OUTSOURCED PHARMA

Sterile Injectable Drug Product Manufacturing

Market Overview and Outlook:
A Look at Non-Large Biopharma

February, 2021

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Analysis Note: Outsourcing Requirement

In order to participate in this market research study, it was a requirement for a respondent's company to **outsource sterile injectable manufacturing**. Therefore, the data in this report should not be interpreted as industry-wide outsourcing rates for non-large biopharma companies, rather these are aggregate rates specific to the outsourcing community within the industry. Again, this sample of non-large biopharma companies **does not include** companies that conduct all sterile injectable drug product manufacturing in-house.

Introduction

How are non-large biopharma companies navigating the world of sterile injectable drug product manufacturing? This report brings you one step closer to learning the answer to that question. Industry Standard Research originally surveyed a variety of respondents involved in the outsourcing of this type of manufacturing. We learned quickly that their manufacturing practices, CMO use, and future plans vary by company size. And we know drug innovators and CMOs alike are interested in knowing these differences in more detail.

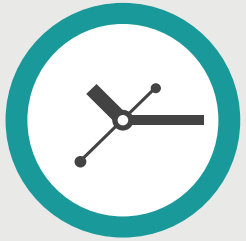
Current demand for sterile injectable drug product manufacturing is fed by multiple dynamics – why an injectable is needed in the first place, biologic vs small molecule demands, and the gradual decline of in-house manufacturing, among others. Indeed, one major reason non-large biopharma companies outsource is this: 75% of the respondents in this report must outsource to meet their sterile injectable manufacturing needs. Why? Nearly half do not have the internal capacity for manufacturing and have no choice but to outsource. Another third need to look to CMOs specifically for sterile injectable manufacturing.

When a non-large biopharma company makes the decision to outsource, there is a spectrum of options. Which way do they lean and why? Several components drive CMO selection for this subset, such as a history of sterile injectable quality, project fit for facility, previous experience with a CMO, and of course, regulatory history. The degree of regulation tied to ensuring safety in the sterile injectable world is complex and precise, impacting those players (remaining) in the game and available CMO capacity.

With this report, non-large biopharma companies and service providers can learn industry practices, contract manufacturer usage patterns, and current and projected market dynamics. Key statistics include development-stage and marketed product volume, the proportion outsourced, the number of CMOs respondents work with, products by delivery format, and the likelihood of outsourcing based on delivery device. CMO perceptions, selection drivers, and motivators of satisfaction in outsourcing relationships are also explored. Drug innovators will discover how industry peers evaluate service providers and CMOs will determine if their capabilities and marketing messaging align with what buyers of outsourced manufacturing services regard as important.

Methodology

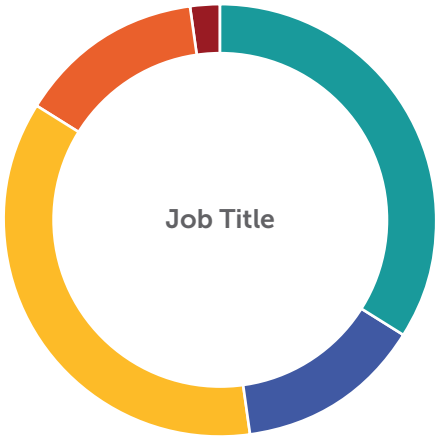
Data collected in Q2, 2019



25-minute web-based quantitative online survey

56 respondents from North America, Europe, Asia, and the Middle East

Demographics



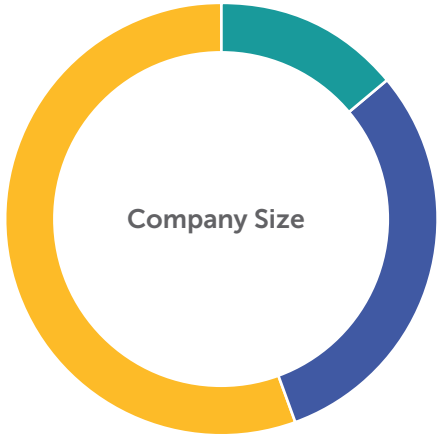
C-level - 34%

Vice President - 14%

Director - 36%

Manager - 14%

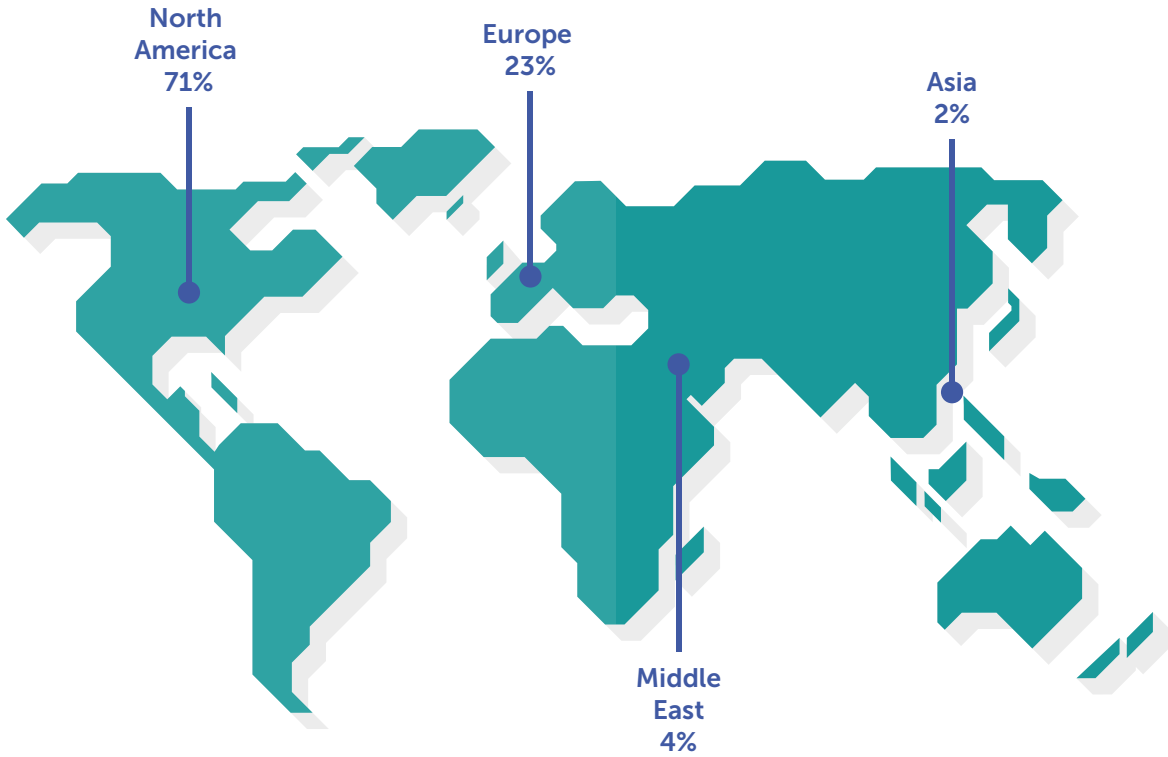
Scientist or Engineer - 2%



R&D $500M-$999M - 14%

R&D $100M-$499M - 30%

R&D less than $100M - 55%



Participant Criteria

Respondents were required to pass several screening criteria to qualify and participate in this survey:

- Must work at a pharmaceutical or biotech company
- Must have an annual R&D spend of less than $1B
- Must have responsibilities in at least one of the following categories: executive management, clinical trial manufacturing, commercial manufacturing, drug formulation and/or drug delivery, outsourcing/purchasing management, or supply chain
- Must have significant influence over outsourced manufacturing
- Must have been involved in outsourced manufacturing for sterile injectable products within the past 18 months
- Must play a role in gathering information about service providers, selecting service providers and/or managing contract manufacturing activities

Non-large Biopharma Segment

This report aims to shed light on the needs and practices of non-large companies in the sterile injectable manufacturing space. Data are based on the 56 respondents who meet this demographic, as taken from the original data set of 101 respondents in ISR's *Sterile Injectable Drug Product Manufacturing Market Overview and Outlook (2nd edition)* report. Those interested in learning more about the wider industry of sterile injectable manufacturing, including the needs and practices of large biopharma companies, can find more information at the product page below. Note that ISR will likely produce an updated version of this report in 2021. Keep an eye out for a fresh release sure to provide a more recent look at the impact of COVID-19. Feel free to contact ISR if you would like to be sent a preview – send an email to info@isrreports.com or call 1-919-301-0106.

Find this report at isrreports.com/reports/sterile-injectable-drug-product-manufacturing-market-overview-and-outlook/

Major Sections

1 Market Dynamics

2 Service Provider Selection and Perceptions

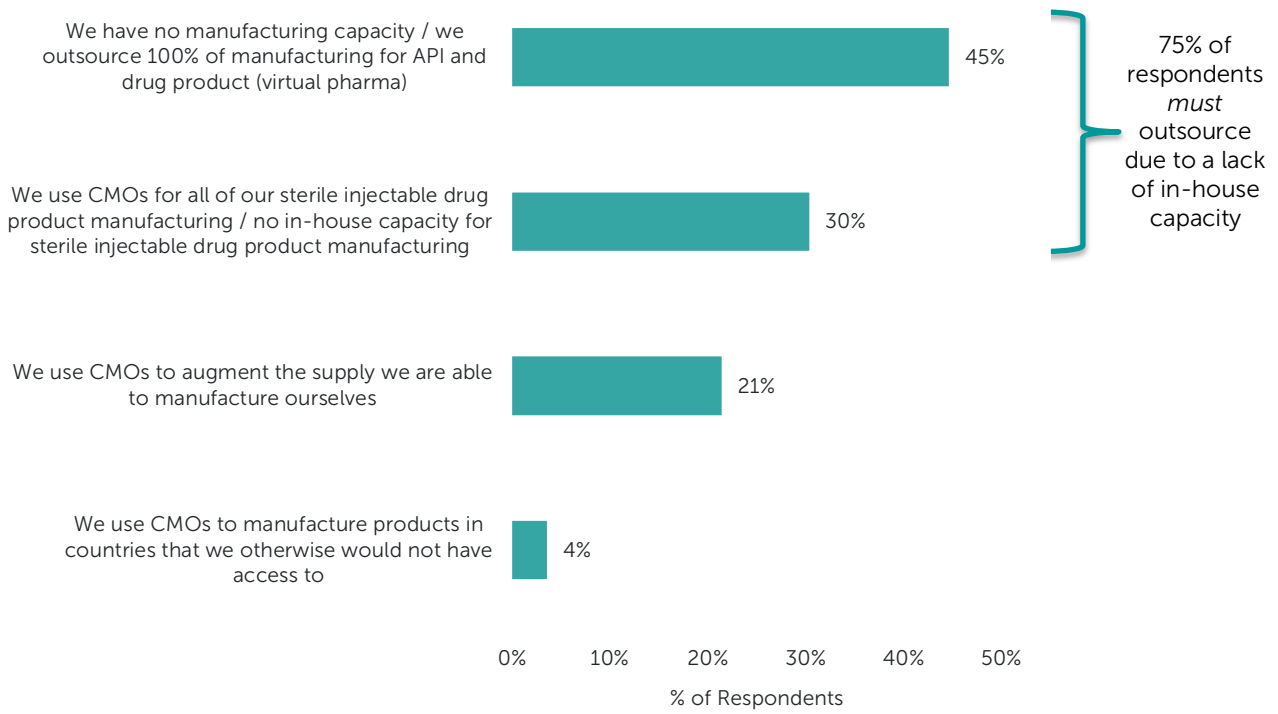
3 Trends, Predictions and Geographic Preferences

Market Dynamics

Outsourcing Drivers

The majority of respondents (75%) at non-large companies must engage CMOs for their sterile injectable drug product manufacturing needs. The most common reason for outsourcing is not having any manufacturing capacity therefore all manufacturing is outsourced (45%). Another 30% use CMOs specifically for this type of manufacturing. One-in-five respondents use CMOs to augment the supply they are already able to manufacture themselves.

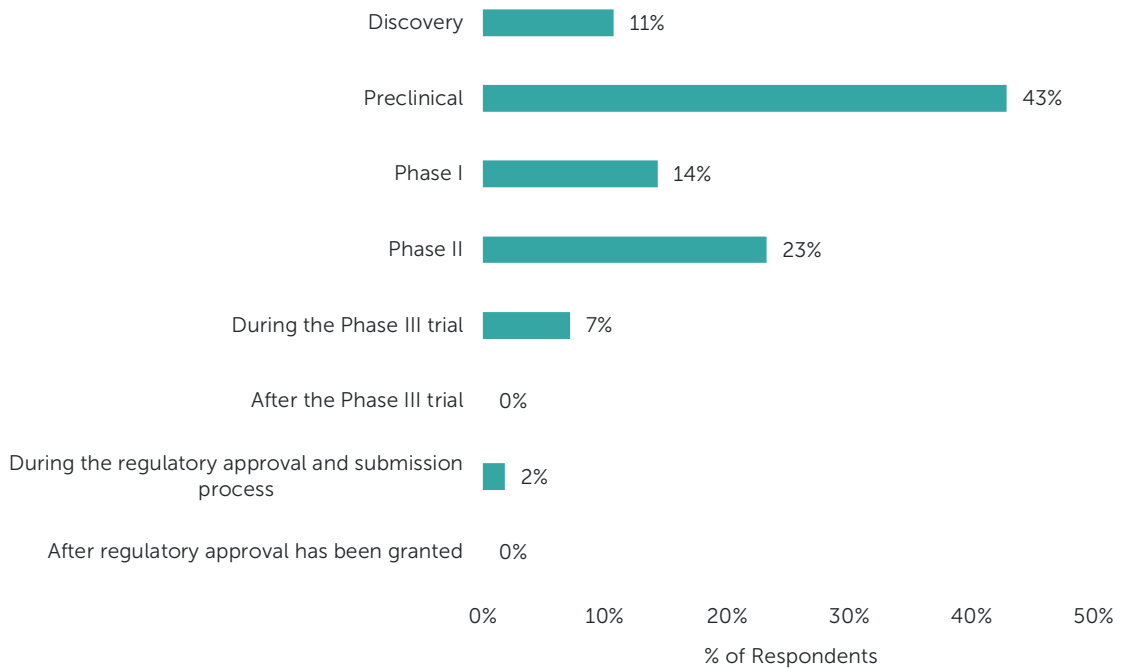
"Select the main reason your company engages contract manufacturers / CMOs for sterile injectable drug product manufacturing." (n=56)



CMO Engagement Timeline: Commercial Drug Product

About 43% of respondents at non-large companies start looking for a CMO for outsourced commercial sterile injectable manufacturing during the *Preclinical* phase. *Phase II* followed by *Phase I* are the next most popular times to do so, as reported by 23% and 14% of respondents, respectively.

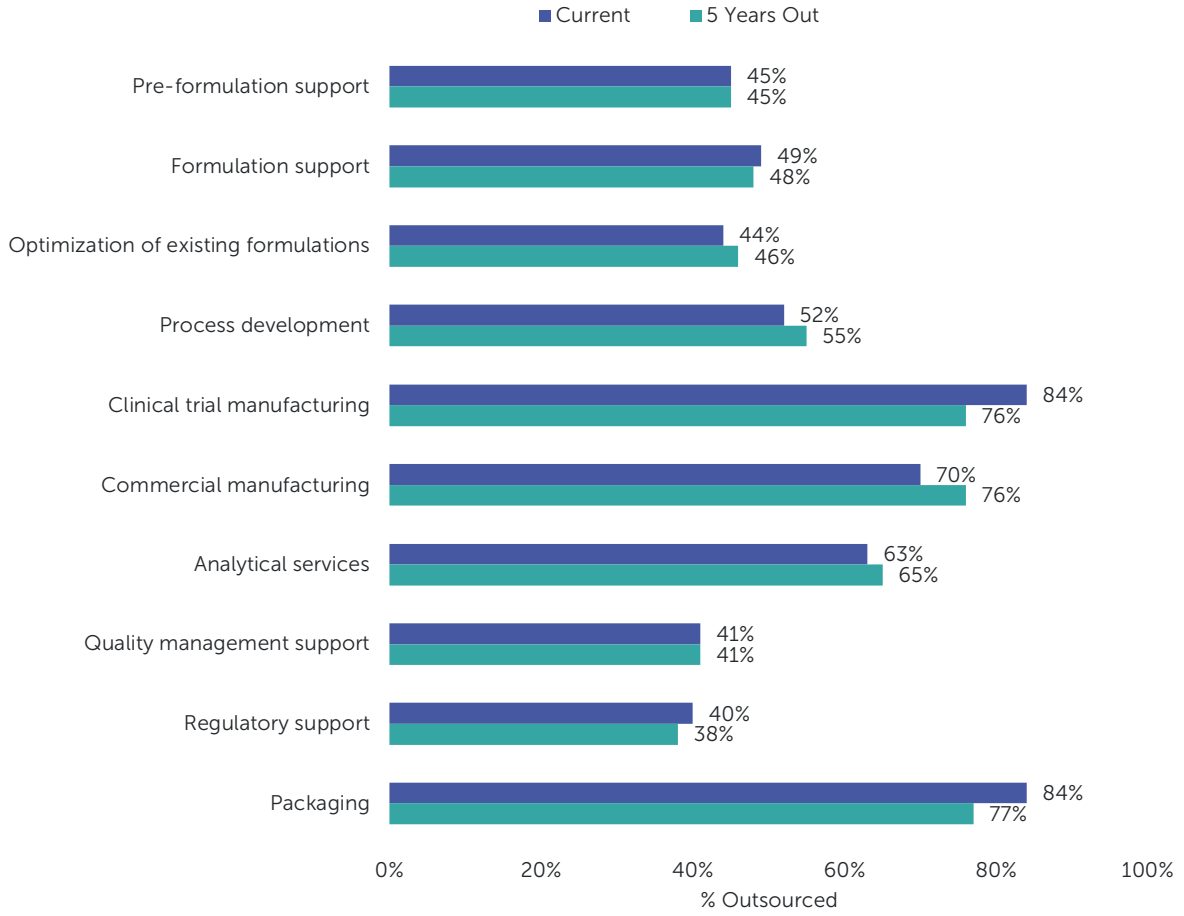
"Let's assume your company is going to outsource commercial manufacturing for a sterile injectable product. During which stage of development will your company start to look for a CMO?" (n=56)



Manufacturing Activities Outsourced for Sterile Injectable Products

Clinical trial manufacturing and *Packaging* (both 84%) and *Commercial manufacturing* (70%) are outsourced at the highest rates among respondents at non-large companies. While these three activities have notable outsourcing shifts projected for the future, the rest of the data show that respondents* do not anticipate much change in their outsourcing rates for sterile injectable manufacturing activities over the next five years.

"Thinking specifically about the compounds/products with sterile injectable formulations (either in development or marketed), what percentage of the following activities is outsourced and what percentage will be outsourced in 5 years?" (n=56)



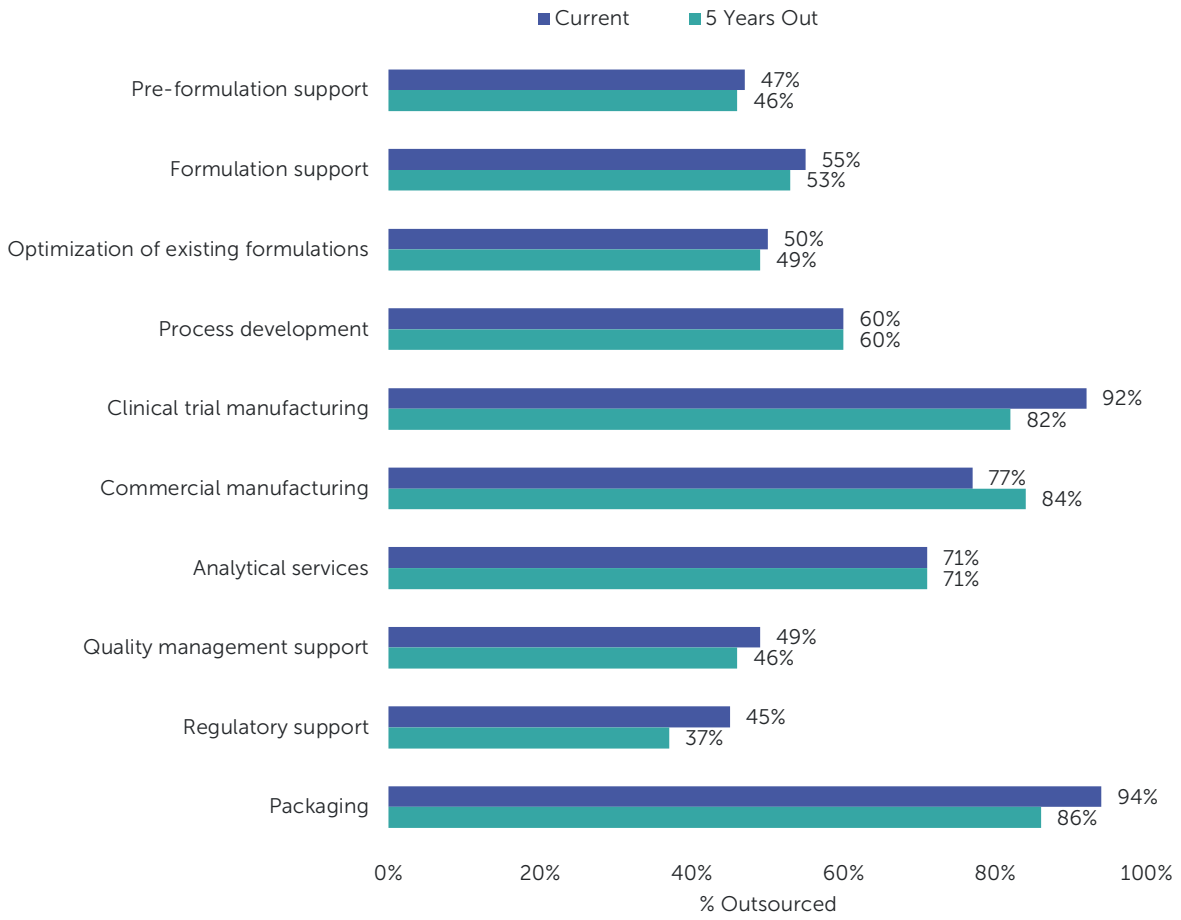
**Outsourcing sterile injectable manufacturing was a requirement for survey participation. The data above do not reflect industry outsourcing trends for sterile injectables because it does not factor in companies that do all sterile injectable drug product manufacturing in-house.*

Manufacturing Activities Outsourced by Company Size

The previous chart showed outsourcing rates for manufacturing activities by all 56 respondents. The next series of charts goes a step further by analyzing each non-large R&D segment separately, giving a sharper look at the differences that exist across these companies.

For many activities in the adjacent chart, the highest outsourcing rates lie with respondents at companies with R&D spend of less than $100 million compared to the other two segments. For example, the outsourcing rates for clinical trial manufacturing and packaging are 92% and 94%, respectively, for this smallest segment. Neither of the other segments have this high of an outsourcing rate for any activity.

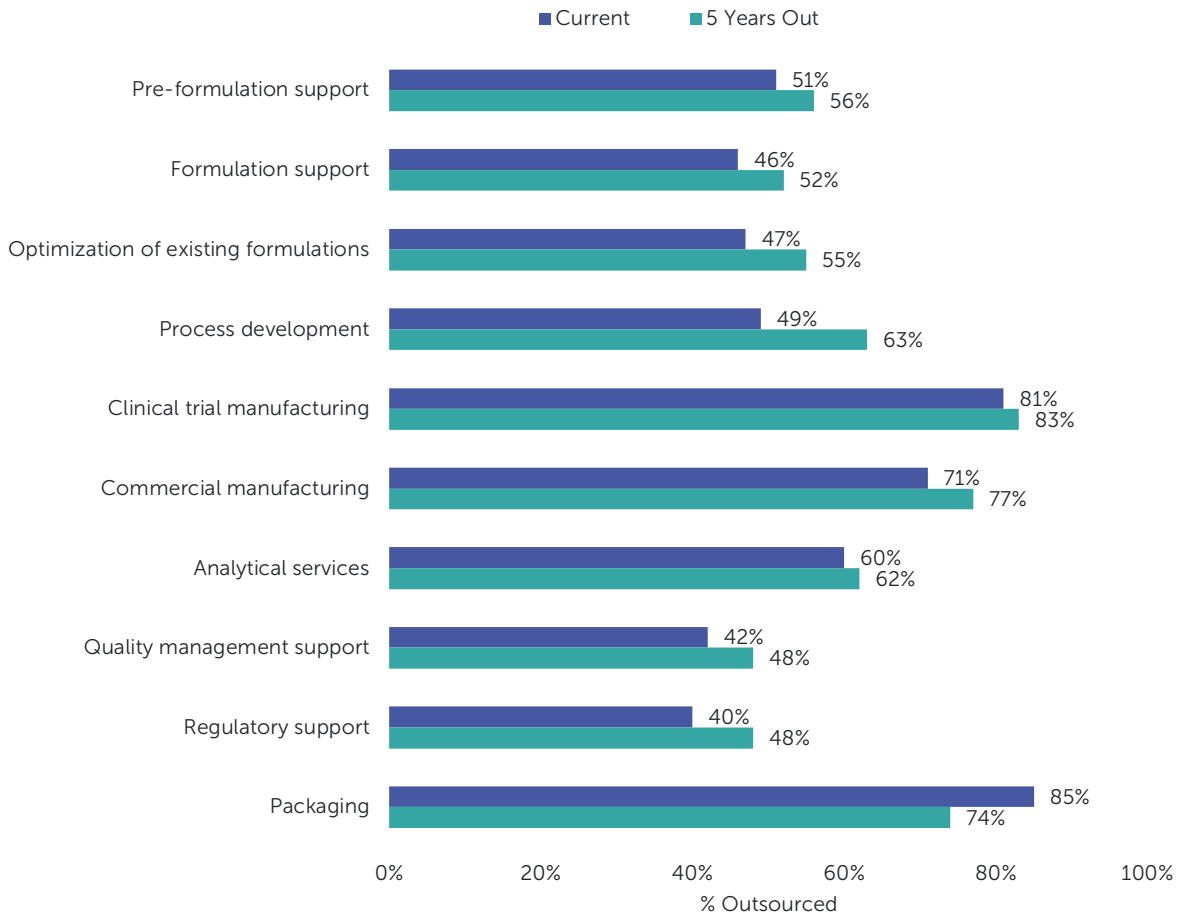
Non-large companies, R&D less than $100M (n=31)



Manufacturing Activities Outsourced by Company Size (continued)

Those respondents at companies with R&D spend of $100M-$499M reported similar outsourcing rates to those in the smallest segment (R&D less than $100M), but variation exists by activity. For example, the outsourcing rates for this middle segment for clinical/commercial manufacturing and packaging are about 10 ppts lower comparatively. At the same time, outsourcing rates for activities such as pre-formulation support and regulatory support are expected to be 10 ppts higher compared to the smallest segment five years from now.

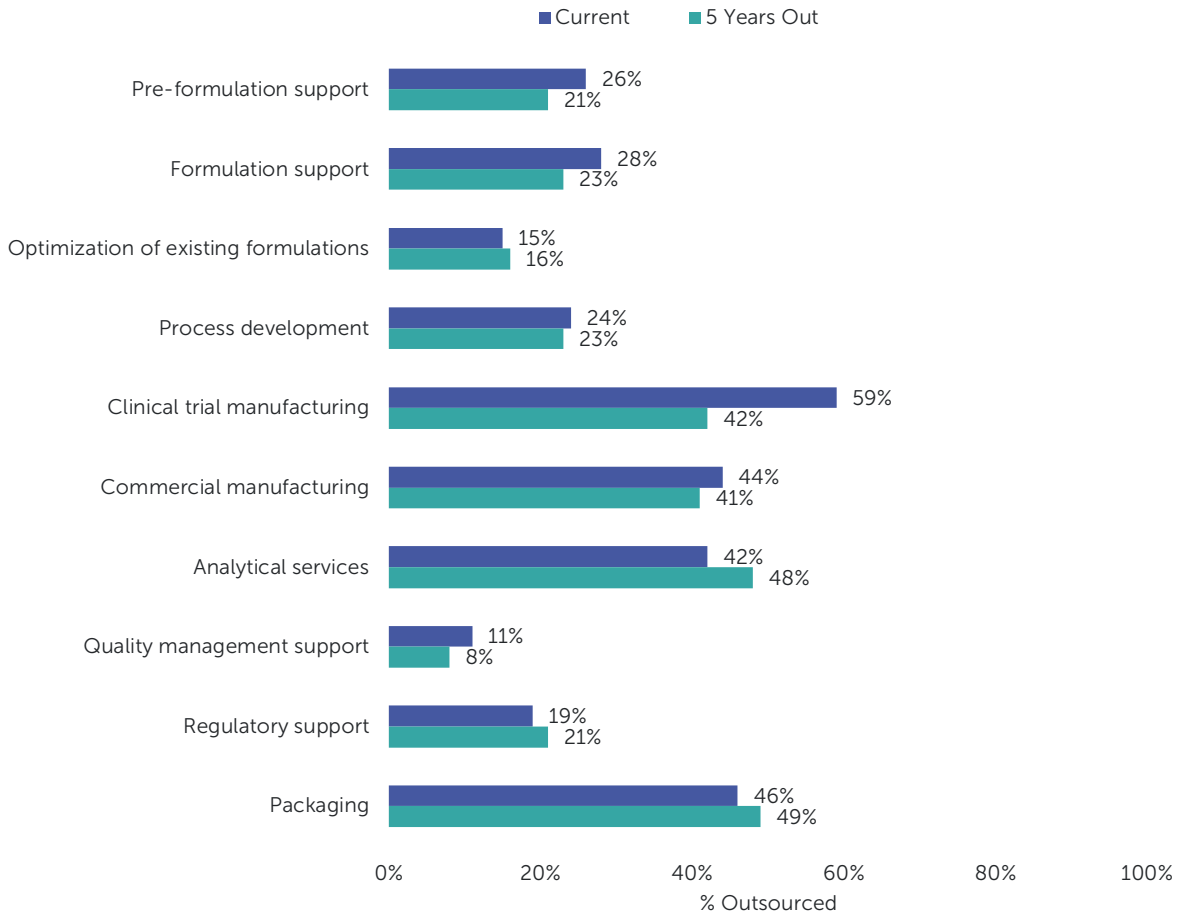
Non-large companies, R&D $100M-$499M (n=17)



Manufacturing Activities Outsourced by Company Size (continued)

Those respondents at companies with R&D spend of $500M-$999M have notably lower outsourcing rates compared to the other two segments. For example, while the other R&D segments have rates of 55% and 46% for formulation support, this segment has a rate of 28%. An even greater contrast is found with manufacturing. While the other segments have rates of 92% and 81% for clinical trial manufacturing, this segment has a rate of 59%.

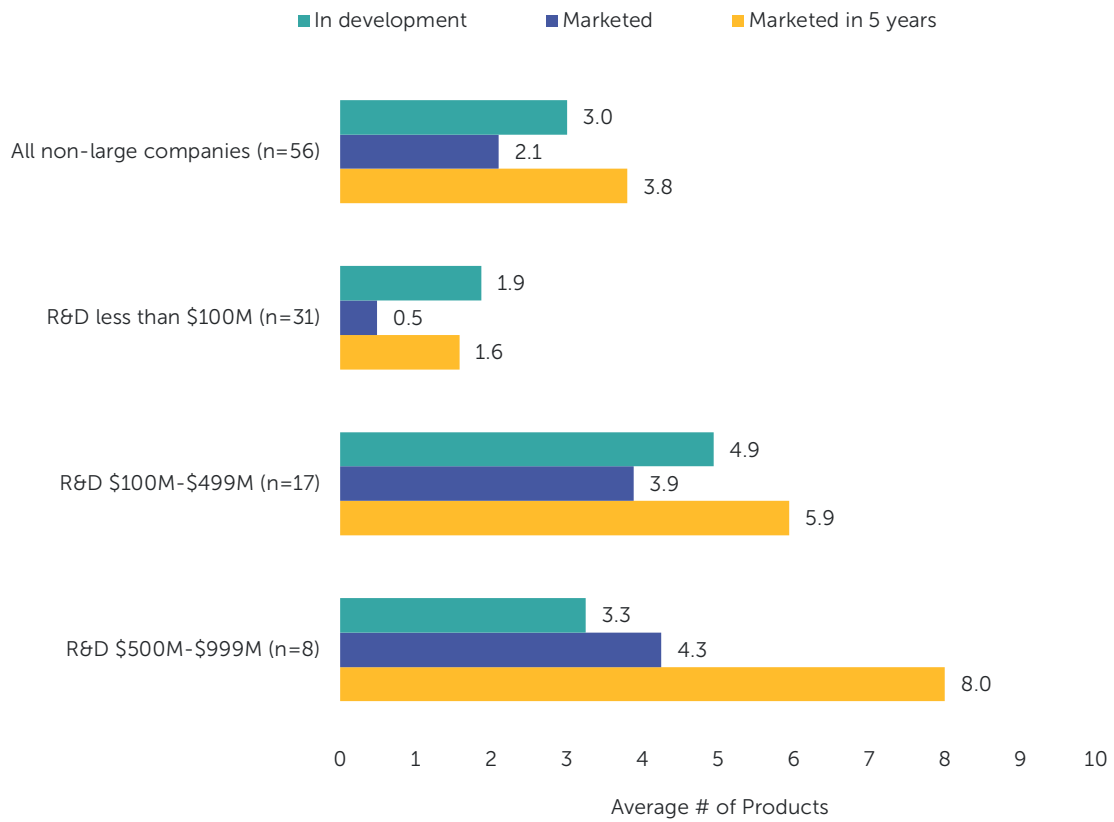
Non-large companies, R&D $500M-$999M (n=8)



Product Volume

Overall, respondents at non-large companies reported 3 compounds in clinical development, 2 marketed compounds, and 4 compounds will be marketed in the future. When taking a look at each R&D segment individually, product volume varies considerably. Respondents in the smallest segment (less than $100M) reported less than 2 compounds across all stages while respondents in the middle segment reported 4 to 6 compounds, on average. The greatest variation lies with the largest segment, in which 8 compounds are expected to be marketed five years from now.

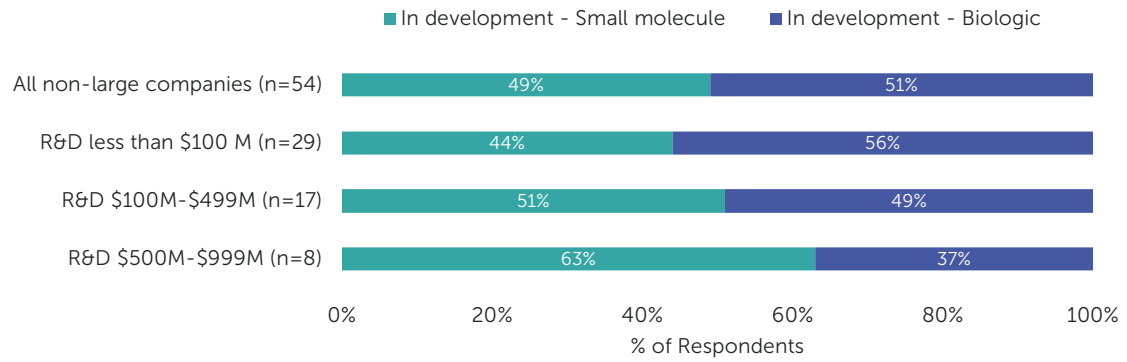
"About how many compounds does your company have that will be sterile injectable formulations?"

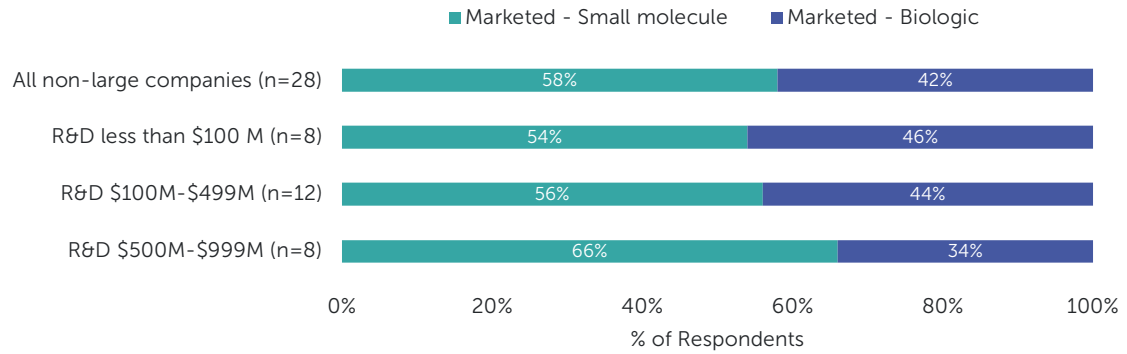


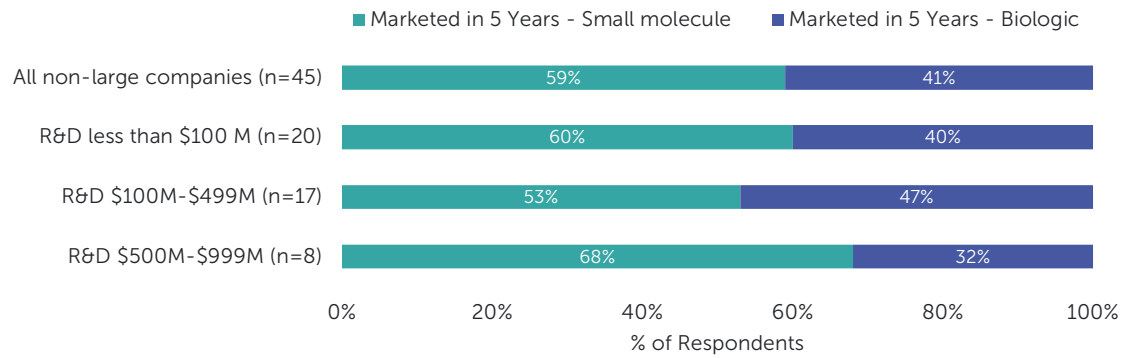
Formulation Type

For the 54 respondents at non-large companies who have compounds with sterile injectable formulations in development, an even split exists between small molecule (49%) and biologic (51%), however, the percentage of small molecule ticks upward as R&D size increases. For those respondents with marketed compounds (n=28) and expectation for future compounds (n=45), a greater percentage of formulations are small molecule (~60% vs ~40%).

"What percentage of your compounds with sterile injectable formulations are small molecule versus biologic? (in clinical development / marketed / marketed in 5 years)"



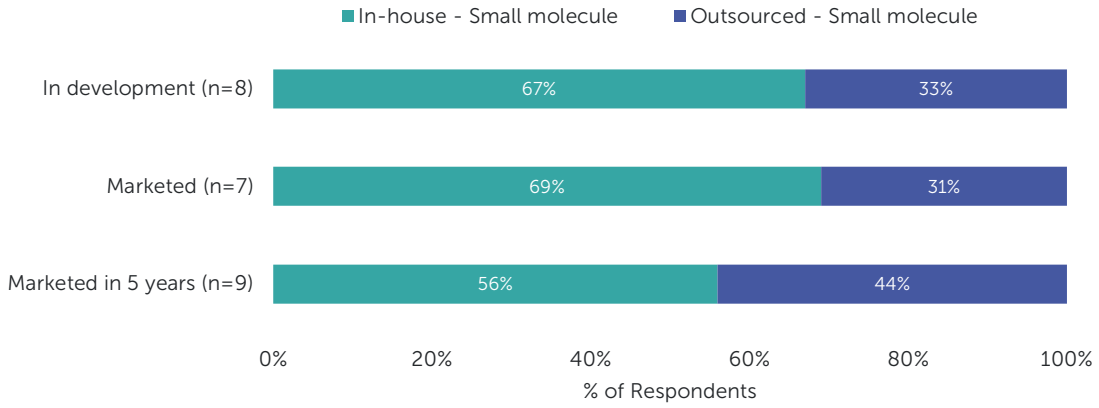




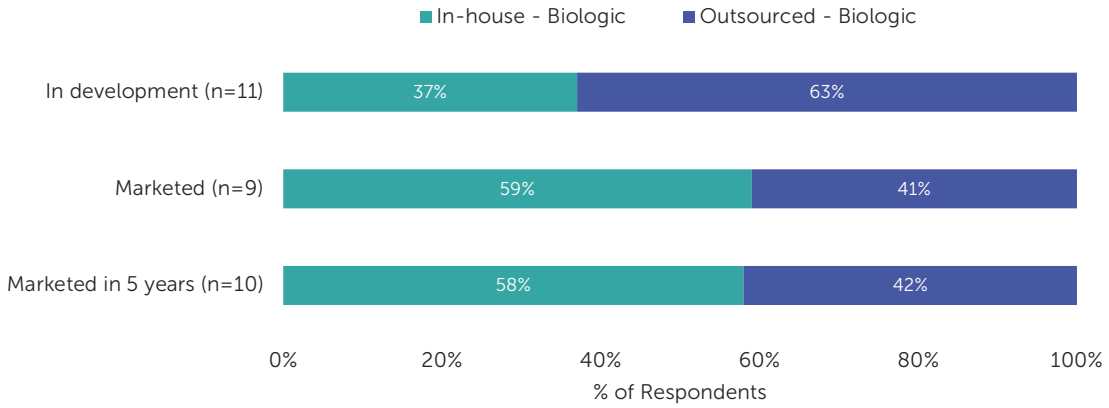
In-house Manufacturing vs Outsourcing

Respondents at non-large companies reported a greater proportion of compounds with sterile injectable formulations being manufactured in-house as opposed to outsourced. The one exception lies with biologic compounds in development – 37% in-house vs 63% outsourced.

"Please allocate the proportion of small molecule compounds with sterile injectable formulations that are manufactured in-house vs outsourced. (in clinical development / marketed / marketed in 5 years)"



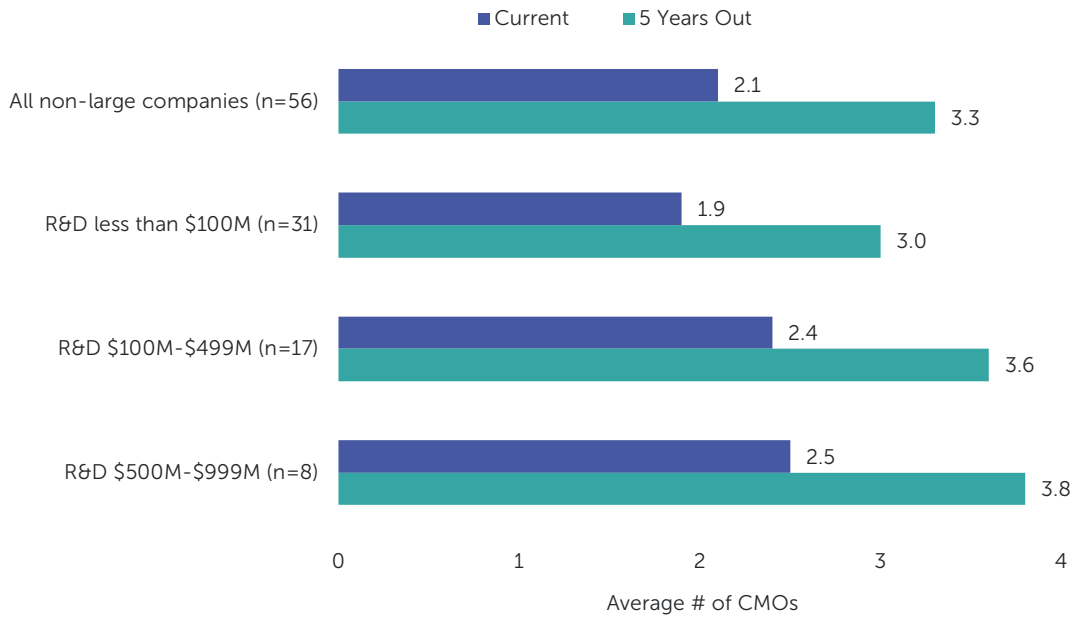
"Please allocate the proportion of biologic compounds with sterile injectable formulations that are manufactured in-house vs outsourced. (in clinical development / marketed / marketed in 5 years)"



CMO Usage

The number of CMOs that respondents at non-large companies work with varies. As R&D spend increases, so does the number of CMOs. Those respondents at the smallest segment (less than $100M) reported working with 1.9 CMOs on average, while those in the middle segment indicated 2.4. Projected CMO use follows the same pattern – the smallest segment plans to work with 3.0 CMOs five years from now while the largest segment plans to work with 3.8 CMOs to meet their sterile injectable drug manufacturing needs.

"How many CMOs does your company work with to meet your sterile injectable drug manufacturing needs?"



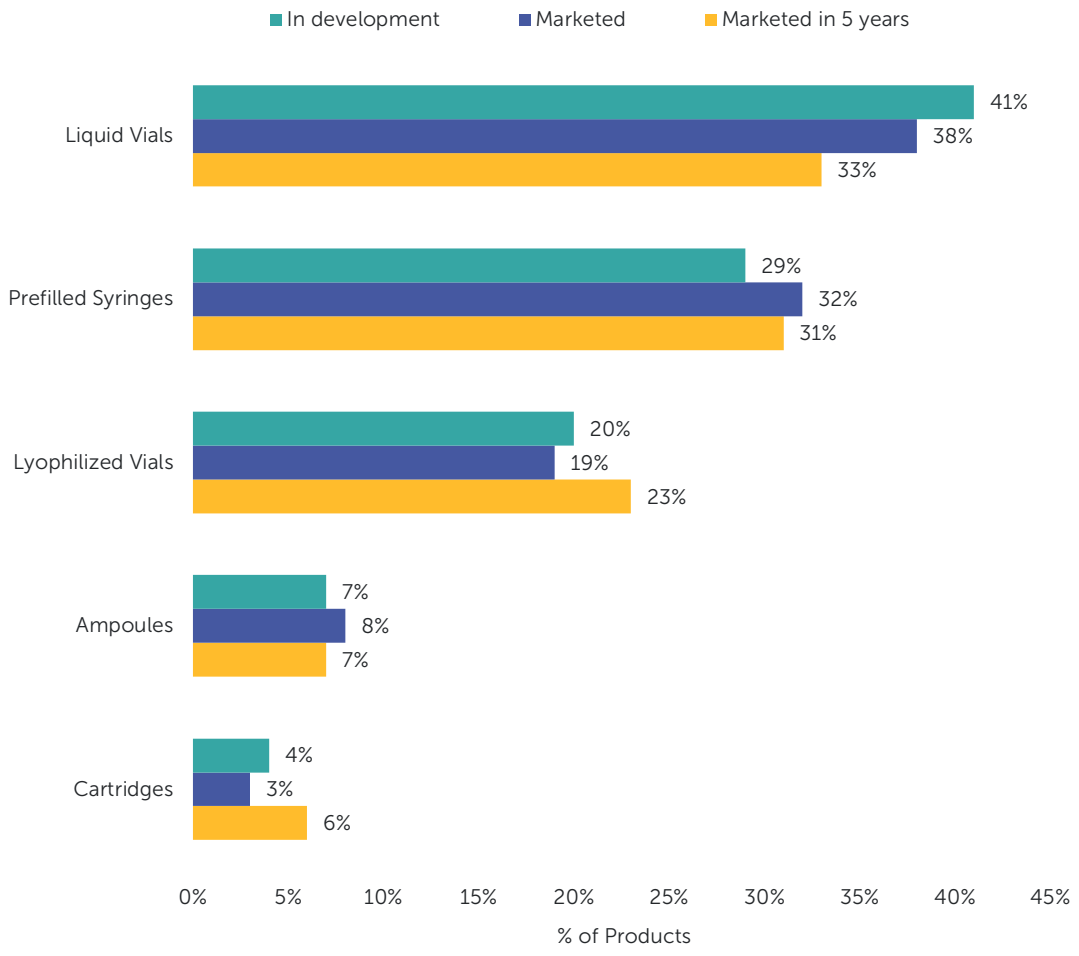
Products by Delivery Format

Liquid vials top the chart as the delivery format carving out the greatest percentage of products across the board (in development, marketed, projected-to-market) per respondents at non-large companies. Prefilled syringes follow, accounting for one-third of products for each. Cartridges make up the lowest proportion of the product portfolios. Lyophilized vials and cartridges are expected to be utilized more five years from now.

"What percentage of your company's products in clinical development that will be sterile injectable formulations will use the following delivery formats?" (n=54)

"What percentage of your company's marketed products with sterile injectable formulations use the following delivery formats?" (n=28)

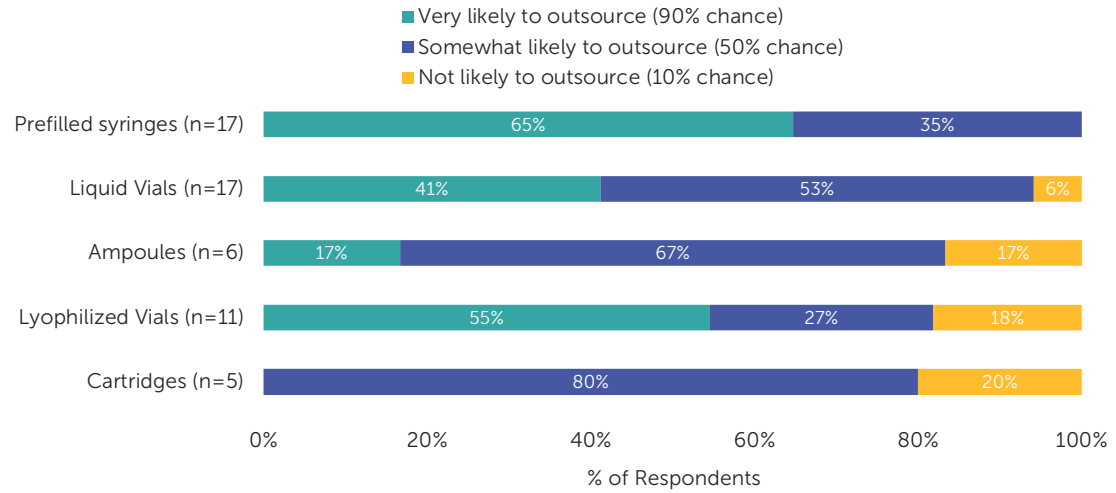
"Five years from now, what percentage of your company's marketed products with sterile injectable formulations will use the following delivery formats?" (n=45)



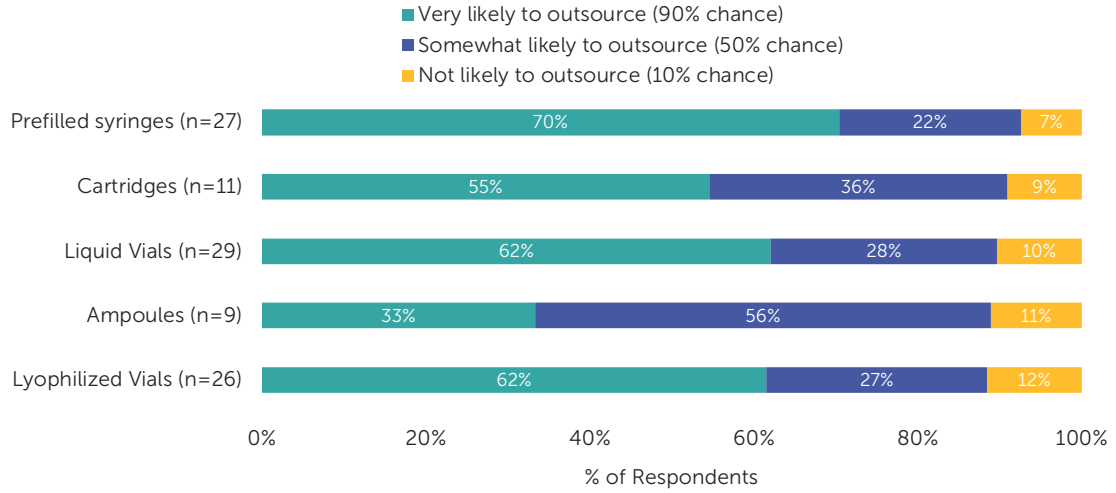
Likelihood of Outsourcing by Delivery Format

The adjacent charts compare the likelihood of outsourcing by delivery format at two points in time – currently and five years from now. While prefilled syringes top both charts (93-100% of respondents are somewhat to very likely to outsource), a notable shift is expected for cartridges (currently 0% very likely to outsource vs 55% in the future). A similar shift is also expected for ampoules, although to a lesser degree.

"For the products that are currently marketed, what is the likelihood of your company outsourcing sterile injectable drug product manufacturing for each delivery device/system?"



"Five years from now, what is the likelihood of your company outsourcing sterile injectable drug product manufacturing for each delivery device/system?"

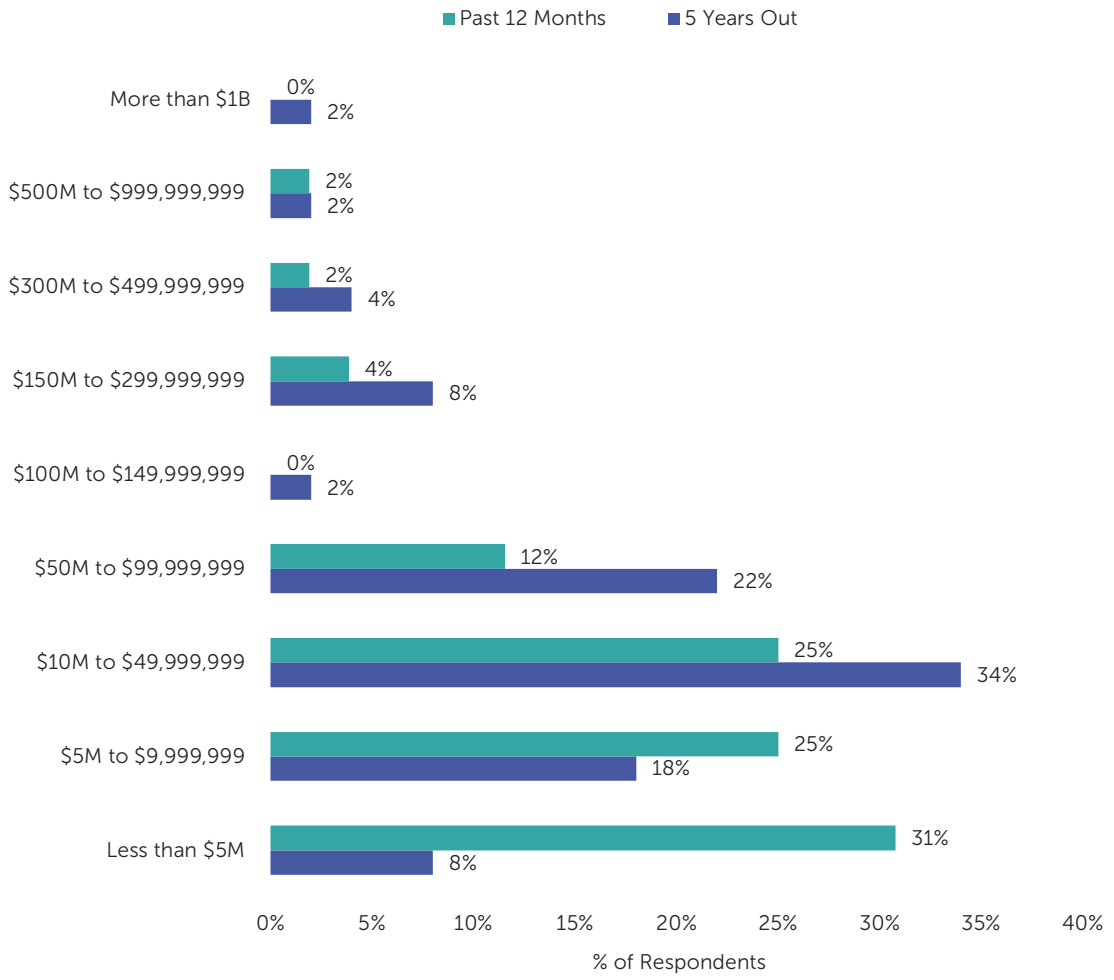


Sterile Injectable Manufacturing Annual Outsourced Expenditure

More than 90% of respondents at non-large companies said their expenditure over the past 12 months on outsourced sterile injectable drug product manufacturing was below $100M. While that seems to be the sweet spot for non-large companies both now and into the future, respondents do anticipate bumping up their expenditure over the next five years. The greatest projected shift can be found in the proportion of respondents at non-large companies spending less than $5M – 31% of respondents said this was the case over the last year, however, only 8% predict to spend less than $5M in five years.

"How much, in US dollars, is your company's annual spend on outsourced sterile injectable drug product manufacturing in the past 12 months? Your best estimate is fine." (n=52, Don't Know responses removed)

"How much, in US dollars, would you estimate your company will spend on outsourced sterile injectable drug manufacturing five years from now?" (n=50, Don't Know responses removed)

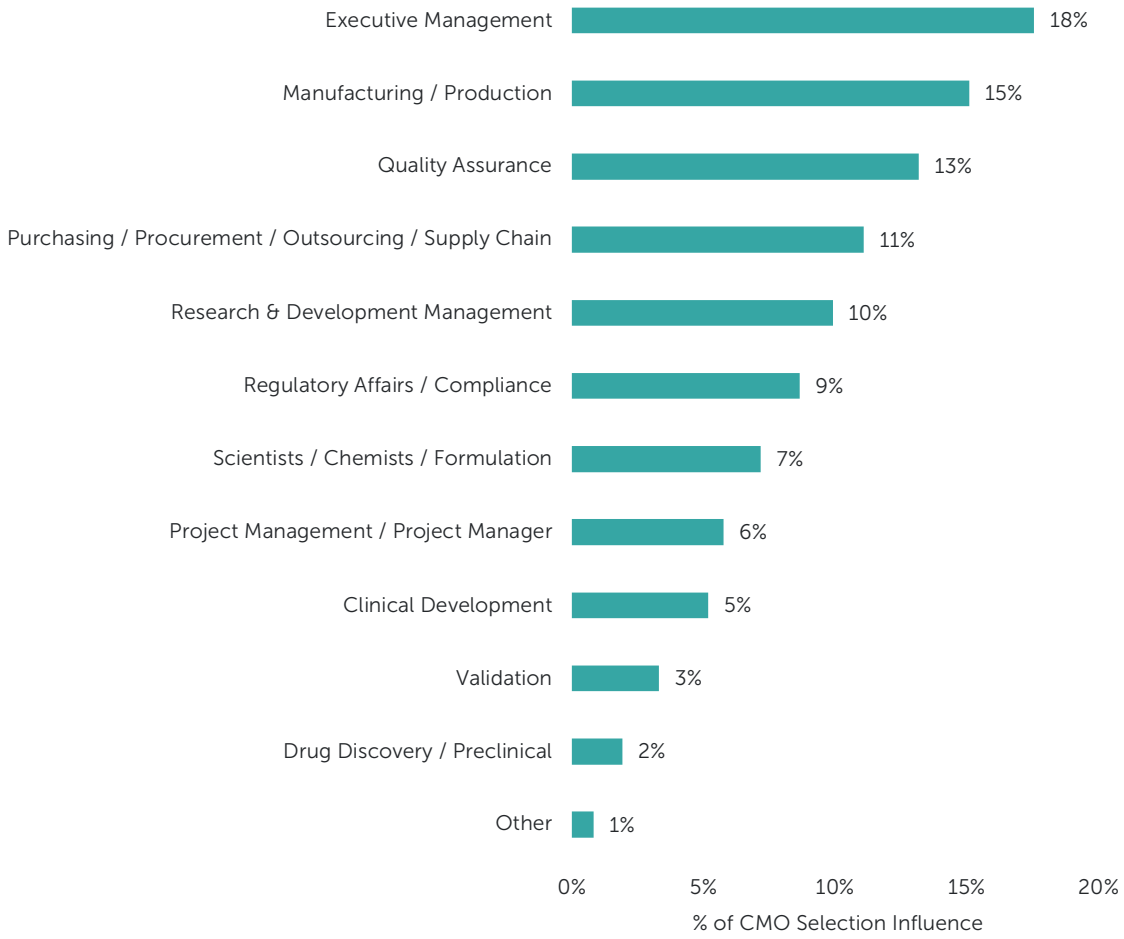


Service Provider Selection and Perceptions

Department Influence on CMO Selection

Five departments have double-digit influence over CMO selection for sterile injectable drug product manufacturing per respondents at non-large companies. *Executive Management* landed at the top as the most influential department with 18%, followed by *Manufacturing / Production* (15%) and *Quality Assurance* (13%).

"Please allocate the amount of influence each department has on the selection of a new contract manufacturer for sterile injectable drug manufacturing. Please ensure your allocation totals 100%." (n=56)

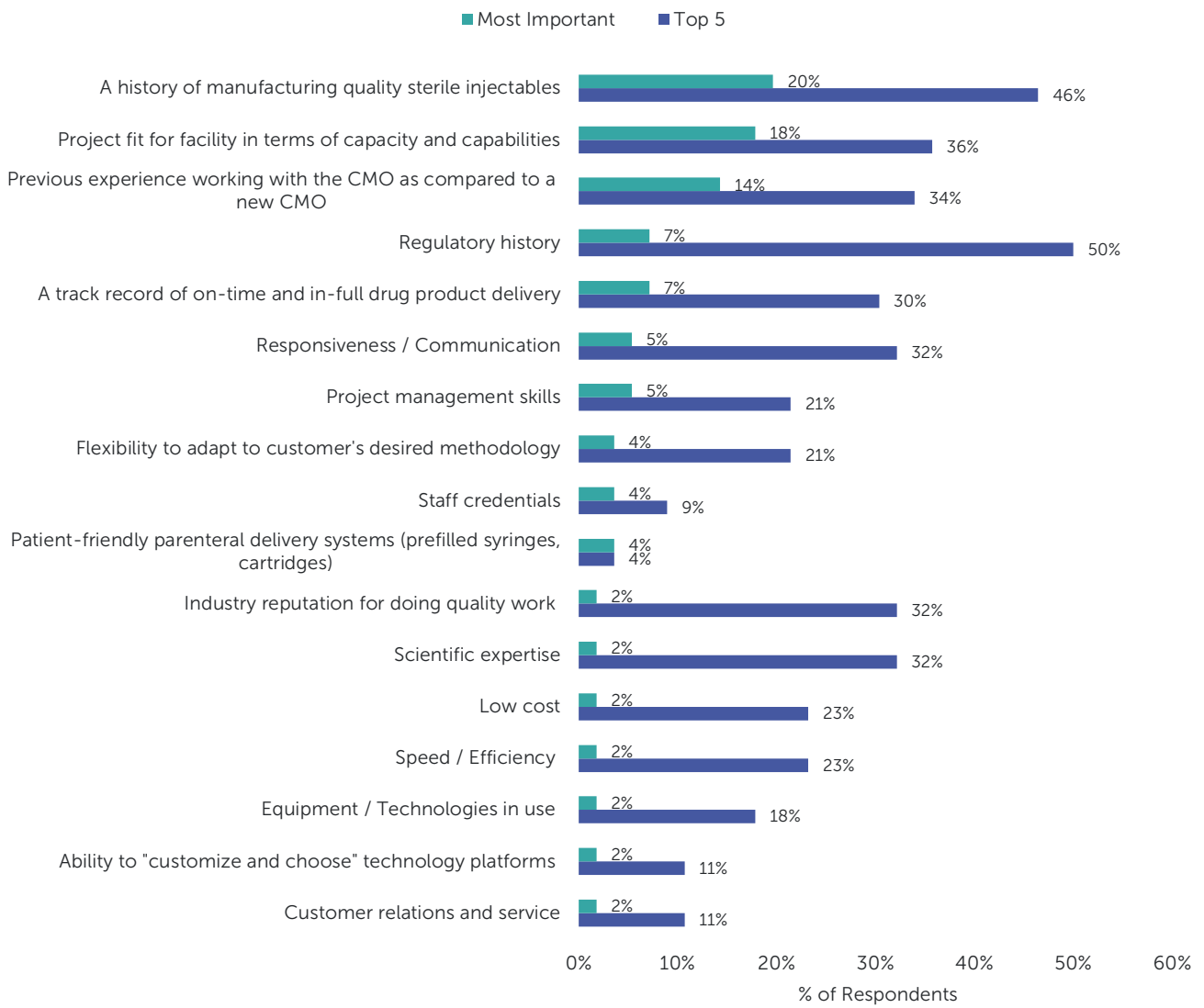


Top CMO Selection Attributes

A history of manufacturing quality sterile injectables garnered 20% of votes from respondents at non-large companies as the Most Important attribute. *Project fit for facility in terms of capacity and capabilities* followed with 18%. Even though *Regulatory history* garnered 50% of respondents' votes overall (Top 5), just 7% of respondents deemed it Most Important when outsourcing sterile injectable drug product manufacturing. Furthermore, several attributes such as *Track record* and *Industry reputation* captured one-third of respondents' votes overall, however, few respondents percentagewise selected them as most critical.

"Thinking of the service provider attributes that you value the most when selecting a CMO for outsourced sterile injectable drug product manufacturing, which attributes do you find important? Select five." (n=56)

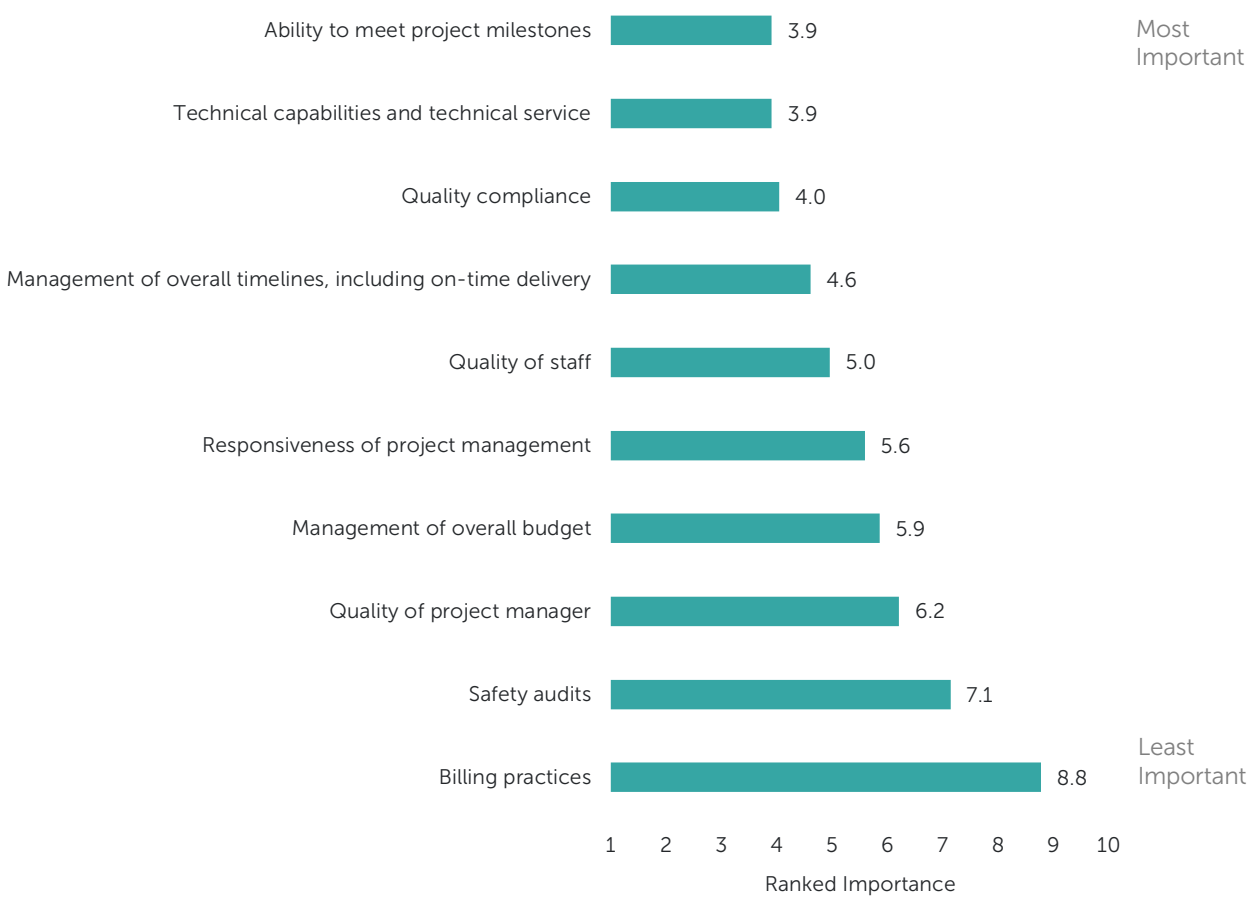
"From these attributes, which one attribute do you value most when selecting a CMO for outsourced sterile injectable drug product manufacturing? Select only one." (n=56)



CMO Satisfaction Drivers

Ability to meet project milestones and *Technical capabilities and technical service* tied for the top ranked CMO satisfaction driver (mean rank of 3.9). *Quality compliance* followed closely (4.0). Drivers such as *Safety audits* and *Billing practices* were less important in terms of satisfaction with a contract manufacturer's performance. With half of the drivers below garnering an average ranking of 5 or less – meaning quite a few are motivating user satisfaction – this lets CMOs know that non-large biopharma companies have diverse outsourcing objectives.

"In your experience with using CMOs for biologic sterile injectable drug product manufacturing, what usually drives your satisfaction with a contract manufacturer's performance? Rank the following from most important (#1) to least important (#10)." (n=56)

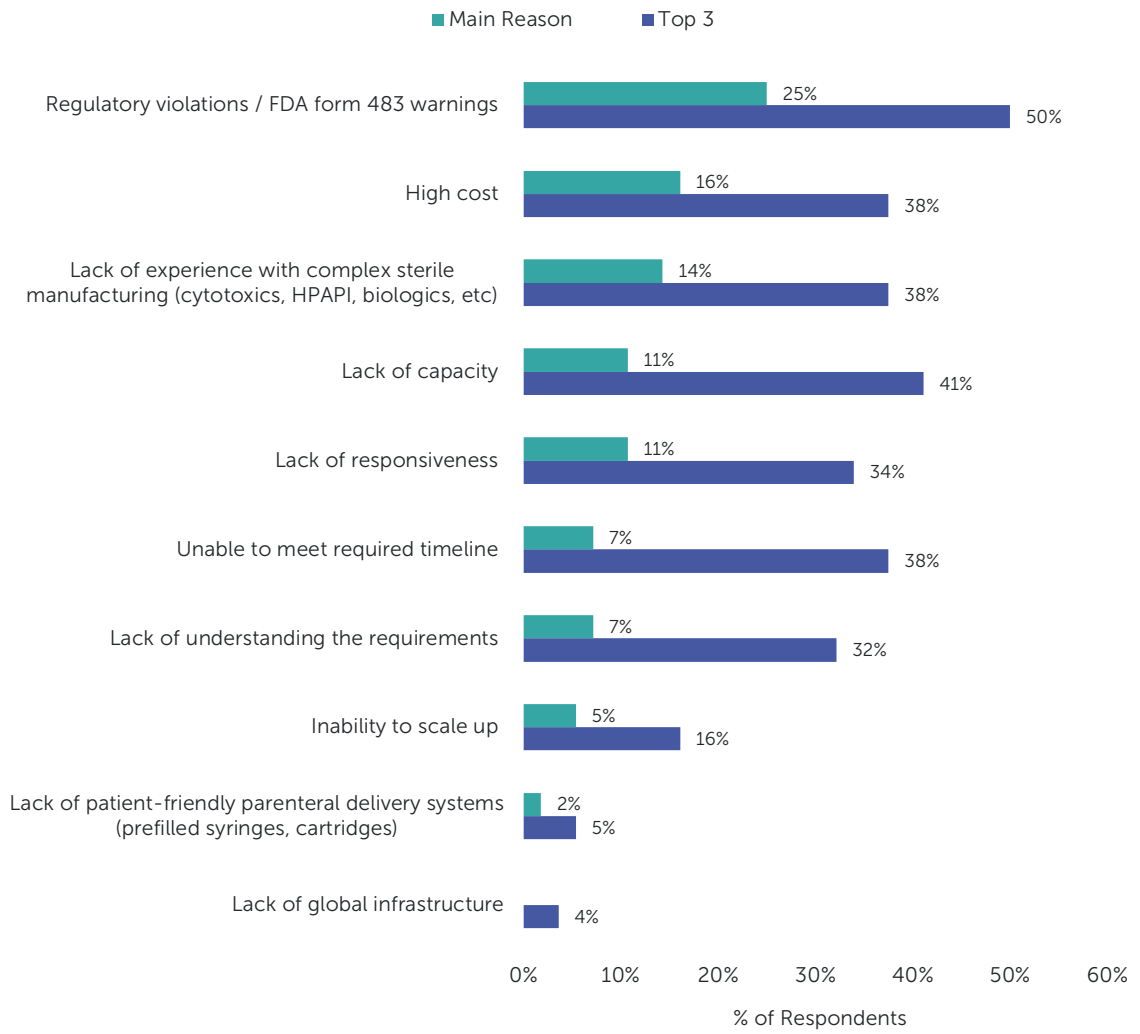


Top Reasons CMOs Lose Bids

Respondents at non-large companies selected *Regulatory violations* as the runaway Main Reason (25%) and top reason overall (Top 3, 50%) for why a CMO may lose a bid for outsourced sterile injectable drug product manufacturing. *High cost* (16%) trailed as the second most cited Main Reason, followed by *Lack of experience* (14%). At least one-third of respondents deemed seven of the ten issues shown as a Top 3 reason for losing a bid.

"What are the top three reasons why a CMO may lose the bid for outsourced sterile injectable drug product manufacturing with your company?" (n=56)

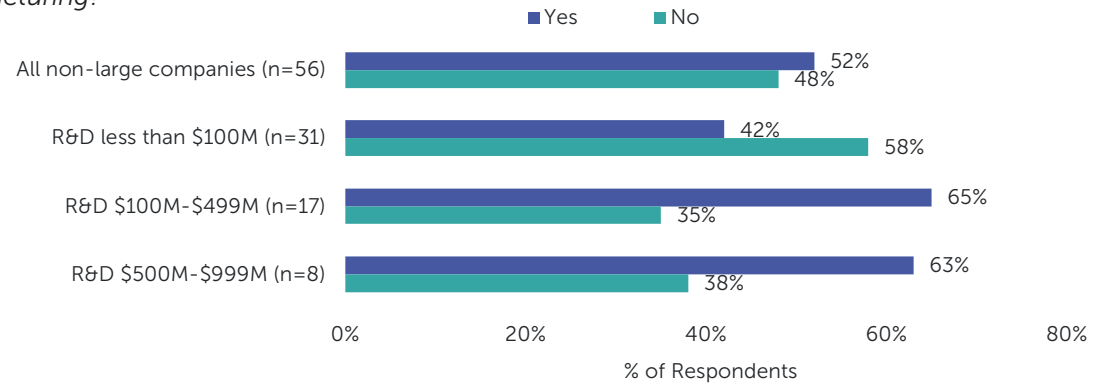
"What is the one main reason why a CMO may lose the bid for outsourced sterile injectable drug product manufacturing with your company?" (n=56)



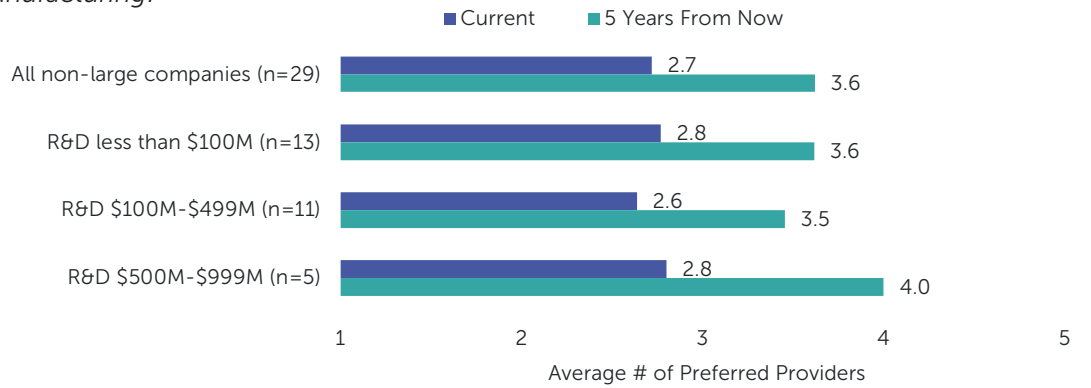
Preferred Provider Use

Just over half of respondents (52%) at non-large companies said they use a preferred provider list for sterile injectable manufacturing. The smallest R&D segment, however, uses a preferred list to a lesser degree (42% of respondents vs two-thirds of the larger segment respondents). The average number of preferred providers, however, is fairly aligned across the different segments. On average, respondents have 2.7 preferred providers and expect to have 3.6 in the future. The majority of respondents (86%) find it more difficult than not to use a CMO that is not on their preferred list.

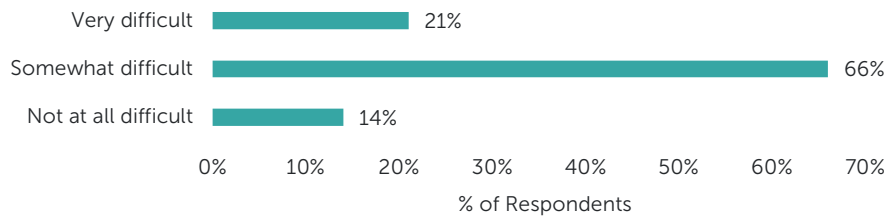
"Does your company use a preferred provider list of contract manufacturers for outsourced sterile injectable drug product manufacturing?"



"How many preferred providers does your company [currently have/will have 5 years from now] for sterile injectable drug product manufacturing?"



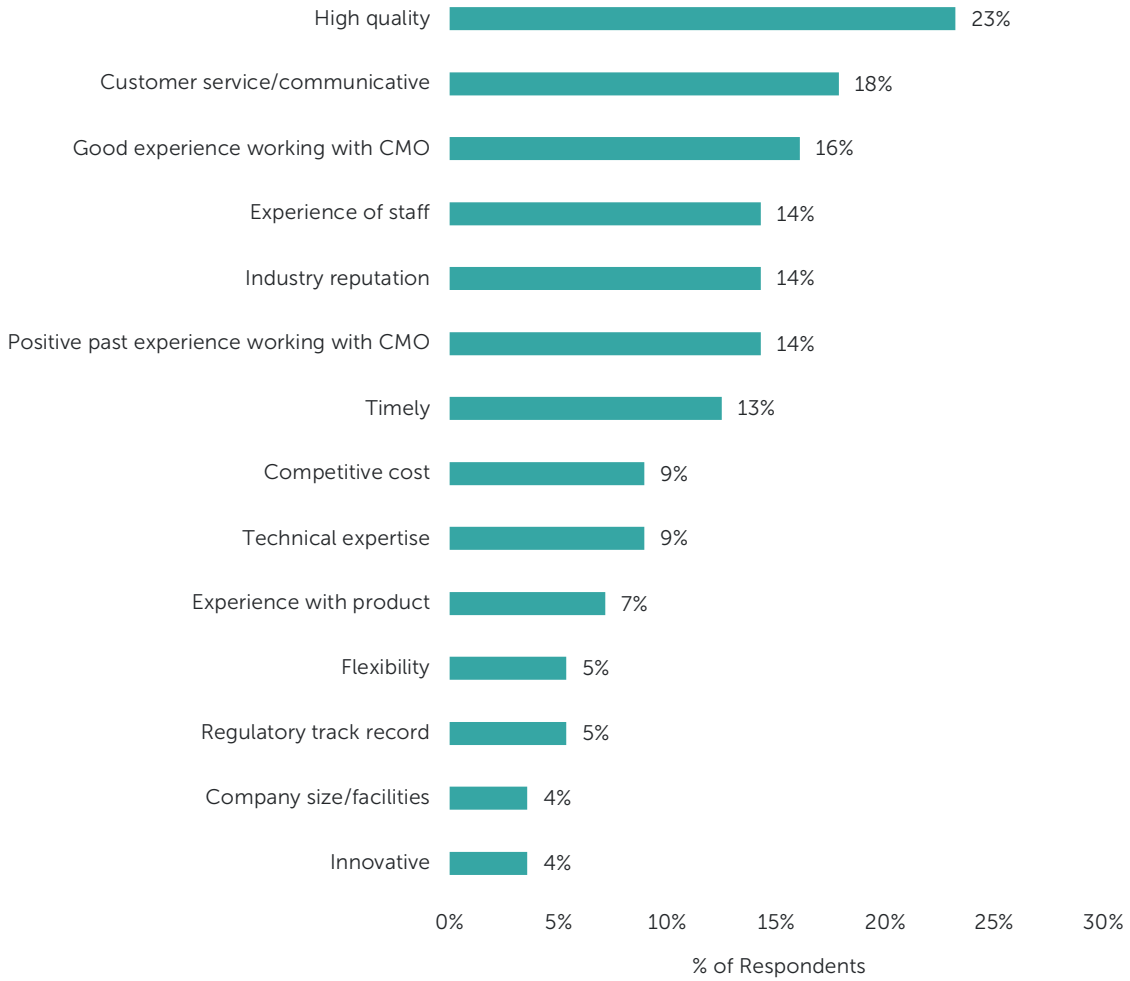
"How difficult is it to use a CMO for a sterile injectable project that is not on your preferred provider list?" (n=29)



Reasons for Favoring a CMO Provider

Why use a particular CMO provider over another? Respondents at non-large companies were asked what a CMO does differently to drive use of their services. Per the adjacent chart of themed responses, quite a few things drive respondents' companies to look to a specific provider. A variety of responses were given, however, three differentiators were mentioned most often and by more than half of respondents collectively (57%). Landing at the top and not surprisingly was *High quality* of services and products, as cited by one-quarter of respondents. *Customer service/ communicative* followed as the next most cited differentiator with 18% of respondents. *Good experience working with CMO* rounded out the top three with 16%. Similarly, and tied for the fourth spot, was being able to speak to a *Positive past experience* with a CMO (14%).

"What does [insert CMO] do differently that causes you to prefer their services?" (n=56, open-ended question, multiple responses allowed)



Reasons for Favoring a CMO Provider – Respondent Comments

Verbatim comments are provided below from respondents at non-large companies.

"What does [insert CMO] do differently that causes you to prefer their services?" (n=56)

- *Best in class in their field*
- *Big company*
- *Budget friendly*
- *Consistent high quality and good reputation*
- *Correct size of organization for our stage of development. SR&ED (Canadian) tax credits*
- *Cost effectiveness - knowledgeable staff - flexible pricing*
- *Customer service, responsiveness, communication, innovative solutions, quality & regulatory track record, experience*
- *Delivers with no issues*
- *Easy to contact sales rep and get updates on the progress of the program. Lots of flexibility to make different changes and they will confirm the process/steps are correct prior to manufacturing*
- *Excellent performance on the latest product*
- *Excellent project management; quality and on time*
- *Experience with current lead API, established relationship*
- *Experience with the specific product*
- *Extremely honest and upfront on capabilities and limitations, excellent technical expertise across wide dimensions of different types of molecules, good project management, deliver on promises*
- *Flexibility and understands client expectations on a project*
- *Good experience*
- *Great experience so far dealing with them*
- *Great facility and staff. Good responsiveness*
- *Historical experience which has been positive*
- *I have another development program with them and am comfortable with them*
- *I know what it is like to work with them and our collaboration works fine*
- *Just overall high quality, timely delivery and strong regulatory/compliance history*
- *Large capacity of multiple technologies*
- *Long history of meeting our needs*
- *Long personal track record. I know what I'm getting*
- *Most experienced personnel*
- *Multiple sites meet timelines*
- *On time delivery, knowledgeable staff, efficient on cost*
- *One stop shop for all work*
- *On-time, on-budget delivery. High quality product and project management*
- *Past experience*

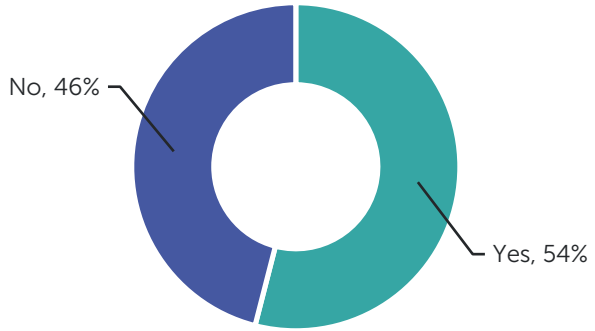
- *Past experience and good regulatory history*
- *Preferred vendor, worked with them before, have the therapeutic expertise and technology to develop and produce for clinical supplies the sterile injectable and also the pre-filled syringes and cartridges - scale up the manufacturing for commercial supplies and follow the GCP and regulatory compliance*
- *Previous good experience (on-time delivery, fluid interaction with project management)*
- *Price, responsiveness of the management support*
- *Proactive team that is easy to work with on this and other activities*
- *Probably the best CMO in the industry. Is, however, very expensive and somewhat inflexible*
- *Produce quality product on time*
- *Quality and price*
- *Quality of service*
- *Quality product*
- *Quality services and good reputation with a global reach*
- *Quality services*
- *Reliable, considered best in class, can move from clinical to commercial*
- *Reputation*
- *Responsiveness, technical and scientific capability, regulatory compliance and quality assurance*
- *Service on time and quality*
- *Technical expertise, quality, and schedule adherence. Solid program management, follow through at a decent price point. Experience with our products and processes, and personal connections with various folks in the organization*
- *The level of expertise and experience is very high compared to the others I have had contact with*
- *They do things in a way that is easy to see and transparent*
- *They provide strong internal regulatory support for contract-manufactured drug products versus just leaving it up to the client/customer regulatory team that may not be as familiar with many of the technical/scientific details*
- *Track record, experience, facilities, executive management*
- *Very quality orientated*
- *Very responsive management. Easy to work with. Adherence to quality GMP*
- *Well run organization with smart people and good compliance history*
- *Works with blood products regularly*

Trends, Predictions and Preferences

Sterile Injectable Life Cycle Management

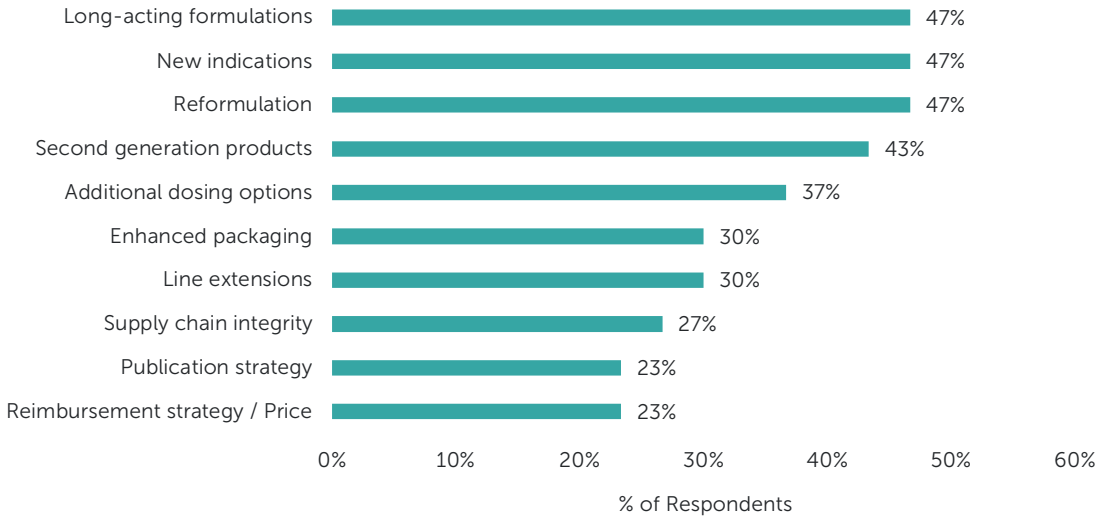
Just over half of respondents (54%) said their non-large companies are investigating life cycle extension strategies for their sterile injectable drug products. Nearly half of the respondents investigating extension plans are considering or have acted upon *Long-acting formulations*, *New indications,* and *Reformulation* (47% each).

"Is your company investigating improving products or extending the life cycle of its sterile injectable drug products?" (n=56)



Life Cycle Extension Strategies

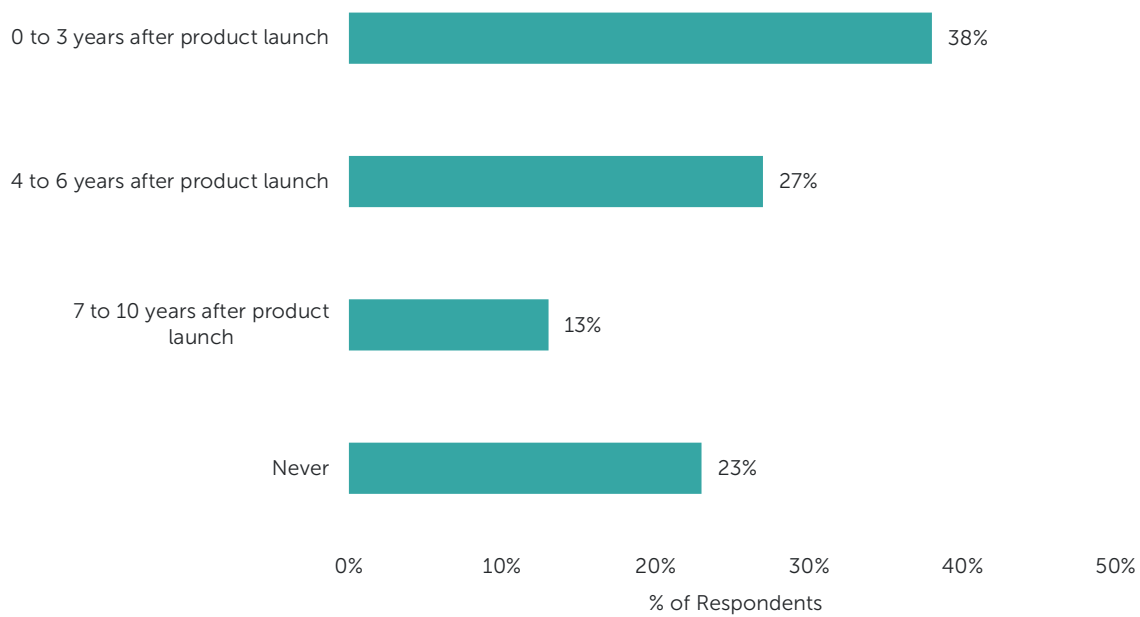
"Select each of the life-cycle management strategies your company is currently considering or has acted upon within the past year for sterile injectable drug products." (n=30)



Delivery Format Conversion Timeline

Respondents at non-large companies were mixed regarding the time they would take to convert their liquid vial products to more patient-centric options. While three-quarters of respondents indicated some time frame (immediately to 10 years after product launch), one-quarter said their company would never introduce a more patient-centric option.

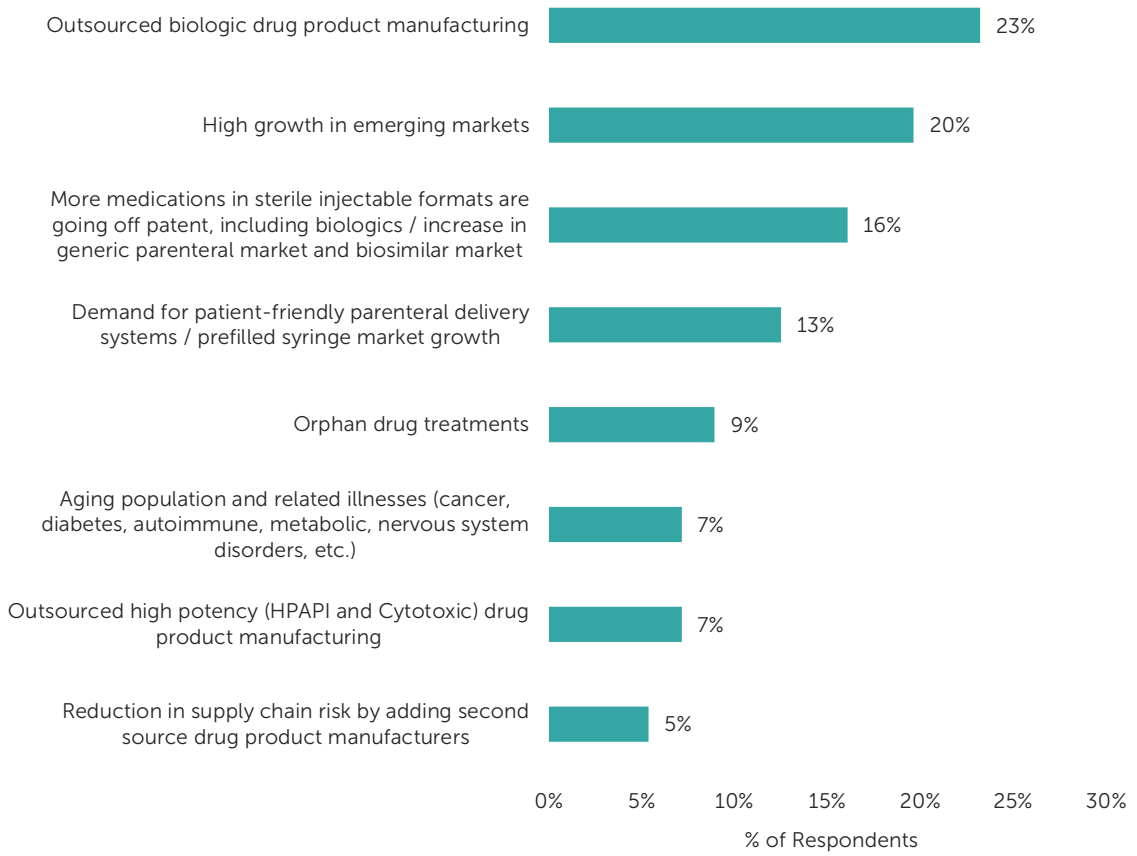
"For products introduced to the market as liquid vials, in what time frame might your company convert to, or additionally offer, a more patient-centric option such as a pre-filled syringe or cartridge?" (n=56)



Sterile Injectable CMO Market Growth Drivers

Respondents at non-large companies cited *Outsourced biologic drug product manufacturing* (23%) and *High growth in emerging markets* (20%) as the top drivers they believe will have the greatest impact on sterile injectable CMO market growth over the next five years.

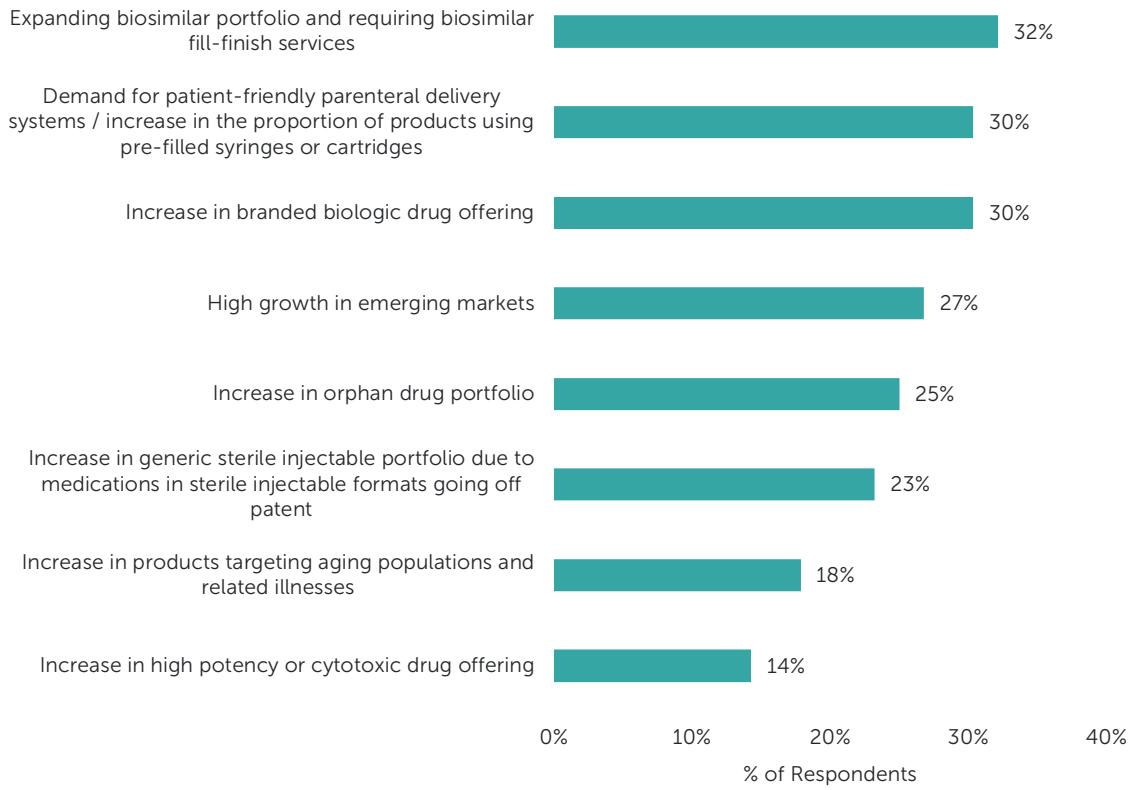
"In your opinion, which of these drivers will have the greatest contribution to sterile injectable CMO market growth over the next five years?" (n=56)



Factors that May Increase Outsourcing

Quite a few factors are expected to increase future sterile injectable outsourcing per respondents at non-large companies. Three factors captured the most votes by nearly one-third of respondents each: *Expanding biosimilar portfolio* (32%), *Demand for patient-friendly delivery systems* (30%), and *Increase in branded biologics* (30%).

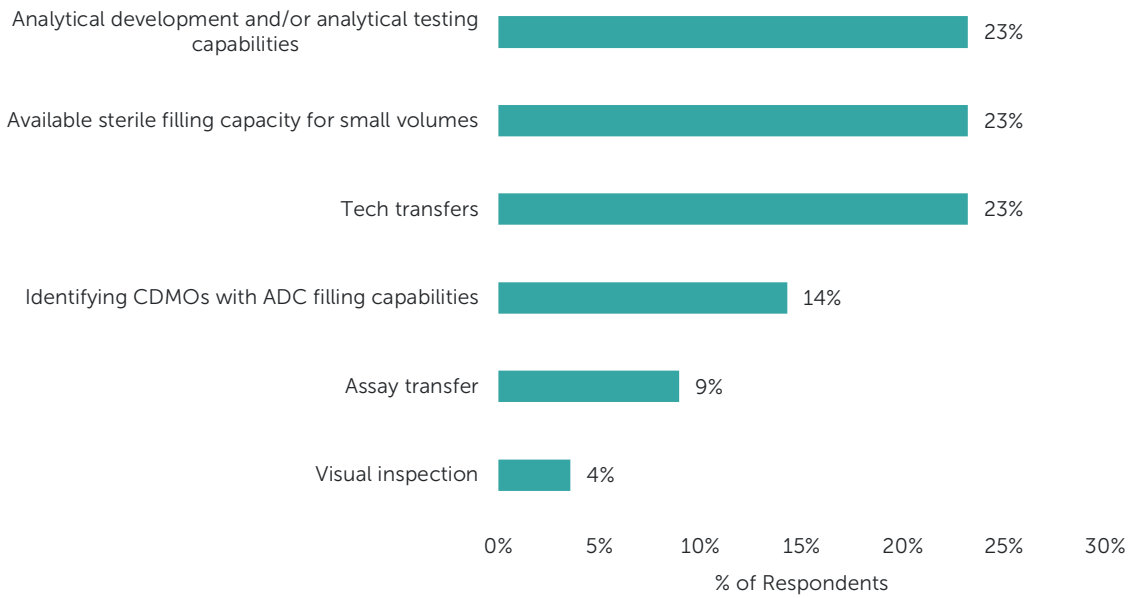
"Which of the following factors will cause the proportion of products/compounds for which your company outsources sterile injectable manufacturing to increase over the next five years? Select all that apply." (n=56)



Challenges to Outsourcing Sterile Injectable Manufacturing

Three challenges are equally considered the biggest obstacle faced by respondents at non-large companies when outsourcing sterile injectable drug product manufacturing. Nearly one-quarter of respondents (23%) selected for each: *Analytical development*, *Available filling capacity*, and *Tech transfers*.

"What is the biggest challenge your company faces when outsourcing sterile injectable drug product manufacturing to CDMOs/CMOs?" (n=56)



Challenges to Outsourcing – Respondent Comments

Verbatim comments are provided below from respondents at non-large companies. Comments are grouped accordingly by selected challenge.

"Please describe why [selected challenge] is the most challenging aspect of outsourcing sterile injectable drug product manufacturing."

Analytical development and/or analytical testing capabilities

- *Complexity of analytical development and timelines*
- *Difficulty with our CMO correctly managing 3rd party labs for outsourced analytical. Frequently need to jump in and work with them directly, even though it should be CMO managing them*
- *Extractables*
- *Getting customized solutions, chromatography (liquid or Gas), with latest technology, method development, etc. are some of the challenges*
- *Lack of experienced personnel*
- *Lack of internal resources to guide the CMO*
- *Most complex to be aligned*
- *Not an area of expertise for this company*
- *Our drug's physical properties*
- *Specific activity tests*
- *This may be unique to our chemistries, however, the analytical methods developed earlier in development often do not transfer*
- *Very few CMOs have all the analytical methods required by us which will require third party vendors*

Assay transfer

- *Ability to do this well and meeting regulatory requirements*
- *Capable scientists, attention, and time at vendor for this part of the chain*
- *It is difficult*
- *Needs to be reproducible*
- *The transfer process is very complicated; the accuracy is most critical and often has complications*

Available sterile filling capacity for small volumes

- *Cost effectiveness of small manufacturing campaigns*
- *Few companies offer services at a reasonable cost*
- *For clinical trials it could be difficult to find CMOs for small volumes*
- *Hard to audit*
- *Hard to find partners at an appropriate price for smaller volumes*
- *Have to use smaller companies for low volume*
- *Low volumes vs too high prices*
- *Many CMOs do not want to handle the small batches needed for Phase 1 studies*

- *Small potatoes generally for clinical fills*
- *Small volumes mean small spend and this acts as a counter incentive for the CMOs*
- *SMO looking for service provider willing to fill small volume*
- *Specialty fill capabilities are hard to find*
- *Timelines are unrealistic to manufacture clinical supply*

Identifying CDMOs with ADC filling capabilities

- *Each product has its own specific requirements*
- *Finding the correct technologies and resources for a complex product*
- *Hard to find companies with powder dispensing capabilities*
- *Inadequate manufacturing capability*
- *Not too many have these capabilities and the ones that have them charge more than premium prices*
- *Size of our organization puts us as a low priority with manufacturers, occasionally resulting in timeline and quality issues*
- *Track record*
- *We have been challenged to find CDMOs with ADC filling capabilities that have the capacity we need within our budget*

Tech transfers

- *Collaboration between source company and CMOs is always difficult*
- *Cost and time*
- *Current vendor has poor infrastructure and takes longer than the standard timeframe to complete tasks*
- *Finding the right line fit*
- *Long and costly process*
- *Manufacturing process and nature of work requires a more specialized skill set*
- *Products are highly technically challenging; providers often say yes to a TT, then work out whether they can do it*
- *Regulatory limitations*
- *Scale up, equipment variation factors have lots of complexities*
- *Takes the most internal resources and time*
- *The proposed new CMO typically tries to force fit the currently approved manufacturing process into their existing equipment/processes, and are typically unwilling to be flexible and make the changes needed at a reasonable price and acceptable timeframe*
- *This is where most of the delays occur*
- *We deal with very complex molecules. Special handling considerations (not for safety) are required and many CDMOs tend to downplay the importance of this leading to failed batches until they come around to understand*

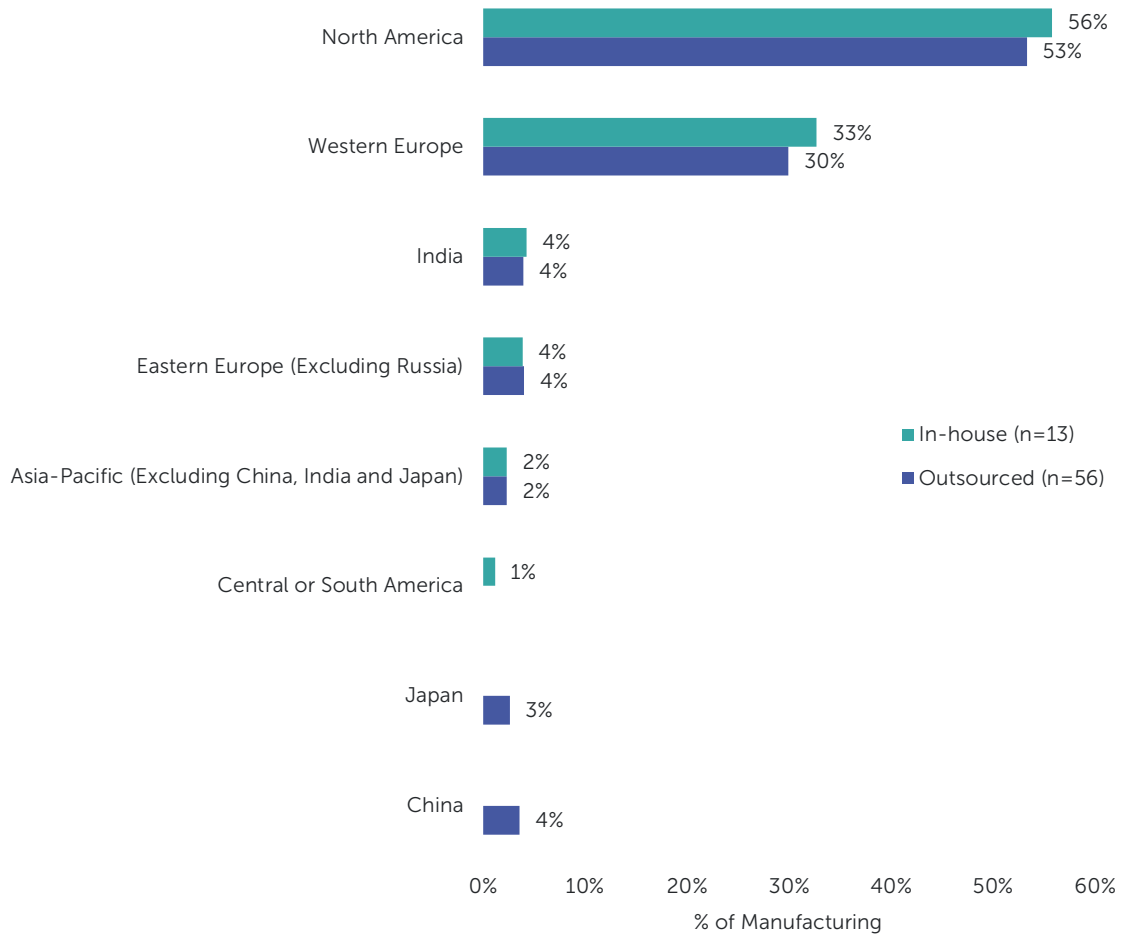
Visual inspection

- *Can be subjective*
- *Several observations or batch rejected from Asia authority because of visual non-conformity*

Manufacturing by Region

Per respondents at non-large companies, more than half of in-house (56%) and outsourced (53%) sterile injectable drug product manufacturing occurs in North America. Western Europe follows as the next most utilized location – 33% of in-house and 30% of outsourced manufacturing occurs here.

"When performed in-house / outsourced, please estimate the percentage of sterile injectable drug product manufacturing performed in each country/region. [Sum must equal 100%.]"



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