

## 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. 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.

For 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 biologics API, biologics 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.

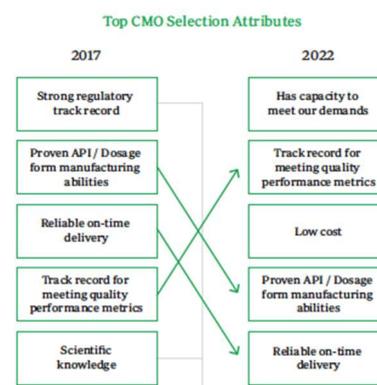
In the surveys, respondents evaluate suppliers they have worked with in the past 18 months on 23 performance metrics, which include attributes related to company strengths, capabilities, staff characteristics, services, and more. These attributes form the basis of the six main award categories: Capabilities, 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 winning CDMOs.

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 questionnaire 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 selection 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 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

**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 (7<sup>th</sup> Ed.)
- Biologic Drug Product CDMO Benchmarking (5<sup>th</sup> Ed.)
- Small Molecule API CDMO Benchmarking (7<sup>th</sup> Ed.)
- Small Molecule Drug Product CDMO Benchmarking (5<sup>th</sup> Ed.)

Reference:

[Have CDMO Selection Criteria Changed Over the Past Five Years \(pharmaceuticalonline.com\)](https://www.pharmaceuticalonline.com/2017/05/23/have-cdm-selection-criteria-changed-over-the-past-five-years/)