



CDMO

OUTSOURCING MODELS





Report Overview

ISR's CDMO Outsourcing Models report takes an in-depth look at current outsourcing practices among drug innovators to gain insight into the adoption and application of different outsourcing strategies. Biopharma report buyers are encouraged to use its content to navigate the benefits and drawbacks of various outsourcing models, to understand the cost breakdown of a manufacturing project by molecule type and stage of development to see where potential savings can be optimized, and to prepare for potential difficulties and challenges that peer outsourcers have encountered when using contract manufacturers. CDMO readers will gain insight into the service provider selection process, including details on budget, the use of consultants, the timeline for engaging CDMOs, and who is involved in the selection process. Contract manufacturers will also learn sponsor drivers for choosing different outsourcing models, their satisfaction with different models, and the challenges associated with each outsourcing approach. CDMOs can use this report's content to plan for changes in outsourcing model usage, to capture new business by zeroing in on the elements that drive the outsourcing model's success, and to anticipate future customer needs.



Data collection in Q3, 2020



15-minute web-based quantitative survey



108 respondents from North America, Europe, and Asia



148 pages

What you will learn:

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Drug Developers

- Benefits and drawbacks of using each of three different outsourcing models for development and/or commercial manufacturing needs
- Understand the cost breakdown of an outsourced manufacturing project by molecule type and stage of development to identify areas where potential savings may be gained
- How to prepare for challenges and difficulties that peers have encountered when using contract manufacturers through various outsourcing models

Contract Manufacturers

- Gain insight into how sponsor experience and capacity influence outsourcing strategies as well as which drug products and components are most likely to be outsourced
- Learn decision-making hierarchies and outsourcing drivers influencing CDMO selection then use this information to improve your sales pitch and approach
- Use this report to plan for changes in outsourcing model usage, to understand why those changes may transpire and to capture new business by zeroing in on the elements that drive an outsourcing model's success



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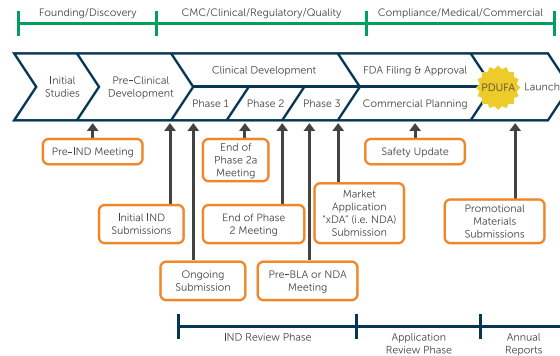
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For Sales and Business Development at a CDMO

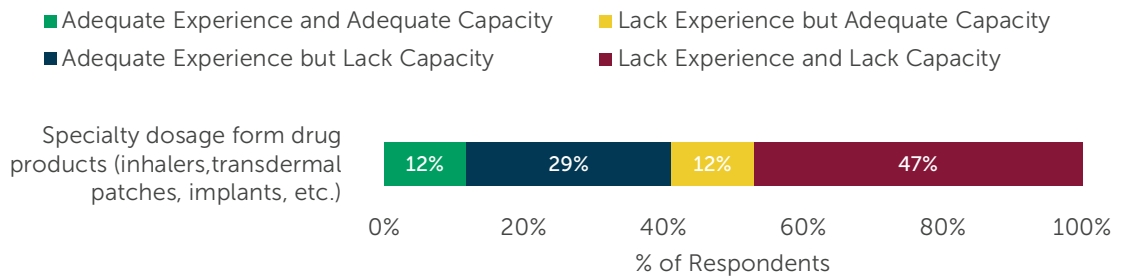
My name is Lindsey and I am a VP of Business Development at a mid-size, full service CDMO. Part of my job is to drive revenue for the specialty dosage form drug product manufacturing segment of our business. Ideally, my outreach occurs right as sponsors are getting ready to look for a CDMO. It would be helpful to know when their selection process begins and why they are outsourcing.

As a mid-size CDMO, we're hoping to grow with our clients via strategic relationships. What drives interest in partnering with a CDMO like ours, and what partnership traits can we focus on to capture outsourcer's attention?

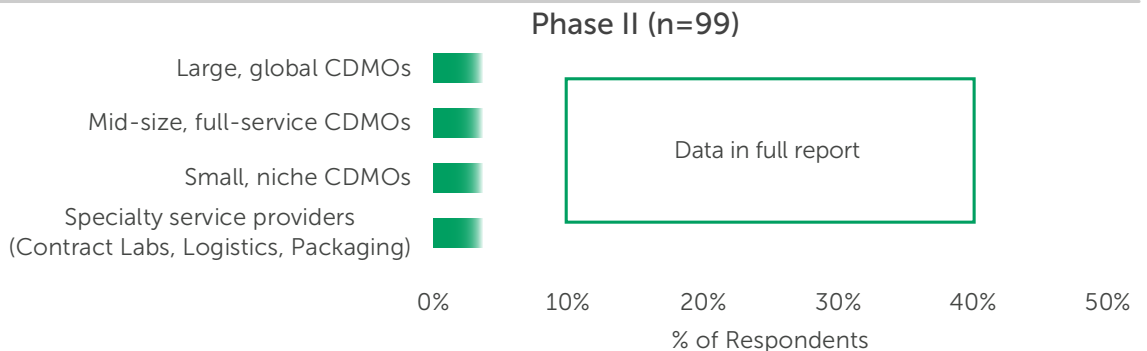


CDMO Engagement Timelines

Experience and Capacity Influence Outsourcing Strategies



Ideal Service Provider Type





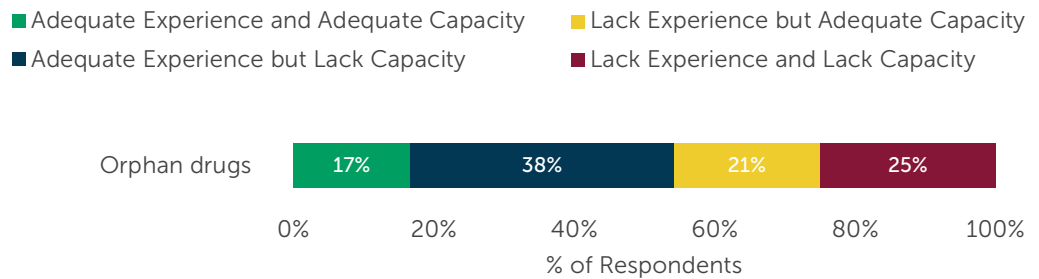
For Marketing

My name is Daniel and I am the Director of Marketing at a small, niche CDMO. My job is to build awareness of our brand and position the company as a leader in the field of Orphan Drug manufacturing. Ideally, a sponsor engages our services during clinical development and scales up manufacturing with us when their drug receives FDA approval.

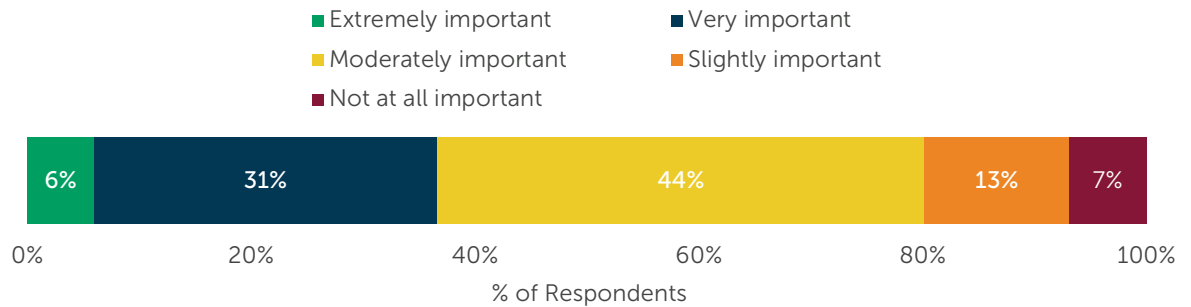
To do my job, I need to understand where outsourcers need my company's help and how best to communicate our capabilities to them. I'd also like to convince them that forming a strategic partnership is the way to mutual success.



Experience and Capacity Influence Outsourcing Strategies



Use of Same CDMO for Development and Commercial Manufacturing



Strategic Partnership

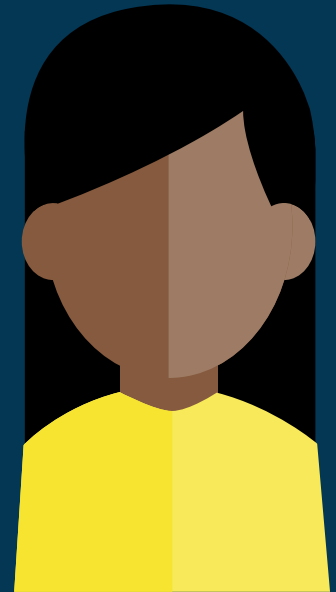
	Strategic Partnerships	
	Development (n=44)	Commercial (n=42)
Strategic importance of the product	2	



For Chief Scientific Officers at an Emerging Biopharma Company

My name is Whitney and I am the CSO at an emerging biopharmaceutical company. My role is to lead all aspects of pharmaceutical development for our company's product pipeline, which includes identifying the right approach to outsourcing in order to save both time and money while bringing our medicines to market sooner. We will be hiring a CDMO for the first time. What sorts of outsourcing challenges should I expect?

It would be helpful to know which outsourcing relationships have the greatest success rates for companies like mine and why. Where can we learn to save on costs from experienced outsourcers?



Drug Development Manufacturing Difficulties – Direct Quotes

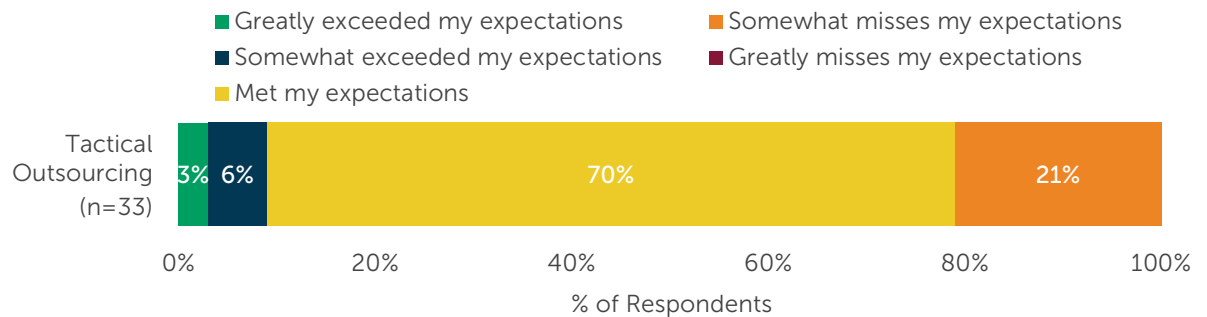


Length of lead time to manufacture and length of manufacturing time

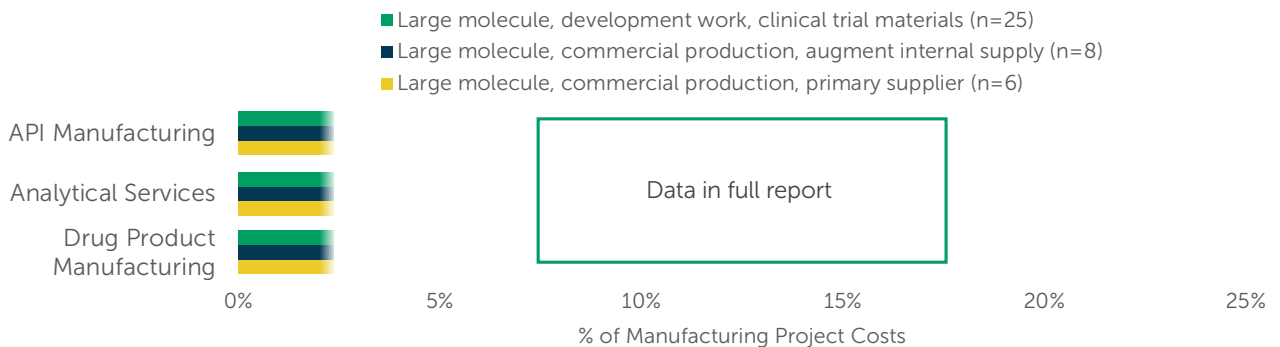


Managing multiple CMOS and maintaining consistent quality and compliance standards as well as managing the business relationships

Outsourcing Model Performance vs Expectations – Commercial Manufacturing



Large Molecule Costs by Activity





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UNDERSTAND YOUR MARKETS

Leverage ISR's experience and institutional knowledge to create a fit-for-purpose market research project that addresses the business decisions you need to make.

Are you:

- Developing a new product or service?
- Evaluating a new market?
- Targeting a new customer segment?
- Entering a new geography?
- Needing a deeper understanding of your customer or potential customer base?

UNDERSTAND YOUR CUSTOMERS

Who makes the decisions and in what contexts? ISR can help you gain a deeper understanding of your customers' decision-making units (DMUs) and decision-making processes (DMPs).

Key Questions Addressed:

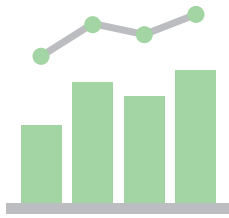
- What motivates the purchase decision?
- How are companies, products, solutions, and/or brands evaluated?
- What factors drive the final buying decision?
- Where are your customers won or lost in the purchasing process?
- Why were specific opportunities won or lost?
- How do you keep customers engaged and manage their loyalty over time?

CUSTOM RESEARCH SERVICES

- Investigator Forum
- Brand, Advertising, and Message Testing
- Loyalty Management
- New Product and Service Development
- Competitive Intelligence
- Strategy War Games
- MORE

6 Questions to Ask About your Market Research

How do you know the research products and services you buy will give you confidence in the decisions you make? Here is how Industry Standard Research ensures you are getting the value you should expect from quality market research.



1. WHEN WERE THE DATA COLLECTED?

This should be the first question someone asks you during a presentation and saying “I don’t know” doesn’t sound so good. Whether in custom research or our syndicated library, ISR collects up-to-date data relevant to the project at hand and we tell you when the data were collected.



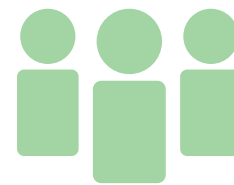
3. WHAT IS THE RESPONSIBILITY PROFILE FOR THE PARTICIPANTS?

Knowing how many people participated in the research is one thing, knowing they are decision-makers is quite another. Nothing stops a presentation faster than senior management questioning the fundamental basis of your research. Confidently present the research findings because you know that ISR collected data from decision-makers.



5. WHO SPONSORED THE RESEARCH?

We are an independent, third-party data source. We provide clean, unbiased data and clean data means you can confidently stand behind your analysis, presentation, and recommendations. Also, when we do a custom piece of research, your data is your data—you won’t see it anywhere else, ever.



2. HOW MANY PEOPLE PARTICIPATED IN THE RESEARCH?

Understanding your margin of error allows for better expectation setting, making you more likely to hit your performance metrics. ISR ensures our studies reach the correct sample size needed for accurate analysis.



4. WHERE DID THE PARTICIPANTS COME FROM?

Eliminating sample bias translates into accurate information and improves service quality by ensuring your decisions are the right ones. ISR’s Health Panel provides an array of participant profiles from within the pharmaceutical industry ecosystem. If we need outside panels (e.g. physician, patient, pharmacist, payer), we will use them, no questions asked.



6. WHAT IS THE BACKGROUND OF THE ANALYST WHO MANAGED THE PROJECT AND REPORT?

ISR offers experienced analysts with hands-on industry knowledge. Our analysts will produce insights that you can quickly turn into fit-for-purpose recommendations for your organization.