www.pwc.de

Current trends and strategic options in the pharma CDMO market

pwc

Table of contents

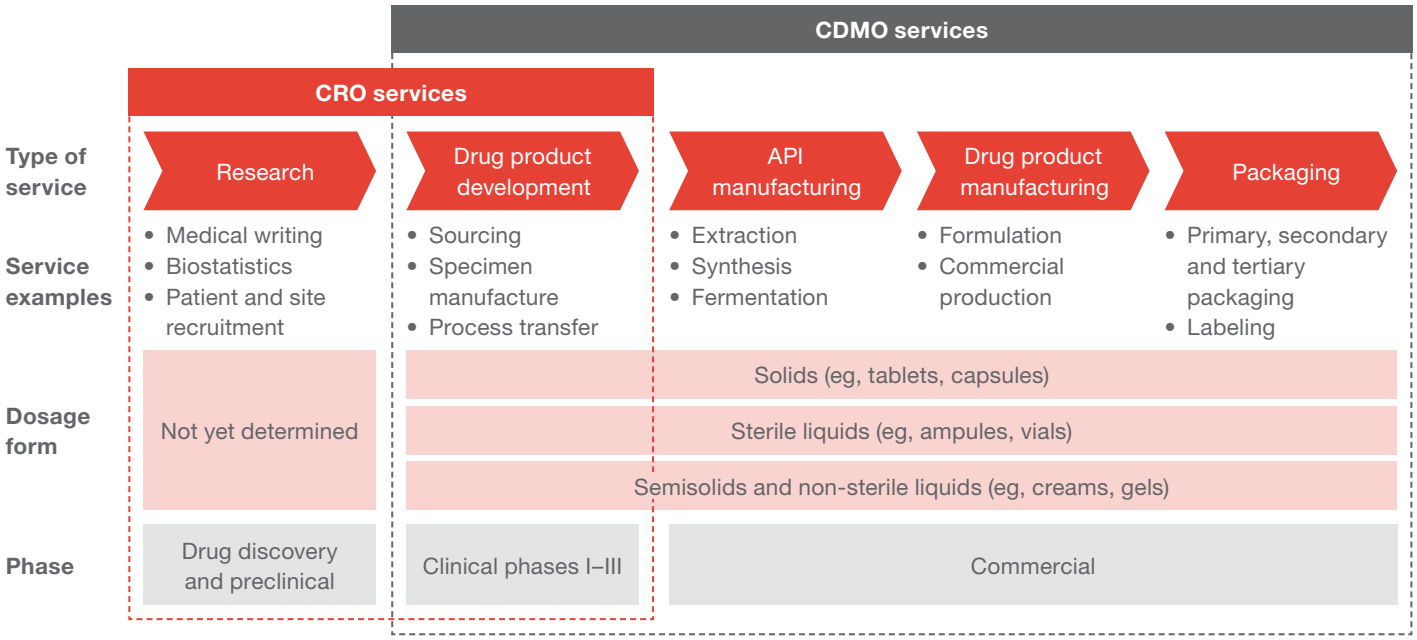
Table of figures

A Introduction

Contract development and manufacturing organisations (CDMOs) have established themselves as viable alternatives to the in-house development and manufacturing units of pharmaceutical companies over recent decades. The increasing outsourcing trend in the pharmaceutical industry demonstrates the success of this business model, as CDMOs are increasingly becoming integral parts of pharmaceutical companies' value chains. However, while the industry as a whole is thriving, many CDMOs are finding themselves confronted with unprecedented challenges. Fierce competition, cost pressure, constant technological innovations and increasing consolidation activities raise the question of which steps companies can take to secure or expand their position in this contested market. Should they focus on their core business or broaden their range of services? Should they follow the market trend and consolidate or try to grow organically?

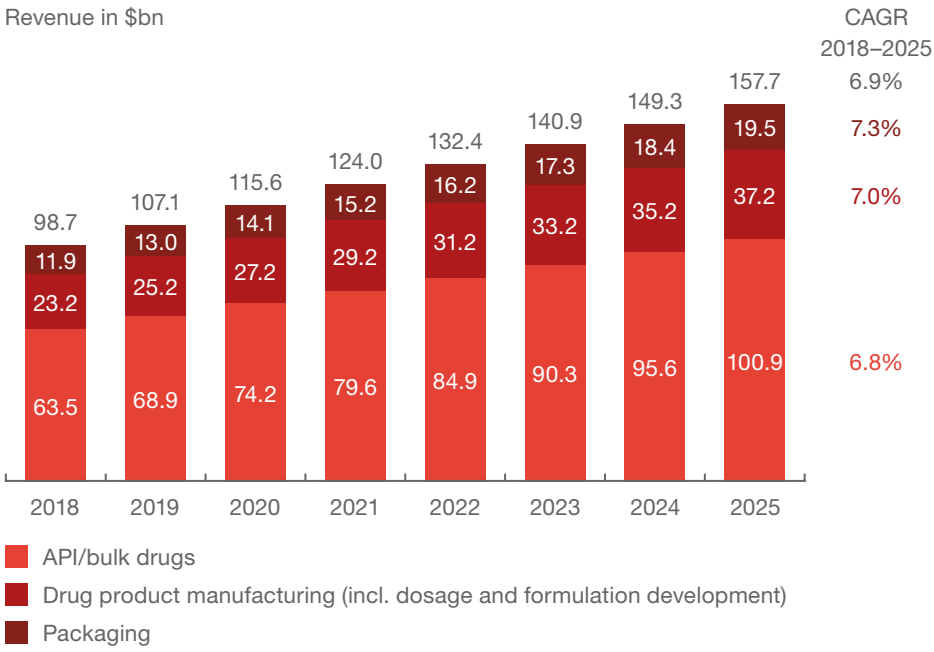
Contract research organisations (CROs) and contract development and manufacturing organisations (CDMOs) offer outsourcing services for pharmaceutical research, development and manufacturing. CROs support pharmaceutical companies in their drug discovery and clinical research efforts. Typical CRO services include patient and site recruitment, clinical monitoring, analytics, biostatistics, medical writing and regulatory affairs consulting. CDMOs, on the other hand, take over parts of the drug product development and manufacturing activities of pharmaceutical companies. They offer drug product development and manufacturing services, and active pharmaceutical ingredient (API) production and packaging services. There is an increasing degree of overlap between these two types of service providers: some CDMOs are starting to offer CRO services and vice versa, with the aim of becoming "one-stop shops" covering the whole value chain from drug discovery to commercialisation.

Fig. 1 Overview of CRO and CDMO services



B Market trends

Fig. 2 CDMO market by service

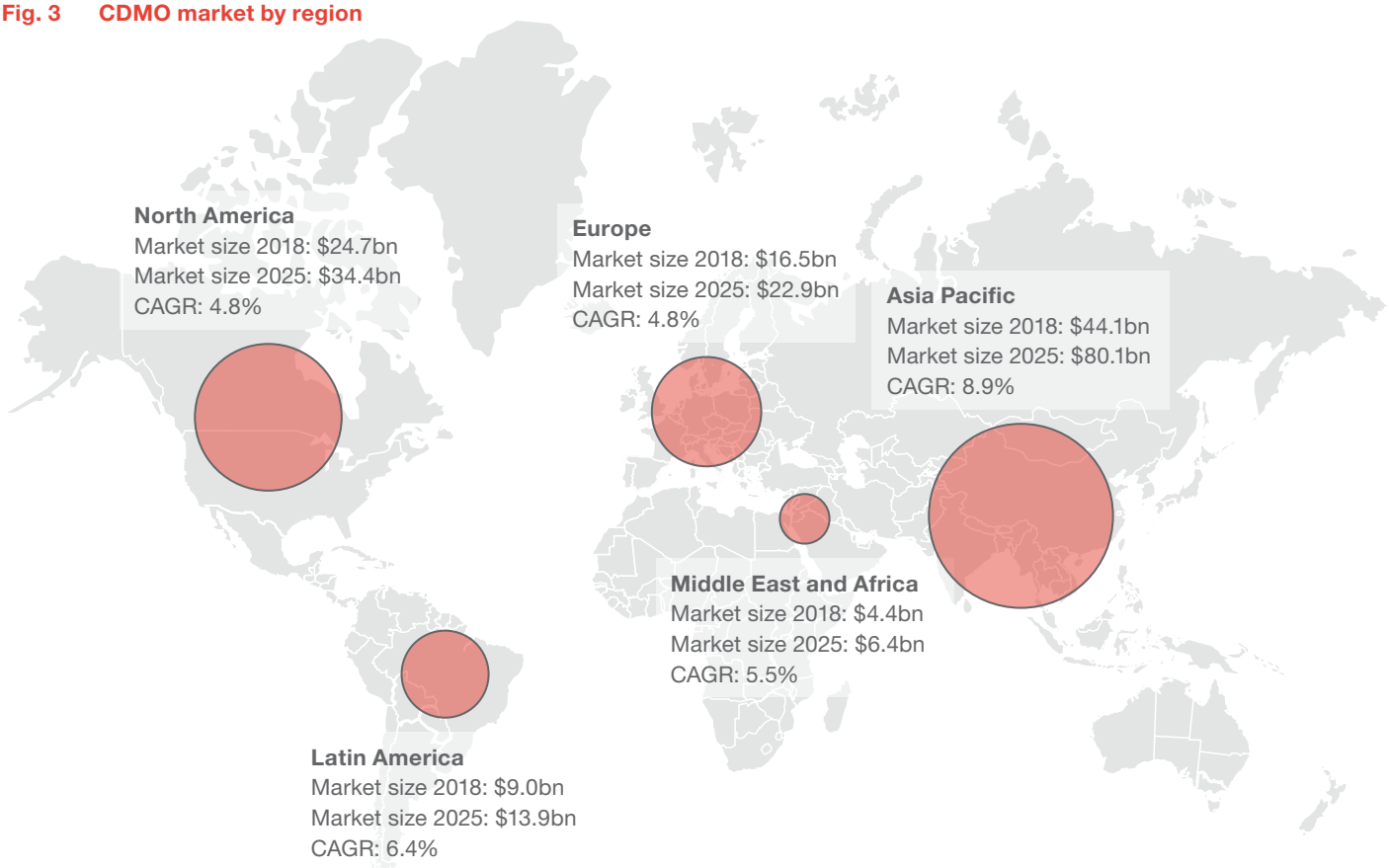


Source: Grand View Research (2017), pp. 43–48 https://www.grandviewresearch.com/industry-analysis/pharmaceutical-contract-manufacturing-market Ask for Mr. Kaustubh Hinge if you call or mention the name in website form to get assistance on this report.

1 Global market outlook

According to Grand View Research estimates, the CDMO market will grow from $98.7 billion in 2018 to $157.7 billion in 2025. With a compound annual growth rate (CAGR) of 6.9%, this growth will outpace the pharmaceutical industry as a whole. The strong development of the CDMO market can thus not only be attributed to an increasing overall need for pharmaceuticals due to an increasing global population, better insurance coverage in developing countries and ageing societies in industrialised countries; it is also a result of the greater willingness to outsource among pharmaceutical companies, which increasingly use outsourcing services as a means to decrease time to market, save costs, reduce complexity and reallocate internal resources.

Fig. 3 CDMO market by region



Source: Grand View Research (2017) https://www.grandviewresearch.com/industry-analysis/pharmaceutical-contract-manufacturing-market Ask for Mr. Kaustubh Hinge if you call or mention the name in website form to get assistance on this report.

2 Regional developments

The Asia Pacific region, and particularly China and India, continues to be the leading growth market in the CDMO industry due to considerably lower manufacturing costs than in North America and Europe and favourable regulations. While China and India have established themselves as the major suppliers of API manufacturing services, the US remains the primary hub for pharmaceutical development outsourcing. This is mainly due to the large amounts of available funding as well as the unique concentration of university-affiliated pharmaceutical research clusters. In addition, issues related to quality, logistics, regulations and intellectual property rights make developing countries unattractive for pharmaceutical development outsourcing.

3 Development of main dosage forms

While solid dosage forms have long been the largest segment, sterile liquids are currently enjoying the strongest growth, taking up an increasingly large share of the pharmaceutical development and manufacturing outsourcing market. The high growth in the sterile liquids segment is mainly due to the increasing importance of biologics. Given the overall outsourcing trend in the pharmaceutical industry, outsourcing of development and manufacturing activities for solids, semisolids and non-sterile liquids will continue to increase as well, but at a slower pace than sterile liquids.

4 Mergers and acquisitions (M&A)

The CDMO market is characterised by great fragmentation. However, there have been strong merger and acquisition activities in the sector in recent years. Most pharmaceutical companies are looking to work with a small number of suppliers in order to limit the costs and risks involved in technology transfers and to save time. To strengthen their competitiveness, CDMOs are thus choosing to merge, either to extend their range of services for existing dosage forms or to enter the market for another dosage form. However, it is not only CDMOs that are actively acquiring their competitors in this rapidly growing market. Large life sciences companies and private equity firms were responsible for some of the largest deals in the sector. The acquiring companies are often willing to pay large multiples for their targets. In 2017, Thermo Fisher Scientific paid 18.2 times Patheon's earnings before interest, taxes, depreciation and amortisation (EBITDA) to acquire the leading CDMO. In the same year, private equity firms The Carlyle Group and GTCR paid an EBITDA multiple of 14.7x to acquire AMRI and Lonza paid an EBITDA multiple of 15.1x to acquire Capsugel in 2016.

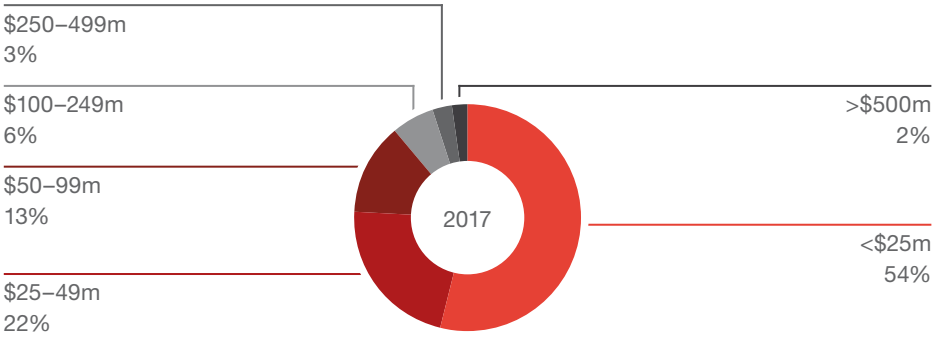
Fig. 4 Acquisitions with disclosed deal values >$100m between 2016–2019

Year	Acquirer	Area of business (acquirer)	Acquirer location	Target	Target location	Deal value ($m)
2017	Thermo Fisher Scientific	Life sciences	USA	Patheon	USA	7,200
2016	Lonza	CDMO	CH	Capsugel	USA	5,500
2019	Thermo Fisher Scientific	Life sciences	USA	Brammer Bio	USA	1,700
2017	Carlyle, GTCR	Private equity	USA	AMRI	USA	1,500
2019	Catalent	CDMO	USA	Paragon Bioservices	USA	1,200
2017	Fosun Pharma	Pharmaceuticals	CN	Gland Pharma	IN	1,090
2017	Catalent	CDMO	USA	Cook Pharmica	USA	950
2016	Mylan	Pharmaceuticals	USA	DPT Laboratories	USA	950
2016	Ardian	Private equity	FR	Unither	FR	715
2017	AGIC Capital	Private equity	CN	Ritedose	USA	600
2016	Humanwell Health-care, PuraCap	Healthcare solutions, CDMO	CN, USA	Epic Pharma	USA	550
2017	AGC Asahi Glass	Glass, electronics, chemicals, ceramics	JP	CMC Biologics	DK	500
2018	Cambrex	CDMO	USA	Halo Pharma	USA	425
2016	AMRI	CDMO	USA	Euticals	IT	358
2018	Cambrex	CDMO	USA	Avista Pharma	USA	252
2016	Recipharm	CDMO	SE	Kemwell Biopharma	IN	205
2017	Clinigen	Pharmaceuticals, clinical trials	GB	Quantum Pharma	GB	192
2018	Aurobindo Pharma	Pharmaceuticals	IN	Generis Farmacêutica	PT	154
2018	Clinigen	Pharmaceuticals, clinical trials	USA	CSM	GB	150

As of today, the CDMO market remains highly fragmented, with more than 75% of participants having revenues below $50 million[1] and the five leading CDMOs holding only 15% of the total market share.[2] Large CDMOs lead the consolidation of the industry, as acquisition activity is highest among CDMOs with revenues above $250 million, while most targets are small companies with revenues below $50 million.[3] Despite efforts of traditional, often family-owned businesses to resist this trend and the high debt ratio of a lot of larger market participants, consolidation in the CDMO market is likely to continue, especially since involvement of private equity firms is growing. A good point of reference is the CRO market, which had been highly fragmented until consolidation started a few years ago. Today, the top five companies in the CRO market account for 70% of the total market share.[4]

Fig. 5 CDMO market concentration

only contract dose manufacturers, API manufacturers not included



∑ 282 players

Source: Recipharm Annual report 2017, p. 7.

"There have been strong merger and acquisition (M&A) activities in the CDMO sector in recent years. The current M&A trend is likely to continue, and is comparable with the CRO consolidation trend. The acquirers will be both large market participants and smaller, private equity-backed CDMOs driving market consolidation."

[1] Cf. PharmSource, Contract dose manufacturing industry by the numbers, 2017, p. 5.
[2] Cf. Melissa Fassbender, "Less is more: Significant CDMO consolidation expected as pharma looks to work with fewer suppliers", October 22nd 2018, www.outsourcing-pharma.com/Article/2018/10/22/Top-5-CDMOs-hold-15-of-the-market-as-industry-consolidation-is-expected-to-continue.
[3] Cf. PharmSource, Trend report: M&A in the contract manufacturing industry: implications & outlook, 2018, pp. 43–49.
[4] Cf. Melissa Fassbender, "Less is more: Significant CDMO consolidation expected as pharma looks to work with fewer suppliers", October 22nd 2018, www.outsourcing-pharma.com/Article/2018/10/22/Top-5-CDMOs-hold-15-of-the-market-as-industry-consolidation-is-expected-to-continue.

C Opportunities and risks

Fig. 6 Opportunities and risks in the current CDMO market

Opportunities	Risks
• Increasing pharmaceutical outsourcing • Co-Investments • Technological advancements • New operational techniques • Increasing number of small- and medium-sized pharmaceutical companies • Higher company values • Higher profitability in a more consolidated market	• Strong competition on costs, technology and service range • Lack of skilled labor • Outsourcing of low-volume and complex drugs • Reliance on a small number of customers • Governmental healthcare cost containment measures • Increasing regulation

1 Opportunities

The increasing outsourcing trend among pharmaceutical companies represents a promising opportunity for CDMOs. As pharmaceutical companies shift their focus towards scientific research and pharmaceutical marketing, CDMOs can further establish themselves as vital partners and build strategic, integrated partnerships with their customers. These cooperations can even lead to co-investments, as some pharmaceutical companies help finance specialised development and manufacturing facilities at strategic CDMOs. Given the increasing number of complex and high-potency compounds, CDMOs can stand out through advanced technology and specialised expertise. Keeping up with the latest technologies is particularly important for niche CDMOs specialising in a certain segment or dosage form. One-stop-shop CDMOs, on the other hand, can differentiate themselves through the convenience and complexity reduction that they offer to their customers. They can also profit from upselling opportunities by capturing projects at an early stage in this market with high transfer costs.

New operational approaches such as continuous manufacturing will allow CDMOs to increase the efficiency of their manufacturing processes, minimising waste and reducing costs. CDMOs will find new market opportunities with the growing number of small and medium-sized pharmaceutical companies, which are responsible for an increasing share of new drug approvals and often have no manufacturing capacity of their own. A main concern for these customers is that their projects will be of secondary importance to CDMOs that also serve larger pharmaceutical firms. Paying attention to smaller customers and understanding their particular needs can therefore be a lucrative differentiation strategy for CDMOs. While the current M&A trend is a threat to the survival and independence of many CDMOs, resistance to consolidation also presents an opportunity to increase company value in this heated market. In contrast to the current fragmented and contested market environment that keeps prices down, a more consolidated market is also likely to offer higher profitability for the remaining CDMOs.

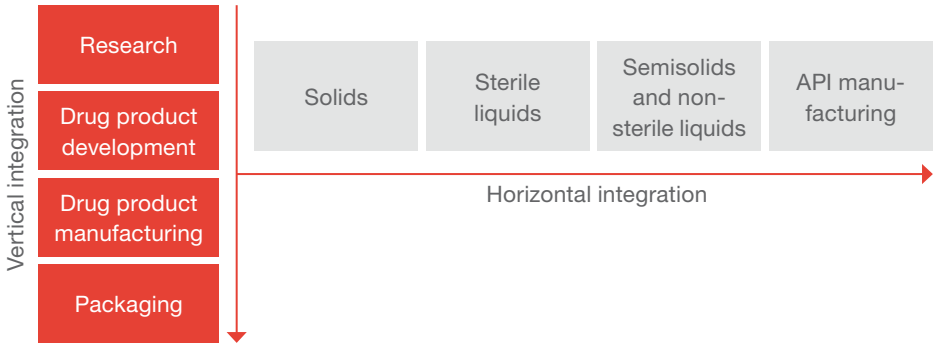
2 Risks

Growing market consolidation is a major risk for many CDMOs. Smaller CDMOs in particular might be unable to compete on costs, technology or service range with the growing number of large CDMOs that consistently expand their services and technological capabilities by acquiring other market participants. They also face the threat of being unable to compete for skilled employees. Qualified scientists and experienced project managers are in high demand for companies throughout the sector, and CDMOs thus not only have to compete for talent with their immediate competitors but also with large, global pharmaceutical companies. Pharmaceutical companies are increasingly outsourcing low-volume formulations, such as niche and orphan drugs, which involve high risks and low revenues. The current high level of fragmentation of the market implies that some CDMOs have to rely on only one or more customers for a large part of their revenues. This dependence is dangerous and creates a lot of negotiating power for the customer to exercise downward pressure on prices. Even more price pressure comes in the form of governmental healthcare cost containment efforts coupled with increased regulation in many countries.

D Strategic options

CDMOs looking to enhance their growth generally have two options: they can either integrate vertically by offering new services for existing dosage forms or API production, or integrate horizontally by offering existing services for new dosage forms. While vertical integration is in many cases the more straightforward expansion strategy, horizontal integration reduces a CDMO's dependence on one dosage form.

Fig. 7 Strategic options for CDMOs



1 Vertical integration

CDMOs can strengthen their core areas and establish themselves as one-stop shops for a specific dosage form by extending their service portfolio. In general, this kind of expansion is less costly and involves lower initial risks than horizontal integration because the CDMO can build on existing knowledge. It also fulfils most of the regulatory requirements and enables cross-selling of new services to existing customers.

The core activity of CDMOs has traditionally been commercial drug product manufacturing to help pharmaceutical companies bridge capacity shortages or manufacture complicated drugs. However, the high margins in drug product development outsourcing have led many former contract manufacturing organisations (CMOs) to start offering development services. CDMOs support the development activities of pharmaceutical companies through the manufacturing of clinical samples (small-scale production). Pharmaceutical companies are outsourcing development services to decrease time to proof of concept for clinical stages I and II, and time to market for products in clinical stage III. The growing number of new drug approvals[5] indicates that drug development continues to be a major focus in the pharmaceutical sector.

As the trend in the pharmaceutical market is towards high-potency drugs, with 25% of APIs currently under development being highly potent,[6] offering development and manufacturing services for high-potency medications is the next logical step for many CDMOs. Building development and manufacturing facilities with high-potency capabilities can be a costly investment since the requirements are more stringent than for non-potent drugs.

In addition to drug product development and manufacturing services, CDMOs can offer packaging of finished products. The pharmaceutical packaging outsourcing market is forecast to grow at a CAGR of 7.3% between 2018 and 2025 due to new and more rigorous packaging and handling requirements. New technologies, such as smart packaging, allow for improved functionality and can help a CDMO stand out from the competition.

CDMOs can further extend their range of services through backward integration into the CRO space. While this allows them to provide customers with even more convenient services, CDMOs risk brand dilution effects and a loss of focus on their core business.

[5] Cf. Alex Keown, "FDA approves record-breaking 59 novel drugs in 2018", January 15th 2019, www.biospace.com/article/fda-approves-59-novel-drugs-in-2018.
[6] Cf. Catherine Hanley, "At-a-glance: highly potent API", September 14th 2017, www.alcaminow.com/blog/highly-potent-api-at-a-glance.

2 Horizontal integration

CDMOs that have reached the limits of growth for a dosage form and want to diversify their risk or position themselves as fully integrated service providers can start offering services for other dosage forms and start producing APIs. However, expanding into a new dosage form tends to be an expensive and risky endeavour and can even, in the case of failure, put the existing business at risk. There are several barriers to entry which make offering a new dosage form difficult, the main ones being high upfront costs, lack of expertise, lack of reputation and the challenge of finding qualified employees.

Sterile liquids are the fastest-growing dosage form in the CDMO market. Profit margins are highest in this segment, making it an attractive dosage form for new market entrants.

Solid dosage forms are becoming less attractive compared to liquid forms but remain a profitable and growing segment. They continue to be the most common dosage form for newly approved drugs due to high patient compliance.

Semisolids and non-sterile liquids are the smallest segment in the CDMO market, making up only 15% of the total market in 2018. They are usually a secondary area of activity for CDMOs which produce sterile liquids as their main dosage form. Over-the-counter and generic products are the main drivers of growth in this segment.

API production is the largest segment of the CDMO market, accounting for $63.5 billion in global revenue in 2018, and many CDMOs are active in this field. Just like other pharmaceutical services, pharmaceutical companies are increasingly outsourcing API production. However, profit margins are low, as most customers in this sector are producers of generics. API manufacturing requires special know-how and large manufacturing capacities. CDMOs looking to enter this market should carefully evaluate their ability to compete in this low-margin sector.

3 Deciding between acquisition and organic growth

In addition to deciding whether to integrate vertically or horizontally, CDMOs have to choose whether they want to grow organically or through acquisition. An acquisition allows a CDMO to expand relatively quickly as production facilities, know-how, human capital and organisational structures are already in place at the target. Building these capabilities organically can be a major challenge. Furthermore, an acquisition can add new technologies to the CDMO's portfolio and give it access to new customer groups, opening opportunities for cross-selling. Some CDMOs are also looking to gain a more global footprint through a merger.

For others, acquisition is the only way to reach and maintain a critical size in this rapidly growing market.

As only about 50% of mergers across all industries succeed,[7] CDMOs should carefully consider such a step. In some cases, a failed acquisition might even threaten the successful core businesses of both acquirer and acquiree. A thorough analysis of internal and external factors helps to assess whether a CDMO is likely to succeed in its M&A activities. Careful searching and screening for appropriate targets and precise valuation and due diligence activities are essential.

The choice of acquisition or organic growth is also strongly linked to the financial means of the CDMO. The funds required will often exceed the equity capital that a CDMO has at its disposal. Especially privately owned CDMOs in particular – with the exception of those that are backed by private equity firms – may therefore refrain from large investments, as taking up large sums of external funding can threaten their independence.

[7] Cf. Godfred Yaw Koi-Akrofi, "Mergers and acquisitions failure rates and perspectives on why they fail". International Journal of Innovation and Applied Studies, 17 (1), 2016, p. 152.

E Conclusion

> *"CDMOs that want to succeed need to consider their reaction to current trends and evaluate their strategic options. Capabilities, company size, ownership, risk preference, organisational culture and available capital are just some of the factors that must be taken into account."*

CDMOs face excellent growth opportunities in a pharmaceutical market environment where using outsourcing services is becoming the new norm. The rise of sterile liquids that has been taking place in recent years will continue and increasingly draw the attention of CDMOs towards this dosage form. The current M&A trend is likely to continue as well, with both large market participants and smaller, private equity-backed CDMOs leading this consolidation. While technological advancements and a growing number of small and medium-sized pharmaceutical companies without their own production facilities bring new opportunities for growth and differentiation, the outsourcing of low-volume and complex drugs, a lack of qualified personnel, and governmental measures to reduce healthcare spending pose major threats to the industry. CDMOs that want to succeed in this fast-moving environment need to consider their reaction to these developments and evaluate their strategic options. Two main strategic directions are available to CDMOs: vertical and horizontal integration. Although it can generally be said that vertical integration is often the less costly path, there is no universal answer to the question of which strategy CDMOs should pursue. Capabilities, company size, ownership, risk preference, organisational culture and available capital are just some of the factors that must be taken into account. Considerations about whether organic growth or acquisition is the more suitable method of expansion should be factored in right from the beginning, as they are closely intertwined with the feasibility of different strategic options. Overall, the attractiveness and fit of different strategies for a CDMO need to be assessed on an individual basis.

Contacts

Prof. Dr. Nikolas Beutin
Partner PwC Management Consulting,
Leader Customer Practice
Mobile: +49 151 62459745
nikolas.beutin@pwc.com

Prof. Dr. Nikolas Beutin has more than 20 years of experience in management and consulting. As a Partner at PwC he leads the European Customer Practice Team and advises companies in the areas of Business Growth Strategy, Pricing, Sales, Marketing and Service.

Dr. Heiko Schmidt
Senior Manager PwC Management Consulting,
Head of the Pharma & Life Sciences business, Customer Practice
Mobile: +49 151 42461793
heiko.schmidt@pwc.com

Dr. Heiko Schmidt is Senior Manager at PwC and Head of the Pharma & Life Sciences business within the Customer Practice. Based on his extensive industry knowledge and over ten years of consulting experience, he supports clients in the area of growth strategies and commercial excellence.

About us

Our clients face diverse challenges, strive to put new ideas into practice and seek expert advice. They turn to us for comprehensive support and practical solutions that deliver maximum value. Whether for a global player, a family business or a public institution, we leverage all of our assets: experience, industry knowledge, high standards of quality, commitment to innovation and the resources of our expert network in 157 countries. Building a trusting and cooperative relationship with our clients is particularly important to us – the better we know and understand our clients' needs, the more effectively we can support them.

PwC. Nearly 12,000 dedicated people at 21 locations. €2.3 billion in turnover. The leading auditing and consulting firm in Germany.