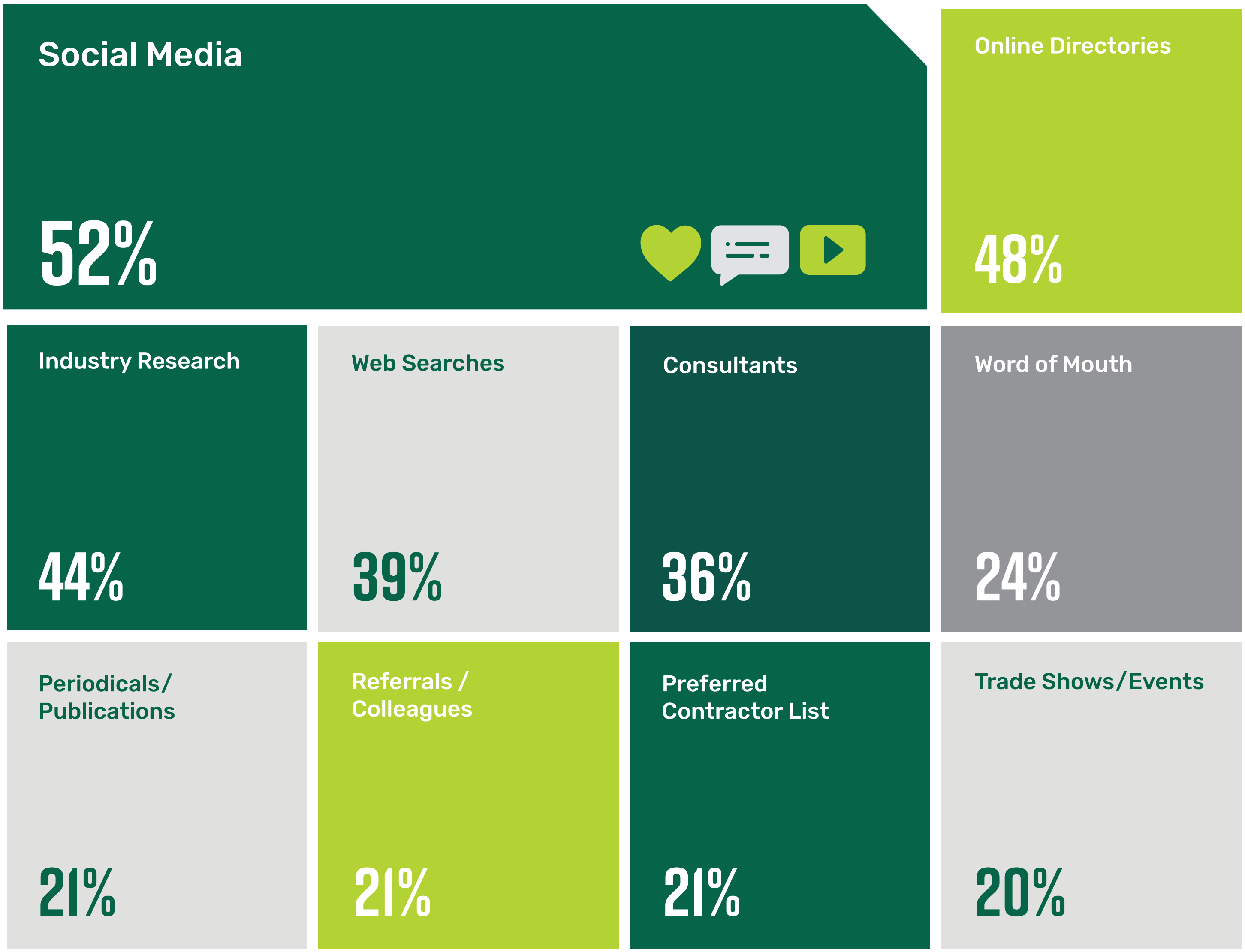
Cost overruns
37%

Unsatisfactory regulatory performance
36%

Lack of technical know-how and support
36%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications. Percentage indicates number of respondents that selected the option as a top 5 frustration.

32. Methods Used by Survey Respondent's Company to Select CDMO(s) for Outsourcing Projects.



NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications.

33. New Methods Used by Survey Respondent's Company to Select CDMO(s) for Outsourcing After Pandemic Impacted Normal Operations.

Digital campaigns
63%

Site videos
45%

Virtual tours
43%

34. Methods Used by the Survey Respondent's Company to Stay Up to Date with Latest Trends and Technologies in the CDMO Outsourcing World.

Online Directories
51%

Social Media
47%

Web Searches
41%

Industry Research
36%

Virtual Conferences/ Meetings
36%

Consultants
35%

Trade Shows/ Events
27%

Referrals/ Colleagues
23%

Periodicals/ Publications
16%

NOTE: Total sample size of this study is 75. The sample size varies for each question based on respondents' qualifications.