Whitepaper

Balancing Cost Efficiencies In The Drug Development Process

The average cost of bringing a drug to market continues to increase as regulation becomes increasingly stringent, treatments become increasingly complex, and as manufacturing supply chains are reshored away from cheaper – but less reliable – locations. Even the lowest estimates put the average cost of bringing a drug to market at $1.3bn, while many estimates put the cost at more than double this.

Either way, the pharmaceutical industry is searching for ways to improve cost efficiencies throughout the drug development process, with the early research and preclinical stages in particular constituting a major drain on resources.

Decisions around manufacturing equipment and facilities are of critical concern to companies across the industry, with small and medium-sized firms facing a choice between developing internal capabilities, partnering with a larger firm or outsourcing to a contract development and manufacturing organization (CDMO). The explosion in new biotechs over the last two decades, along with the proliferation of new and highly innovative treatments, has created a huge demand for capacity and increasingly expensive technology.

Companies looking to increase cost efficiencies have various considerations to incorporate. Decision-making around effective project management, partnerships strategy and developing sustainable processes requires crucial considerations throughout the drug development process. Companies across the industry often look to outsourcing to help achieve success in all these areas, which combine to increase cost efficiency.

Often new technology is needed to develop novel therapies, particularly in the cell and gene space, with scaling up proving to be a persistent bottleneck when dealing with low volumes. Cost efficiencies and expertise again go hand in hand, with companies often outsourcing or partnering primarily to gain access to manufacturing know-how.

To understand company attitudes around cost efficiencies and what actions they have taken, Informa Pharma Intelligence and Cambrex surveyed 113 professionals from across the biopharma spectrum.

How Companies Are Approaching Cost Efficiencies

When asked which stage of drug development was most expensive

Why Cambrex?

Cambrex provides drug substance, drug product and analytical services across the entire lifecycle.

We deliver quality in every aspect of our work, across all of our facilities, systems and teams.

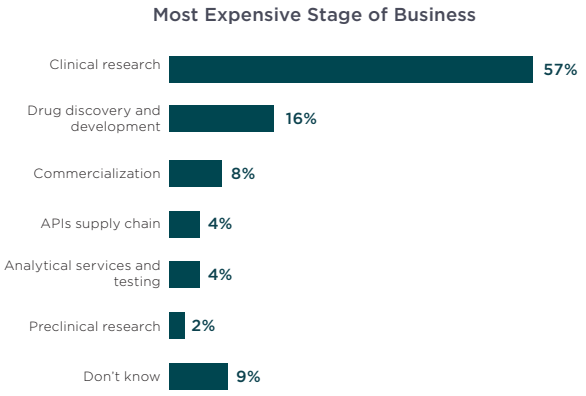
About Cambrex

Cambrex is **the** small molecule company that provides drug substance, drug product and analytical services across the entire drug lifecycle. Enjoy working with our experts to accelerate your small molecule therapeutics into the market.

With 40 years' experience and a growing team of over 2,200 experts servicing our global clients from our sites in North America and Europe, we are tried and trusted in branded and generic markets for API and dosage form development and manufacturing.

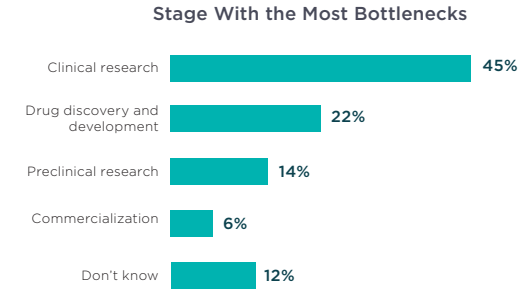
for their business, an overwhelming 57% of respondents selected clinical research, with the second highest response – drug discovery and development – a distant second at 16%. As for the stages with the most bottlenecks, clinical research again came out as a clear leader, albeit at a reduced margin of 45%. Drug discovery and development came a slightly less distant second at 22% (see Figure 1).

Figure 1: Business Stages



Question: Which of the following stages is the most expensive for your business?

Base: All Respondents (n=112)

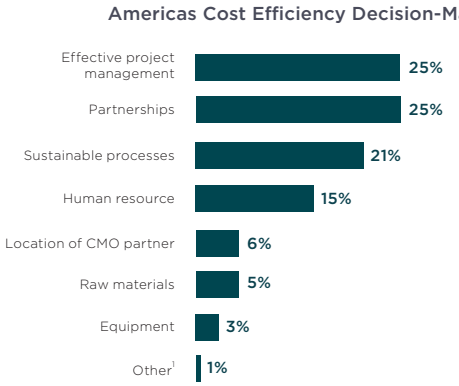


Question: From your experience, which stage of the drug development process causes the most bottlenecks?

Base: All Respondents (n=113)

While there appears to be a broad consensus on the most expensive aspects of drug development, there is divergence in terms of strategy used for managing costs at the top level. Companies are pursuing the creation of sustainable processes, investing to reduce long-term costs or employing cost-saving measures in the near term. Just under 20% said that their entire cost management strategy is to work with a CDMO or outsource in general (see Figure 2).

Figure 2: Cost Efficiency Decision-Making by Region



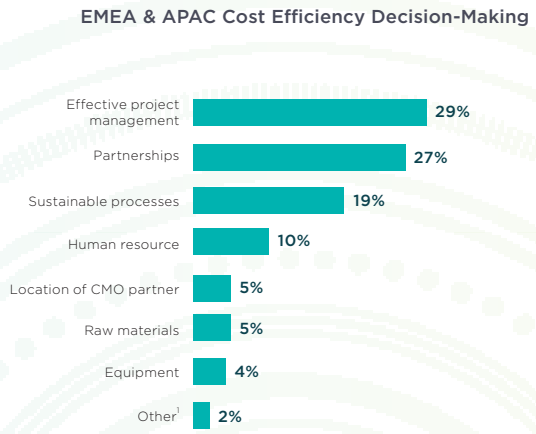
Question: What are the three most important considerations for achieving cost efficiency in the drug development process? (Please select up to three considerations)

Base: All Respondents (n=66); three answers permitted (n=177)

[1]Other Includes: Cost efficiency culture / Reinforced mind set

Delving into cost efficiency at a more granular level, two considerations stand out in companies' thinking – effective project management and partnerships. Sustainable processes were reported by just 20% of companies as being among their top three most important considerations, despite this being cited as the overall cost management strategy for a full 30% of companies. Company thinking is broadly aligned between the Americas, EMEA and APAC, with the exception of human resource – valued 5% higher in the former (see Figure 3).

Figure 3: Cost Efficiency Decision-Making by Region



Question: What are the three most important considerations for achieving cost efficiency in the drug development process? (Please select up to three considerations)

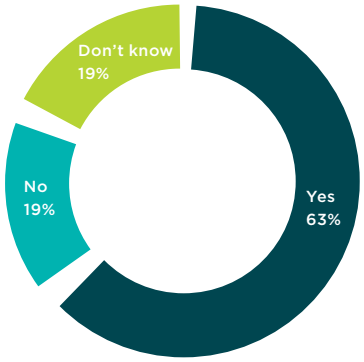
Base: All Respondents (n=112); three answers permitted (n=152)

[1]Other Includes: Technology

Despite being an overall "strategy" for just 20% of companies, outsourcing is widely employed throughout the industry. Two-thirds of organizations reported outsourcing at least some parts of the drug development process, with clinical research and manufacturing the most common areas that are outsourcing (see Figure 4).

Figure 4: Outsourcing Drug Development Processes

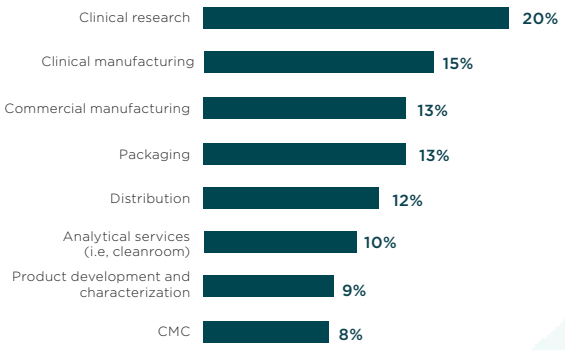
Outsourcing Any Part of the Drug Development Process



Question: Do you outsource any part of your drug development process?

Base: All Respondents (n=113)

Which Part of Your Drug Development Do You Outsource?



Question: Which parts of your drug development do you outsource? (Please select all that apply)

Base: Respondents who indicated they outsource part of their drug development (n=71); multiple answers permitted (n=232)

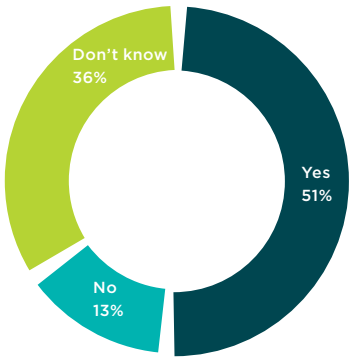
There is some variation depending on organization size, however. Outsourcing is utilized far more by small biopharma companies, with 57% reportedly outsourcing over 50% of drug development, with a further 14% outsourcing 31–40% of the process. Mid-sized pharma still reported outsourcing a significant portion of development, with large pharma outsourcing the least.

"Large pharma" companies responded that they outsource distribution more than any other part of the drug development process, while clinical manufacturing was the most outsourced from small and mid-sized biopharma. (see Figure 5 at the end of report, on page 6).

On outsourcing cost, 51% of companies reported that they made cost savings from outsourcing, with only 13% responding that they did not (the remainder being uncertain). Of those that responded yes, 41% even reported they outsource more than half of their drug development, with 49% of companies reportedly outsourcing between 21% and 50% (see Figure 6).

Figure 6: Cost Savings and Drug Development Outsourcing

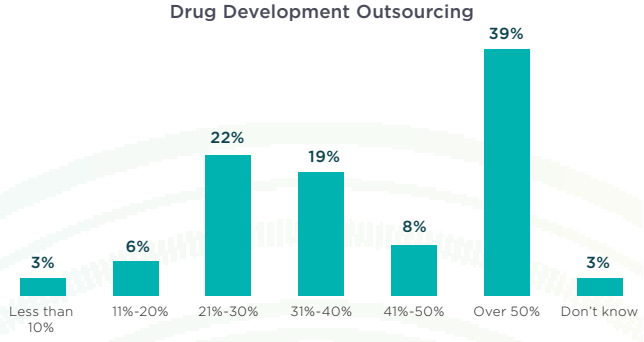
Outsourcing Cost Savings



Question: Have you made cost savings since outsourcing?

Base: Respondents who indicated they outsource part of their drug development (n=70)

Drug Development Outsourcing

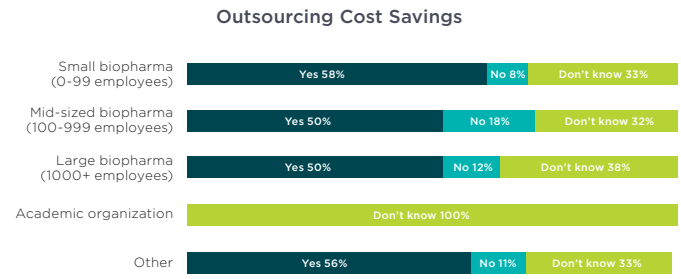


Question: How much of your drug development do you outsource?

Base: Respondents who indicated a cost savings from outsourcing their drug development (n=36)

There is once again some nuance between the varying company sizes, with small biopharma companies reporting 58% cost savings from outsourcing, compared with 50% from mid-sized and large biopharma (see Figure 7).

Figure 7: Cost Savings by Organization Type

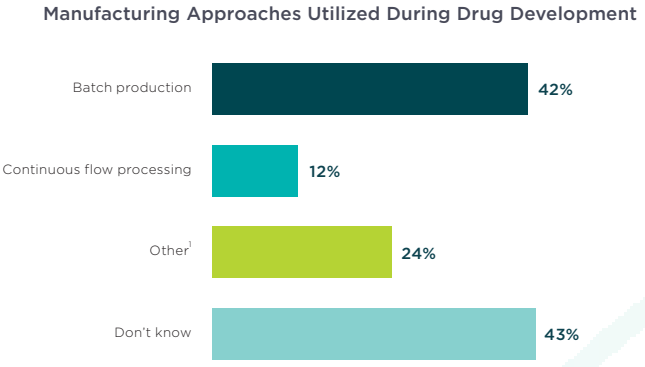


Question: Have you made cost savings since outsourcing?

Base: Respondents who indicated they outsource part of their drug development (n=70) / Small biopharma (0-99 employees) (n=12) / mid-sized biopharma (100-999 employees) (n=22) / Large biopharma (1000+ employees) (n=26) / Academic organization (n=1) / Other (please specify) (n=9)

On manufacturing approaches used for drug development, the majority of companies utilize batch production, citing its quick turnaround and ease of implementation. Several companies also responded that batch manufacturing is better suited to smaller volumes, and more generally that it depends on the type of product being manufactured. Far fewer companies reported that they made use of continuous flow production, despite many believing it to be more efficient, with the results suggesting that it is particularly difficult for smaller organizations to utilize for lower production volumes. (see Figure 8).

Figure 8: Manufacturing Approaches Utilized



Question: What manufacturing approaches do you utilize in your drug development?

Base: All respondents (n=109). Other[1] includes: Both; We are CRO & CMO.

Does one method provide greater cost efficiency?[1]

- Batch production is quicker in the short term. Everything is to have a product available as quick as possible
- Continuous flow is the most efficient but we are only making lots for clinical use
- Continuous would if we can evolve that process
- For small scale runs batch processing is the only way to do it
- Insufficient information to reply
- It depends on the product
- It is the only method used and validated
- Once batch for GLP and GMP early development
- Rare disease - small volume = small batches
- Volume sensitive could change the answer
- We are small and in rare disease
- We are too small to assess various processes
- Yes, batch production is efficient

Does one method provide greater cost efficiency?[1]

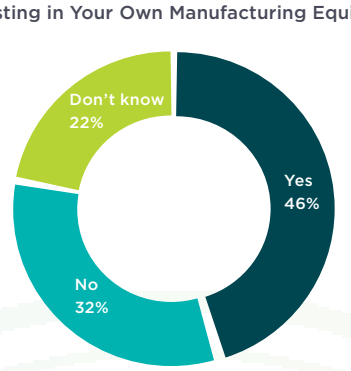
- Batch production is usually more cost effective, unless we greatly under or overestimate demand
- Yes depending on the product. Cell therapies vs. small molecules

Does one method provide greater cost efficiency?[1]

- Relates to partnerships and/or acquisitions vs. current internal manufacturing capabilities

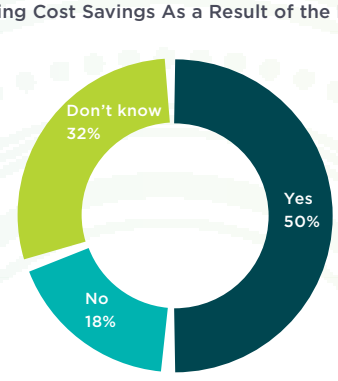
The majority of companies also appear to be increasing investments in internal manufacturing capabilities, alongside the proliferation of outsourcing discussed above. 46% of companies reported investment in internal manufacturing equipment, against 32% of respondents that are not. Of those that are investing, half reported to have experienced cost savings as a result of their investments, with a significant 32% being unsure. Around 50% reported cost savings of between 11% and 30%, significantly less than companies have reportedly saved via outsourcing parts of the drug development process (see Figure 9).

Figure 9: Investing in Your Own Manufacturing Equipment



Question: Have you invested in your own manufacturing equipment?

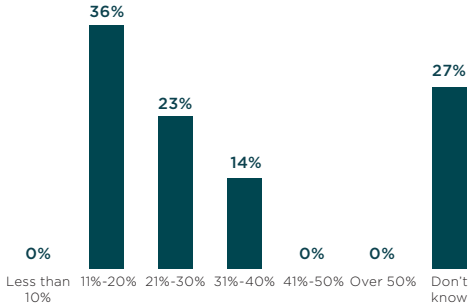
Base: All respondents (n=109).



Question: Have you experienced cost savings as a result of this investment?

Base: Respondents who indicated they have experienced a cost saving (n=50).

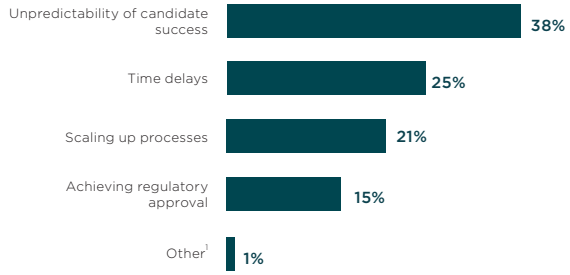
Cost Savings As a Result of Investment in Own Manufacturing Equipment



Question: What percentage of costs have you saved through investment in your own manufacturing equipment?

Base: Respondents who indicated they have experienced a cost saving (n=22).

Biggest Challenges to Cost Efficiency



Question: What is the biggest challenge to cost efficiency in the drug development process?

Base: All respondents (n=100). Other[1] includes: Not sure.

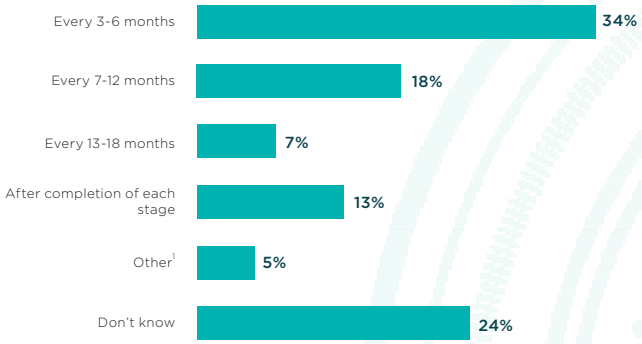
These figures mask a divide between small and mid-sized biopharma companies on the one side and large pharma on the other, however. Only 29% of small biopharma companies reported that they were investing in internal manufacturing capabilities, against 59% that are not. The proportions were much more balanced in mid-sized pharma companies (47% no vs. 40% yes), while the overwhelming majority of large pharma companies are investing in their own equipment – 83% against just 3% of companies who reported that they were not.

Keeping careful track of drug development costs is essential given the difficulty of forecasting, but there is a fair degree of variability among companies regarding how frequently to conduct cost reviews. The majority (34%) conduct such reviews every 3–6 months, 18% every 7–12 months, and 7% only review costs every 13–18 months, with 13% opting to review costs after completion of each stage. Regarding the biggest challenges to achieving cost efficiencies, the unpredictability of candidate success was ranked highest among company respondents. This was followed by timing delays, difficulty in scaling up processes and achieving regulatory approval (see Figure 10).

Finally, just under a third of companies are already working with a CDMO to save costs. Of the 44% of those that are not, 13% are planning to in the future, with a further 42% being unsure (see Figure 11).

Figure 10: Drug Development Cost Reviews and Cost Efficiency Challenges

Drug Development Cost Reviews

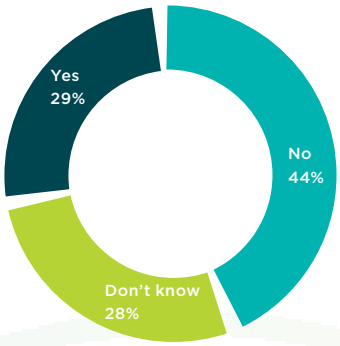


Question: How often do you review costs during the drug development process?

Base: All respondents (n=102). Other[1] includes: We loosely assess costs as we go; Rarely, We don't review costs and Monthly.

Figure 11: Working with a CDMO to Save Costs

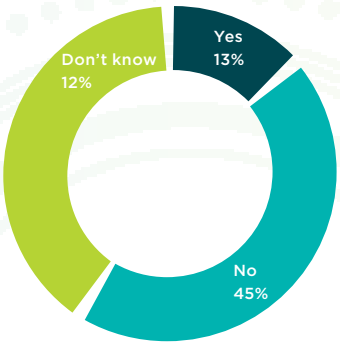
Currently working with a CDMO as a Cost Savings Exercise



Question: Do you currently work with a CDMO as a cost saving exercise?

Base: All respondents (n=100).

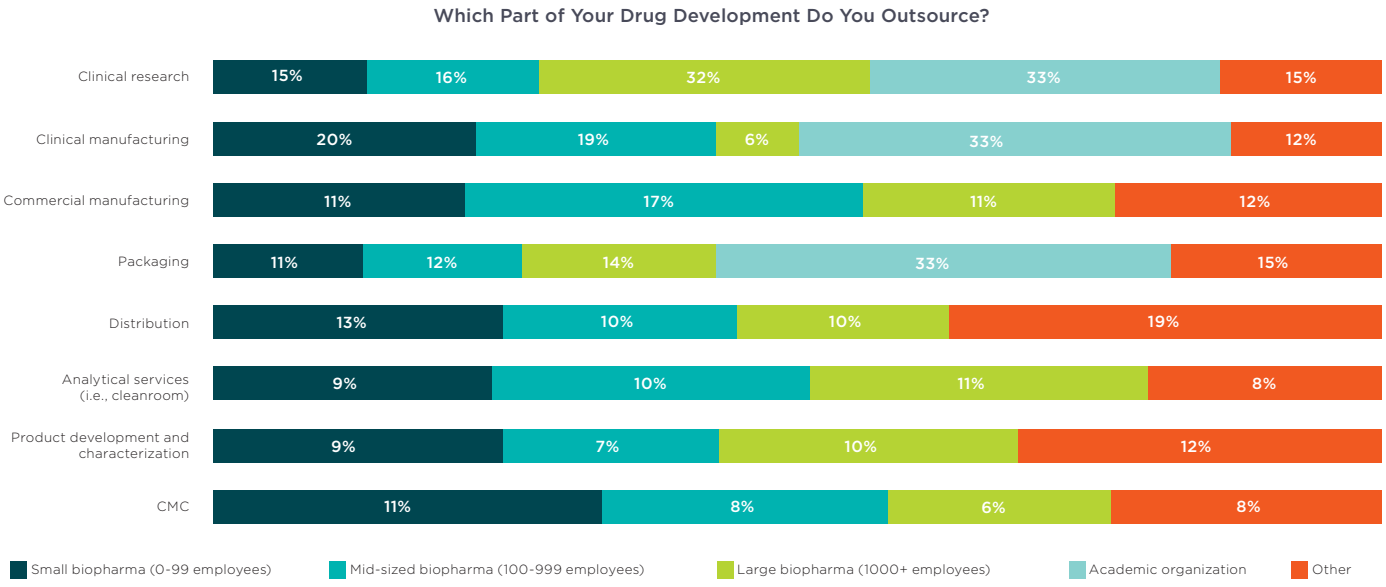
Planning to Work with a CDMO to Save Costs



Question: Do you plan to work with a CDMO to save costs?

Base: Respondents who indicated they currently work with a CDMO (n=45).

Figure 5: Outsourcing Drug Development Processes by Organization Type



Question: Which parts of your drug development do you outsource? (Please select all that apply)

Base: Respondents who indicated they outsource part of their drug development (n=71); multiple answers permitted (n=232) / Small biopharma (0-99 employees) (n=54) / Mid-sized biopharma (100-999 employees) (n=86) / Large biopharma (1000+ employees) (n=63) / Academic organization (n=3) / Other (please specify) (n=26).

Looking Ahead

The increasing outsourcing the industry has witnessed over the past decade is evidence of the value the biopharma industry believes CDMOs can bring, with these companies having established themselves as viable alternatives to in-house development and manufacturing. The growth trend is likely to continue, with the growing number of small and medium-sized biopharma companies having no existing manufacturing capabilities of their own.

The high cost of drug development can most obviously be solved by outsourcing when economies of scale come into play. It often does not make sense for a small biopharma to make huge capital investments in manufacturing capacity to make relatively small quantities of product, when a specialized manufacturing company can scale up and meet that demand at a lower cost per unit. Outsourcing can be positive and save costs even with novel products that require new specialized equipment, by leveraging expertise in similar operations.

This is supported by the evidence generated by the above survey. As would be expected, small and mid-sized biopharma companies have outsourced huge portions of their drug development, with the majority reporting cost savings. This trend is likely to continue, – given the demand on resources and expertise required for each individual company to develop its own capacities and the inefficiencies this would generate – throughout an industry that is trying to bring down the time it takes and the cost incurred to bring life-saving drugs to market.

Large pharmaceutical companies on the other hand are investing predominantly in their own manufacturing capacity, given that they can generate the economies of scale that make such manufacturing efficient.

Going forward, the industry will be balancing cost efficiencies and supply chain security, with decisions on outsourcing dependent on company size and product type.

References

1. Wouters, Olivier J., McKee, Martin, and Luyten, Jeroen. (2020-03-03). "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018." JAMA. 323 (9): 844–853. doi:10.1001/jama.2020.1166. ISSN 0098-7484. PMC 7054832. PMID 32125404.
2. Want to Know Why Early Drug Development Costs So Much? https://www.pcisynthesis.com/want-to-know-why-early-drug-development-costs-so-much/
3. Overcoming Bottlenecks in the Manufacturing of Biologics. https://www.outsourcing-pharma.com/Article/2006/08/01/Overcoming-bottlenecks-in-the-manufacturing-of-biologics
4. Current Trends and Strategic Options in the Pharma CDMO Market. https://www.pwc.de/de/gesundheitswesen-und-pharma/studie-pharma-cdmo-market.pdf