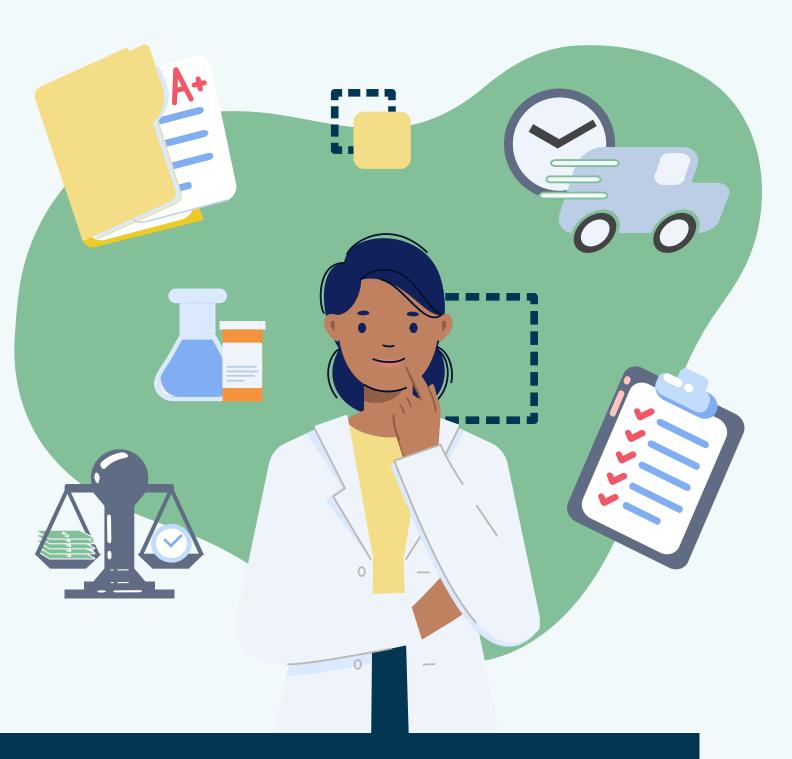


Pharmaceutical Market Research



How Market Research Can Inform CDMO Selection



Are you part of the pharmaceutical space?

Join the industry's leading clinical development and drug manufacturing research panel – The ISR Health Panel!

Participate in research – ISR conducts research through carefully crafted surveys and qualitative interviews in the pharma space. We do yearly benchmarking studies and run research on topics ranging from clinical operations/technology to outsourcing practices, from drug development to commercialization.

Honorariums and charitable donations – Each time you participate in one of our research projects, you will receive a cash stipend or, if you choose, your stipend can be donated to charity. In addition to your honorarium, ISR will donate a predetermined amount to charity.

Stay ahead with industry data – Each quarter we'll send you a newsletter that details exclusive findings from recent projects.



About Industry Standard Research (ISR)

The pharmaceutical industry needs higher-quality market research. We fill that need.

ISR's industry reports utilize primary research methodology, which enables us to offer novel insights into the drug development space. We leverage years of industry experience and a global proprietary Health Panel of over 3,000 healthcare and pharmaceutical professionals to provide our customers with endless innovative possibilities.

This market research is available off-the-shelf in the form of our syndicated reports, but we also frequently take on custom research projects to help drug developers and service providers make data-driven decisions with their B2B partnerships, identify new market opportunities, and stay ahead of the competition.

We host several free resources on our website as well, covering topics such as CDMO and CRO selection, clinical development, drug manufacturing, eClinical technology, decentralized trials, the cell & gene market, and more.

What makes ISR different?

We understand that you're looking for confidence in your market research. With ISR, you'll consistently receive:

Focused Domain Expertise — We've operated in pharmaceuticals for over 15 years and because it's our sole focus, our domain expertise brings value to the work that "generalist" researchers can't deliver.

Genuine Research Expertise — Our market research experience has developed over 20 years in many dynamic industries. We capture appropriate sample sizes, given the research objectives, and we use appropriately sophisticated statistics to uncover everything that's real and to give you confidence in your decisions.

Transparency — If you're like many, you've been disappointed more than once by research providers who fail to live up to their promises, providing you with their "professional judgment" in place of sound data and suspect contacts instead of real decision makers. We deliver the opinions, attitudes, and recommendations of industry experts – and we'll prove it by sharing detailed demographics in our reports.

For additional questions about any of our reports or custom research services, please contact us at info@ISRreports.com.



Smarter questions : Smarter answers

How Industry Benchmarks **Can Inform CDMO Selection**

BRANDON ALLISON

hoosing to partner with a service provider can be among the most consequential decisions that a company makes. The outsourcing process is especially impactful for the biopharmaceutical industry, as drug innovators work across the globe to ensure much needed treatments are successfully managed from discovery to commercialization. To do so, they invariably rely on external companies at different parts of the process, such as partnering with contract development and manufacturing organizations (CDMOs) to augment or even completely support their manufacturing needs.

Drug manufacturing is an ever-changing landscape. To catalogue and understand its evolution. Industry Standard Research (ISR) annually conducts CDMO benchmarking research to ask biopharmaceutical sponsors what they look for in a manufacturing partner. This eBook explores some of the key findings of ISR's primary market research to inform the broader drug development community of the latest trends in sponsor outsourcing behavior.

The first article, "How Industry Benchmarks Can Inform CDMO Selection," offers to alleviate the burden of CDMO selection and explores the key attributes sponsors value in a provider across four manufacturing areas. By leveraging benchmark data, both CDMOs and drug innovators can optimize their strategies and ensure each other's needs are met. These data also present an opportunity to understand and align with what sponsors prioritize the most in their partnerships.

Next, "Tracking the Evolution of CDMO Selection Criteria for Biologic Drug Substance Manufacturing" hones in on trends within the biologic API manufacturing area. Explore the "Most Important" selection attributes in this subset and how outsourcers' responses have varied over a three-year period. By understanding what their peers value most, other drug innovators can compare their own internal priorities and make the best decisions with regard to outsourced biologic API manufacturing.

"Have CDMO Selection Criteria Changed Over The Past Five Years?" examines ISR's findings across a broader span of time, from 2017 to 2022. It describes how selection attributes have shifted in terms of importance and how those attributes form the basis for the CMO Leadership Awards. These accolades are awarded to CDMOs that have exceeded their customers' expectations, helping to simplify the selection process for sponsors and allowing CDMOs to understand their own performance, as well as that of their competitors.

The infographic "Biologic And Small Molecule Drug Substance CDMO Selection Metrics Align" offers a glimpse of the Top Five and Number One selection attributes respondents find "Most Important" when considering a provider. It shows notable similarities between these two manufacturing areas; four of the Top Five metrics sync up between large and small molecule outsourcers.

Finally, "Outsourcers Are Feeling Uneasy About Continuity of Supply" outlines how the COVID-19 pandemic complicated the small molecule and biologic drug product manufacturing processes. Obstacles that arose during that globally shared experience, such as manufacturing delays, continue to persist today, albeit for different reasons than the pandemic alone. Supply chain challenges have caused sponsors to reconsider their selection criteria, one of the many nuanced shifts that companies operating in this space must keep an eye on to be successful.

CDMOs are crucial to this industry, and ISR aims to support manufacturers and drug innovators alike through high-quality, actionable market research. Their trustworthy benchmark data is backed by rigorous methodology and uncovers the unique perspectives of biopharmaceutical professionals, highlighting the strengths and weaknesses of CDMOs that respondents have partnered with. ISR's research offers valuable perspective to outsourcing decisionmakers while helping CDMOs better understand sponsor needs to improve their marketing and operational strategies. To explore the latest benchmarking studies and learn how market research tools can benefit your organization, visit isrreports.com. **1**SR

About The Authors



LAURA MCWHINNEY

Market Research Manager, Industry Standard Research

Laura is a Market Research Manager at Industry Standard Research with 10 years of experience as a communication and marketing professional. She uses her experience in qualitative and quantitative methodologies, along with data analytics to support custom and syndicated research for both contract manufacturer and clinical research clients. Laura earned her bachelor's from Brigham Young University and two master's degrees from the University of Wyoming, in communications and statistics. Passionate about learning, she is graduating this year from Virginia Tech with a third master's in information technology with a certificate in business data analytics.



JENN HOLLOWAY

Market Research Director, Industry Standard Research

Jenn brings over a decade of experience in quantitative and qualitative methods to her role as Market Research Director at ISR. She has successfully designed and executed a variety of research strategies, from multi-year longitudinal studies for federal agencies to custom quick-turn efforts for private equity clients and global consultancies. In addition to studying biomedical engineering as an undergraduate at the University of Virginia, Jenn completed a graduate-level survey design and data analysis program at George Washington University. Her work at ISR focuses on the drug development and manufacturing service provider market.



KATE HAMMEKE

Vice President of Market Research, Industry Standard Research

Kate Hammeke has been working in cross-industry market research for roughly 20 years, with 13 years of CDMO market research and market strategy consulting experience. Her research has informed the CDMO Leadership Awards since its inception. Kate leads the contract manufacturing market research division at Industry Standard Research by overseeing both the syndicated and custom research projects for drug innovator and contract manufacturer clients. Kate has developed and coordinated custom research projects for more than 50 major brands in the Fortune 500. Using her industry knowledge, Kate has written dozens of articles related to pharmaceutical outsourcing for numerous industry publications, including as a regular contributor to Life Science Leader.

Welcome to

Industry Standard Research

HOW MARKET RESEARCH CAN INFORM CDMO SELECTION

@ISRreports

in linkedin.com/company/ISRreports

ISRREPORTS.COM

7 Supplier Evaluation

HOW INDUSTRY BENCHMARKS CAN INFORM CDMO SELECTION

Biopharmaceutical sponsor considerations when selecting a CDMO may include timelines, cost, regulatory requirements, capacity, quality, risks, and previous experience. To help sponsors better understand and prioritize development and manufacturing elements, ISR conducts four annual, manufacturing-specific benchmark studies that ask professionals in the biopharmaceutical sphere about their experiences with CDMOs.

Selection Criteria

TRACKING THE EVOLUTION OF CDMO SELECTION CRITERIA FOR BIOLOGIC DRUG SUBSTANCE MANUFACTURING

Biologic drug substance developers face an ever-evolving slate of challenges related to CDMO outsourcing.

17 Trends

HAVE CDMO SELECTION CRITERIA CHANGED OVER THE PAST FIVE YEARS?

The outsourced manufacturing space continues to evolve each year. New relationship dynamics between sponsors and CDMOs contribute to new trends appearing in the activities and services outsourced as well as the way CDMO selection decisions are made.

15 CDMO Benchmarking

BIOLOGIC AND SMALL MOLECULE DRUG SUBSTANCE CDMO SELECTION METRICS ALIGN

ISR's annual CDMO Benchmarking research asks participants to identify the CDMO attributes that factor into their service provider selection decision.

16 Industry Concerns

OUTSOURCERS ARE FEELING UNEASY ABOUT CONTINUITY OF SUPPLY

Outsourcers relayed pandemic related complications increased from 2020 to 2021. How have these obstacles influenced CDMO selection?

How Industry Benchmarks **Can Inform CDMO Selection**

LAURA MCWHINNEY Market Research Manager, Industry Standard Research

@ISRreports

Biopharmaceutical sponsor considerations when selecting a CDMO may include timelines, cost, regulatory requirements, capacity, quality, risks, and previous experience. To help sponsors better understand and prioritize development and manufacturing elements, ISR conducts four annual, manufacturing-specific benchmark studies that ask professionals in the biopharmaceutical sphere about their experiences with CDMOs.

espondents evaluate suppliers they have worked with in the past 18 months on 23 performance metrics, which include attributes related to company strengths, capabilities, staff characteristics, services, and more. Performance benchmarking (a market research tool) can help to make CDMO selection less arduous.

Every year, ISR asks respondents which attributes are among their "Top Five" in CDMO selection, which attribute is "Most Important," and which attribute is gaining in importance across the four manufacturing areas (i.e., biologic API, biologic drug product, small molecule API, and small molecule drug product). In 2022, the Most Important attributes varied, but the attribute gaining in importance was shared across all four benchmarks (Fig. 1).

While biopharmaceutical professionals selected four different attributes as "Most Important,"

across the four manufacturing areas, it is not hard to see how these attributes correspond with one another. ISR sees this trend every year, with the "Most Important" trait varying but the proportions between attributes not changing significantly. In other words, it is not likely that just one attribute is selected as "Most Important" by a large margin, nor do we see any attributes omitted.

In the 2022 Small Molecule Drug Product CDMO Benchmarking, ⁴ 13% of respondents chose a CD-MO's track record for meeting quality performance metrics as the Most Important selection driver. In 2021, the "Most Important" attributes comprised a three-way tie: *Low cost, Prior positive experience,* and *Ability to smoothly scale up manufacturing.* While each of those criteria fell in ranking in 2022, each remained in the top 10. On the other hand, all benchmarks indicated that respondents see *Reliable on-time delivery* as the attribute gaining importance.

HOW MARKET RESEARCH CAN INFORM CDMO SELECTION

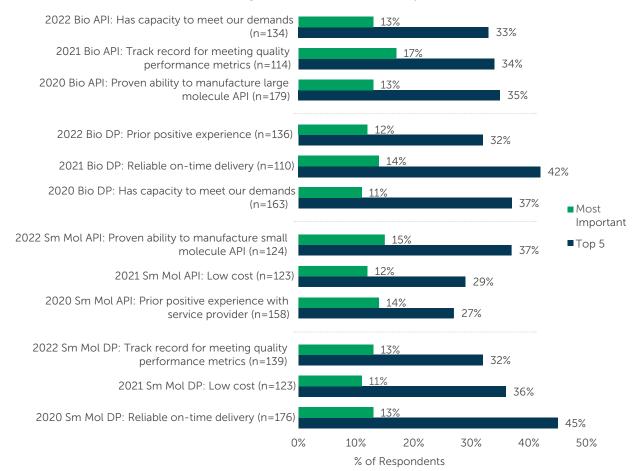
Figure 1: Most Important CDMO Selection Metrics and Attributes Gaining Importance

	Bio API 2022 ¹	Bio DP 2022 ²	Sm Mol API 2022 ³	Sm Mol DP 2022
Most Important attribute	Has capacity to meet our demands (13%)	Prior positive experience (12%)	Proven ability to manufacture small molecule API (15%)	Track record for meeting quality performance metrics (13%)
Attribute gaining importance	Reliable on-time delivery (27%)	Reliable on-time delivery (29%) [tied with Has capacity to meet our demands]	Reliable on-time delivery (36%)	Reliable on-time delivery (30%)

HOW MARKET RESEARCH CAN INFORM CDMO SELECTION ISRREPORTS.COM

Figure 2: Year on Year Most Important CDMO Selection Metrics

"Please review the following attributes and select the [five/one] Most Important to you when selecting a provider for [biologic API/biologic drug product/small molecule API/ small molecule drug product] manufacturing services." (n=listed with study, as it varied)



So how have those trends evolved over the past three years (2020 to 2022)? Four areas stand out as the highest priorities for biopharma sponsors when choosing a CDMO: low cost/affordability, capacity to meet demands and/or the ability to manufacture the specific drug component, and timeliness (Fig. 2).

All things considered, the past three years have been unique, tumultuous, and marked by unusual challenges. The biopharma industry has been and, in many cases, continues to be - impacted by supply chain issues, unemployment, people leaving their jobs, the general disruption of work (e.g., shifting to remote work and back again), plus any number of other factors. Whether on-time delivery or prior positive experience was stated as Most Important by benchmarking respondents, the end message is clear: biopharmaceutical professionals value an affordable, on-time, quality result.

CDMO selection is not an easy process. ISR aims, through our benchmarking reports asking biopharmaceutical professionals about their recent experiences, to alleviate some of that burden. To explore the most recent benchmarking studies and to learn more about how market research tools can serve your organization, visit isrreports.com. **IS**

RESOURCES

1 Biologic API CDMO Benchmarking, 2022: https:// isrreports.com/reports/2022-biologic-api-cdmobenchmarking

2 Biologic Drug Product CDMO Benchmarking, 2022 https://isrreports.com/reports/2022-Biologic-Drug-Product-CDMO-Benchmarking

3 Small Molecule API CDMO Benchmarking. 2022:https://isrreports.com/reports/2022-Small-Molecule-API-CDMO-Benchmarking

4 Small Molecule Drug Product CDMO Benchmarking, 2022: https://isrreports.com/reports/2022-Small-Molecule-Drug-Product-CDMO-Benchmarking

GBBGGGOON GRODERDA

BIOLOGIC DRUG SUBSTANCE

Tracking The Evolution Of **CDMO Selection Criteria For Biologic Drug Substance Manufacturing**

JENN HOLLOWAY Market Research Director, Industry Standard Research



Biologic drug substance developers face an ever-evolving slate of challenges related to CDMO outsourcing. As part of ISR's CDMO Benchmarking research, respondents are asked to review a list of 28 selection attributes and to identify the one criterion "Most Important" to them when choosing a provider for biologic drug substance manufacturing services. This year, survey participants primarily came from large (R&D \$1B+) or midsize (R&D \$100M - \$999M) biopharma companies across North America and Western Europe.

ear-over-year variation always exists in the selection criteria respondents prioritize in an outsourced manufacturer. However, five metrics have exhibited the most noteworthy trends since the start of the decade (2020-2023): of these, Low cost, Experience level of staff, and Provides regulatory support for filing have become less important to outsourcers over the past three years, while Has capacity to meet our demands and Reliable on-time delivery have risen in priority.

TRENDING UP

Outsourcers are increasingly concerned about their service provider's ability to deliver on time, in full (OTIF). Reliable on-time delivery and Has capacity to meet our demands rose from the eighth and seventh "Most Important" attributes sought by study respondents in 2020 to first and second, respectively, in 2023 (Fig. 1).

Faced with numerous lingering pandemic-related challenges, outsourcers are keen to work with CDMOs that deliver the contracted amount of biologic drug substance in a timely manner. Each year, ISR surveys drug innovators who have outsourced biologic drug

substance manufacturing within the last 18 months. Respondents then rate their CDMO's performance on 22 attributes across five main categories: Delivery Factors, Organization Factors, Capabilities, Staff Characteristics, and Service Capabilities. The latest findings, as well as detailed company Service Quality Profiles for providers with 10 or more ratings, are included in the Biologic API CDMO Benchmarking (8th Edition) report.

TRENDING DOWN

Despite being ranked the second "Most Important" selection attribute in 2020. Low cost has fallen to seventh place over the last three years (Fig. 2). On average, outsourcers may be willing to pay more to ensure their biologic drug substance is manufactured on time, selecting providers based on the value of their services, rather than awarding contracts based on low cost alone.

Additionally, Provides regulatory support for filing, which often falls outside the 10 "Most Important" provider attributes named by study respondents, appears to be slipping even further as a CDMO selection consideration relevant to biologic drug substance manufacturing: the criterion dropped from 13th in 2020 to 24th in 2023. This may

HOW MARKET RESEARCH CAN INFORM CDMO SELECTION

ISRREPORTS.COM

ISRREPORTS.COM

HOW MARKET RESEARCH CAN INFORM CDMO SELECTION

Figure 1

Biologic Drug Substance CDMO Selection Attributes
Trending More Important Over Time

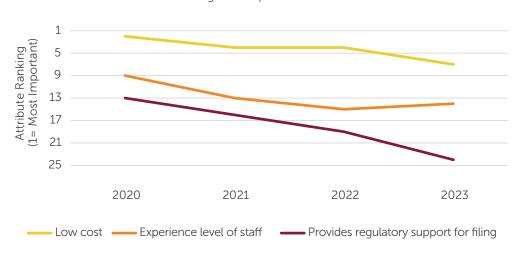


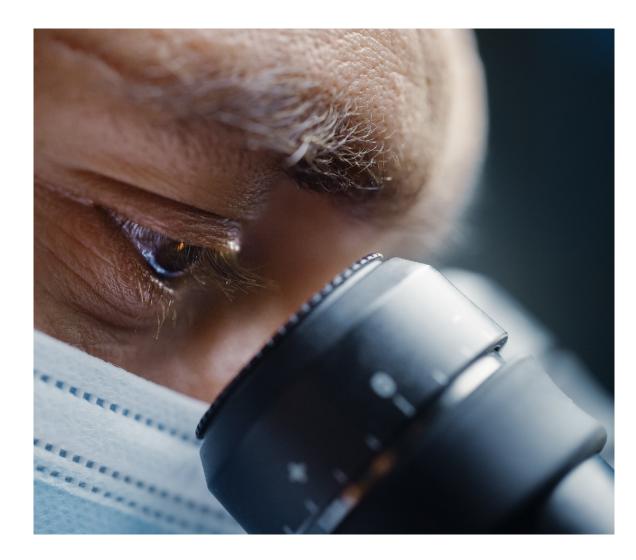
be due to sponsors outsourcing this service adhoc to specialized consultants or through a functional service provider (FSP) model, rather than requiring their primary manufacturing provider to perform the function. Furthermore, declining need for regulatory support may be indicative of investment by larger biopharma companies to grow their internal expertise.

Experience level of staff has also declined in importance as a CDMO selection criterion in recent years (Fig. 2). Though consistently ranked among the top 10 "Most Important" selection attributes pre-pandemic, staff experience ranked 15th and 14th, respectively, in the 2022 and 2023 surveys. Drug developers appear to care more about the ability to complete the job and less about the

Figure 2

Biologic Drug Substance CDMO Selection Attributes
Trending Less Important Over Time





role-specific experience of the CDMO's personnel — perhaps an acknowledgment that turnover and staffing challenges are an issue for many service providers (i.e., role-specific experience may not currently be a reliable differentiator). Moreover, expertise among staff is conceivably less critical now than it was in the early days of biologics development. CDMOs have continued to improve and standardize their organization-wide processes for biologic drug substance manufacturing over the past decade, providing a more structured framework for less-experienced staff to leverage to successfully execute job functions.

CONCLUSIONS

As biologics continue to comprise a growing share of FDA approvals, CDMOs would be wise to understand and address patent holders' frustrations

with drug substance manufacturing activities. Outsourcers responsible for provider selection seek partners who can reliably deliver OTIF and appear to be deprioritizing staff experience and one-off services (e.g., regulatory support) in the evaluation process. It remains to be seen how record inflation may impact drug developers' opinions on the importance and impact of biologic drug substance manufacturing costs going forward. 188

The trends identified here are based on four years of data from CDMO Benchmarking surveys and are not intended to project future results. The data are based on average aggregate findings and may not reflect nuanced variation based on company size, respondent location, or phase of biologic drug substance manufacturing.

HOW MARKET RESEARCH CAN INFORM CDMO SELECTION ISRREPORTS.COM HOW MARKET RESEARCH CAN INFORM CDMO SELECTION

Have CDMO Selection Criteria **Changed Over The Past Five Years?**

KATE HAMMEKE Vice President of Market Research, Industry Standard Research

The outsourced manufacturing space continues to evolve each year. New relationship dynamics between sponsors and CDMOs contribute to new trends appearing in the activities and services outsourced as well as the way CDMO selection decisions are made. One thing that has remained constant is the goal of the CMO Leadership Awards: to help simplify the complex and time-consuming process of choosing and qualifying a contract manufacturer.

or those of you new to the biopharmaceutical outsourcing environment, or simply new to the CMO Leadership Awards, I'd like to share some background information on the data and how they are collected. The CMO Leadership Awards are the result of feedback obtained through four different surveys about outsourced manufacturing activities. There is one each for biologic API, biologic drug product, small molecule API, and small molecule drug product. The research is conducted by Industry Standard Research (ISR), a full-service market research provider to the biopharmaceutical and biopharma services industries.

To take part in the quantitative research, invitees are screened for decision-making influence and authority and questioned about their areas of expertise. Participants are then routed to the surveys that match their credentials. This data collection method gathers feedback on a detailed service level, which is available in ISR's CDMO Benchmarking Reports, and is then aggregated to a company level for the CMO Leadership Awards. The awards are experience-based and recognize contract manufacturers that exceed customer expectations across their entire service offering.

In the surveys, respondents evaluate suppliers they have worked with in the past 18 months on 23 performance metrics, which in-

clude attributes related to company strengths, capabilities, staff characteristics, services, and more. These attributes form the basis of the six main award categories: Capabilities, Compatibility, Expertise, Quality, Reliability, and Service. Each award category is composed of four to six performance metrics that help prospective buyers understand how a CDMO has fulfilled its services for current and recent customers relative to their expectations. The 2022 awards reflect 1,697 service encounters with more than 85 contract manufacturers. ISR aggregated these data to establish the industry averages for each award category. Individual CDMO's scores are then compared to the industry average in each category, as well as in each respondent group breakout, to identify win-

Before asking sponsors to evaluate the service providers with whom they have recently worked, the surveys ask participants about the CDMO selection process at their organization and which contract manufacturer characteristics factor into their decision. Respondents are provided a list of 28 different CDMO characteristics and asked to select the five Most Important when choosing a manufacturing supplier as well as the single Most Important selection criterion. Among these characteristics are the 23 performance metrics and other traits such

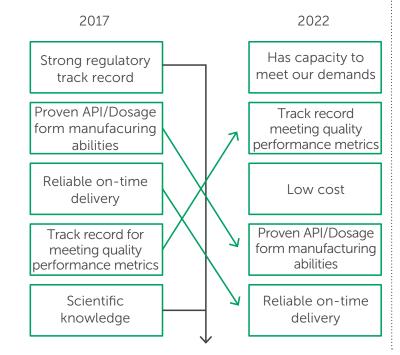
as affordability, the financial stability of the organization, and having a positive prior experience with the supplier.

As the CMO Leadership Awards move into their 11th year, we thought it would be interesting to take a look back and see whether sponsors' selection criteria have changed — either in the attributes sought out in a supplier or in their prioritization of those attributes with regard to choosing a provider — over the past five years. To do this, we compared the responses from the 2017 research to the current results.

DIFFERENT MEMBERS OF THE CDMO DECISION-MAKING GROUP HAVE DIFFERENT PRIORITIES

Consistent with prior years, the 2022 data from this question show a handful of attributes being identified as the "Most Important" by about 10% of respondents, and then a further dispersion of votes such that a dozen attributes are deemed the "Most Important" for 1%-2% of respondents. This pattern reminds us of two important points. First, that different members of the decision-making unit involved in the selec-

TOP CDMO SELECTION ATTRIBUTES



tion process have different priorities, and second, there is no single trait at which a contract manufacturer can excel and be guaranteed to win business. The leading selection attribute from both the "Top Five" and "Most Important" perspectives for 2022 is Has capacity to meet our demands," capturing 41% of respondents' votes as a Top Five selection criteria and 11% of respondents' votes for Most Important. Comparing this attribute's position to the 2017 data, one can surmise it has become more important over the past five years, rising from sixth position to number one.

Landing in second place this year (ranking is tied to the proportion of votes received for the "Most Important" CDMO selection criterion) is a CDMO's Track record for meeting quality performance metrics, earning 28% of respondents' Top Five selection criteria, and 10% (9.75 to be precise) of respondents deemed it to be the Most Important. This characteristic earned a similar proportion of votes as it did five years ago (28% and 9%, respectively); however, it has improved its ranked order by moving from fourth position in 2017 to second in 2022. Capturing the third highest percentage of votes is Low cost. Thirty-two percent of respondents included this characteristic in their Top Five selection criteria and 10% (9.55 to be precise) indicated Low cost is the Most Important CDMO selection criterion. This is another upward move when compared to the 2017 data where Low cost landed in seventh position. A CDMO's Proven ability to manufacture API/ Full range of manufacturing for the dosage forms we require (depending on whether drug substance or drug product is being outsourced) captured the fourth highest number of votes for the Most Important CDMO selection criterion at 9% and is among 40% of respondents' Top Five selection criteria. Interestingly, this attribute received the same proportion of Top Five votes in 2017, but had a higher percentage of Most Important votes, at 11%, which earned it second position in the past. Securing fifth position for Most Important CDMO selection attribute in 2022 is Reliable, on-time delivery. This attribute was narrowly edged out by Proven ability.../Full range... by a fraction of a percentage point, earning 8.73% of respondents' votes

HOW MARKET RESEARCH CAN INFORM CDMO SELECTION

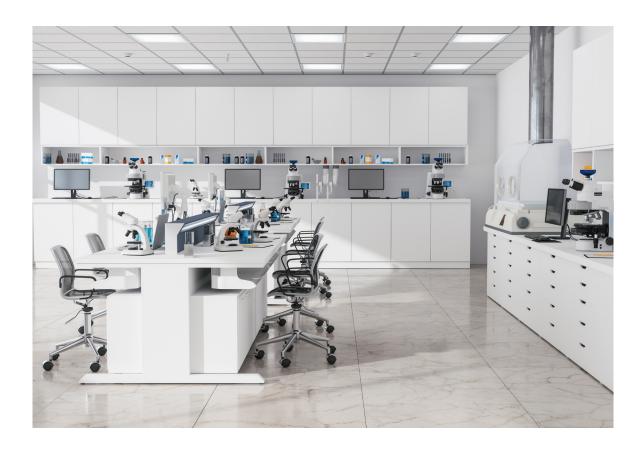
for the Most Important selection attribute; it also secured 40% of respondents' Top Five selection attributes. Reliable, on-time delivery is another attribute to have dropped slightly over the past five years, having earned third position in 2017.

With two attributes earning top rankings in 2022 that were not in first through fifth place in 2017, it is important to share which attributes have been bumped out. Taking first place in 2017 (and landing in seventh in 2022) is Strong regulatory track record. Five years ago, 12% of respondents indicated it was their Most Important selection criterion, and in 2022, 7% percent of respondents reported the same. The other attribute to lose ground in its ranking is Scientific knowledge, which held fifth position in 2017 and fell to 11th place in the 2022 research.

To tie this information back to the CMO Leadership Awards, the award categories that correspond with the top selection metrics for 2022 are: Reliability, Quality, and Capabilities. 198 **Survey Methodology:** Industry Standard Research's Contract Manufacturing Quality Benchmarking research is conducted annually via online surveys. For the 2022 CMO Awards data, more than 85 contract manufacturers were evaluated on 23 different performance metrics. Research participants were recruited from biopharmaceutical companies of all sizes and screened for decision-making influence and authority when it comes to working with contract manufacturing suppliers. Respondents only evaluate companies with which they have worked on an outsourced project within the past 18 months. This level of qualification ensures that quality ratings come from actual involvement with a business and that companies identified as leaders are backed by experiential data.

This article pulled data from the following reports:

- Biologic API CDMO Benchmarking (2nd and 7th Ed.)
- · Biologic Drug Product CDMO Benchmarking (1st and 5th Ed.)
- Small Molecule API CDMO Benchmarking (7th Ed.)
- · Small Molecule Drug Product CDMO Benchmarking (1st and 5th Ed.)



Biologic And Small Molecule Drug **Substance CDMO Selection Metrics Align**

ISR's annual CDMO Benchmarking research asks participants to identify the CDMO attributes that factor into their service provider selection decision. Four out of five of the top metrics sync up among drug substance outsourcers for biologics and small molecules. However, among large molecule outsourcers, a *Track record for meeting quality performance metrics* made the Top Five but landed in 8th position among small molecule outsourcers. Conversely, small molecule outsourcers prized a *Proven ability to manufacture small molecule API* while this attribute ranked 6th for biologic outsourcers.

"Please review the following attributes and select the five most important to you when selecting a provider for [biologic/small molecule] drug substance contract manufacturing services."

"Among the following attributes, please select the one most important to you when selecting a provider for [biologic/small molecule] drug substance contract manufacturing services."

Small Molecule API	Top Five	Number One
Proven ability to manufacture small molecule API	37%	15%
Has capacity to meet our demands	44%	10%
Reliable on-time delivery	40%	10%
Strong regulatory track record	40%	10%
Low cost	35%	9%
Biologic API	Top Five	Number One
Biologic API Has capacity to meet our demands	Top Five	Number One
Has capacity to meet our demands	33%	13%
Has capacity to meet our demands Track record for meeting quality performance metrics	33% 32%	13% 10%

HOW MARKET RESEARCH CAN INFORM CDMO SELECTION ISRREPORTS.COM ISRREPORTS.COM HOW MARKET RESEARCH CAN INFORM CDMO SELECTION

Outsourcers Are Feeling Uneasy About Continuity Of Supply

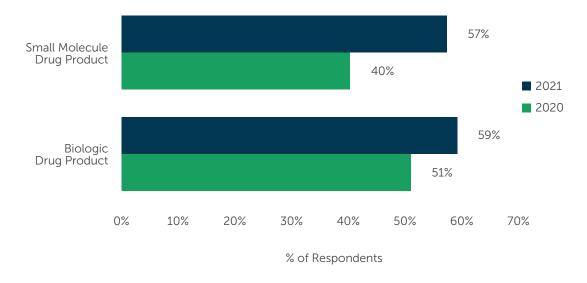
KATE HAMMEKE Vice President of Market Research, Industry Standard Research

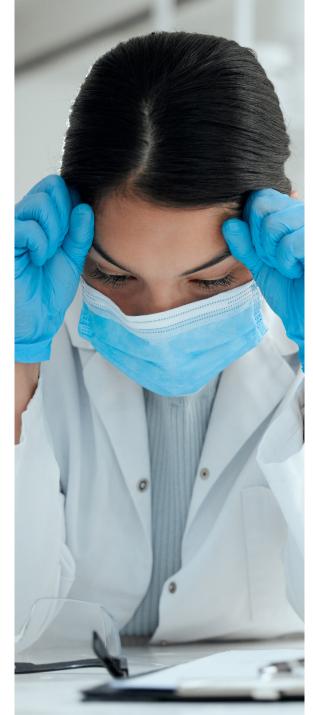
Outsourcers relayed pandemic related complications increased from 2020 to 2021. *How have these obstacles influenced CDMO selection?*

oncerns are particularly strong among drug product outsourcers for both small molecules and biologics. In fact, when reviewing the responses from Industry Standard Research's annual CDMO Benchmarking research, where ISR asked about how the pandemic has impacted outsourced manufacturing, the data show proportionally more outsourcers were impacted in 2021 than in 2020. Among small molecule drug product outsourcers, 40% confirmed their company experienced manufacturing complications tied to the pandemic during 2020. One year later, 57% of small molecule drug product outsourcers said the same, an increase of 17 percentage points. On the biologic side of drug product manufacturing, in 2020, 51% of respondents confirmed manufacturing complications as a result of the pandemic. In 2021, that figure increased by eight percentage points to 59% of respondents.

Counter to my initial thinking — that it would take just one year before we would all be better prepared to deal with the ripples caused by the staff shortages at manufacturing facilities - a variety of new concerns that negatively impact continuity of supply have cropped up. A key challenge among respondents from both

PANDEMIC RELATED MANUFACTURING COMPLICATIONS





groups is facing manufacturing delays, mentioned by 42% of small molecule respondents and 38% of biologic respondents. The delays are in part due to some of the same obstacles that slowed manufacturing in 2020, such as "facility

shutdown and project delays due to COVID-19 infection amongst employees," but delays were also brought on by complications outside of the immediate control of the CDMO: "mainly complications [with] the raw materials and consumables supply constraints."

IT'S NOT JUST A FILL-FINISH CAPACITY SHORTAGE

Material shortages for plastics and staff shortages at couriers affecting whether the materials could be transported are on top of "the slowdown in manufacturing at the height of the pandemic from which there has been recovery, but not complete thus far." In addition to the complications directly related to manufacturing either at the CDMO or due to raw materials shortages, there are also challenges well outside of the biopharma industry that popped up. Staff shortages at customs slowed international deliveries, as did personnel shortages at ports where cargo ships could not be unloaded. Shipping container shortages and a cargo ship blocking the Suez Canal may not have directly affected the delivery of biologic medicines, but they did slow the delivery of secondary and tertiary supplies needed to successfully meet the supply needs of drug developers.

In some cases, supply chain delays have forced a change in thinking about drug development and manufacturing, in particular single-use supplies. These obstacles "required us to change some aspects and become very fluid in certain aspects, including potentially reusing items we previously used as single use only and having contractors try different manufacturing techniques where needed." These complications reinforce the need for a flexible CDMO that can adapt to changing timelines and focus on solutions when presented with challenges.

How are COVID-19 manufacturing challenges changing the way sponsors engage CDMOs? First off, outsourcers have revamped their CDMO selection criteria and moved up the following in importance during the past year: Has capacity to meet our demands and Reliable, on-time delivery. When looking at how drug-product outsourcers choose CDMOs, the data show that more than 40% of respondents have these two attributes in their top selection metrics. 15R

ISRREPORTS.COM HOW MARKET RESEARCH CAN INFORM CDMO SELECTION ISRREPORTS.COM HOW MARKET RESEARCH CAN INFORM CDMO SELECTION

Six Questions to Ask About Your Market Research

How do you guarantee the research you buy will give you confidence in your decisions? Here's how we ensure you're getting the value you should expect from quality market research.



How Many Participants Take the Study?

Understanding your margin of error gives you accurate expectations, making you more likely to hit your performance metrics. We provide a vast sample of participants from our proprietary Health Panel to make sure our studies reach the correct number of participants needed for accurate analysis.



When Were the Data Collected?

This should be the first question you receive during a presentation and saying "I don't know" doesn't sound so good. In all our research products, we collect up-to-date data relevant to the project at hand.



What is the Responsibility Profile for the Participants?

Nothing stops a presentation faster than management questioning the basis of your research. Confidently project the research knowing that we pull information from key decision makers.



Where Did the Participants Come From?

Eliminating sample bias translates into accurate competitive information and improves service quality by ensuring your decisions are the right ones. Our Health Panel provides an array of participants from all company sizes within the pharmaceutical industry.



Who Sponsored the Research?

We're an independent, third-party data source. We provide clean, unbiased data and clean data means you can confidently stand behind your analysis and presentations.



What is the Background of the Analyst Who Managed the Project and Reporting?

We have experienced analysts with hands-on industry knowledge. Their insights can quickly be turned into fit-for-purpose recommendations for your organization.