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2022 Global CDMO Study of Pharmaceutical Operations

How to gain a competitive advantage in a fast-changing pharmaceutical supply ecosystem

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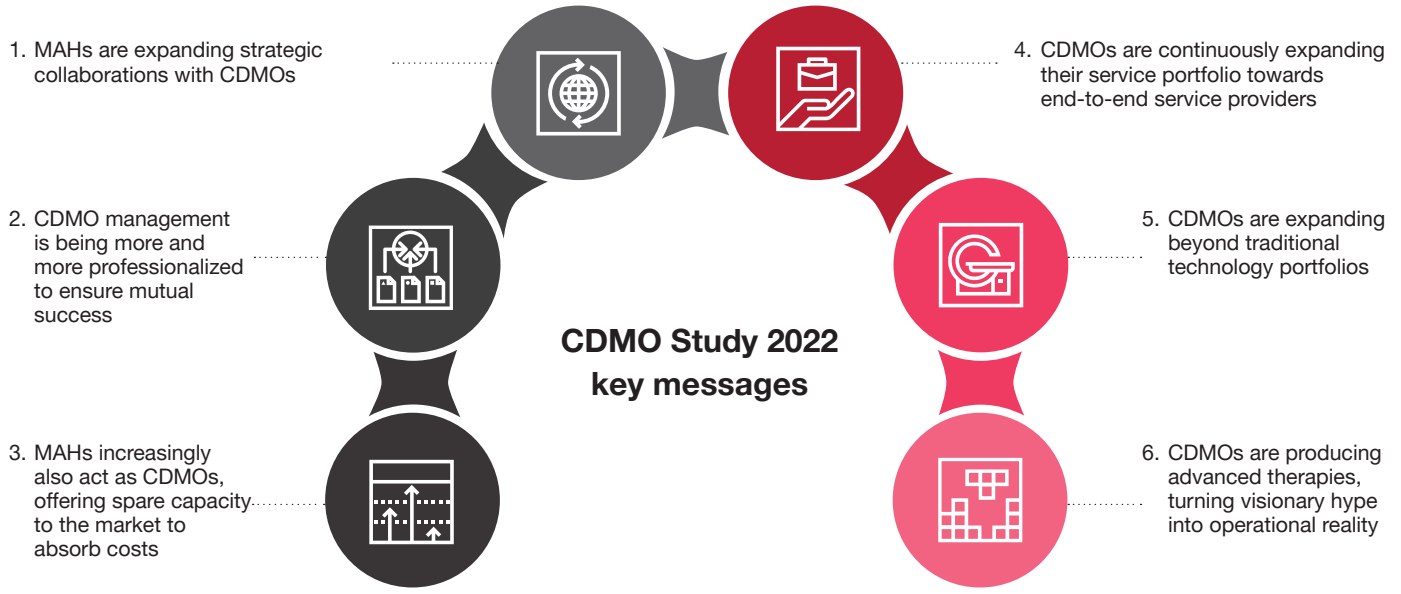
EXECUTIVE SUMMARY

The global Covid-19 pandemic as well as geopolitical tensions and trade restrictions have drawn attention to profound geographical, technical, and structural shifts in pharmaceutical supply chains. Treatments are increasingly produced by highly capable contract development and manufacturing organizations (CDMOs)[1]. As new, extraordinarily sophisticated, advanced therapies (ATx) emerge to complement traditional large and small molecule treatments, this trend looks set to deepen and accelerate. Today, CDMOs are targeting an increasingly attractive business segment, in which pure play CDMOs and other market participants are taking on a growing role.

For the 2022 Global CDMO Study, we put together data from 150 of the world's major players, classified according to the nature of their core business: pure play CDMO, PharmaCo CDMO, generics manufacturing CDMO, and pharma affiliate CDMO. This has given us vital insights into the routes to competitive advantages, especially for marketing authorization holders (MAHs) that are set up to collaborate with CDMOs, for CDMOs positioned to serve marketing authorization holders, and for others that aspire to closer commercial relationships (*see Exhibit 1*).

1 Contract Development and Manufacturing Organizations: both pure CMOs and CDMOs are referred to as CDMOs in this study

EXHIBIT 1
Study key messages



Note: MAH – Marketing Autorisation Holder
Source: Strategy& analysis

Our six key findings are:

1. MAHs are expanding strategic collaborations with CDMOs

To have a pool of strategic CDMO partners can provide an advantage for a MAH, improve their capacity and agility, and allow them to share the costs of developing and manufacturing products. Therefore, it is not surprising that MAHs are finding it increasingly important to establish strategic collaborations.

2. CDMO management is being more and more professionalized to ensure mutual success

To provide the foundations for successful long-term collaboration and build a competitive advantage, MAHs need an individual resource to liaising with the CDMO, supported by an expert internal cross-functional team – a structure that is seen more and more often in collaborations between MAHs and CDMOs.

3. MAHs increasingly also act as CDMOs, offering spare capacity to the market to absorb costs

To offer CDMO services brings numerous advantages for MAHs: additional revenue at potentially higher margins, committed volumes, better cost absorption, and stable production volumes. A majority of the largest MAHs, and a substantial number of smaller MAHs, are embracing these advantages.

4. CDMOs are continuously expanding their service portfolio towards end-to-end service providers

To differentiate themselves from competitors, more and more CDMOs are becoming full-service providers (one-stop shops), with a substantial portion offering end-to-end services, from development to packaging complemented by additional services such as regulatory, analytics or project management.

5. CDMOs are expanding beyond traditional technology portfolios

To uncover new growth opportunities and grow relevance, pure play CDMOs are expanding their portfolio offerings horizontally to include several modalities, while a majority of generics manufacturing CDMOs and pharma affiliate CDMOs are involved with just a single production technology (small molecule, large molecule or advanced therapies).

6. CDMOs are producing advanced therapies, turning visionary hype into operational reality

To gain leading positions in an emerging market (CAGR 2021-2025: advanced therapies 47 percent, in comparison to 8 percent and 5 percent in large and small molecules, respectively)[1], CDMOs are building new capacities and capabilities in advanced therapies.

1 Strategy& analysis based on Evaluate Pharma

What should your organization do?

Our survey findings show that to confront rising technologies and cost challenges, pharma manufacturing leaders – both MAHs and CDMOs – are forming long-term, strategic partnerships as they race for a slice of the future market. To thrive in today's – and tomorrow's – fast-changing pharmaceutical supply market, players need to act now. Based on our experience, our recommendations are as follows:

1. To enhance their competitive advantage, CDMOs need to expand their key capabilities and portfolios across production technology and along the value chain to deliver high-quality solutions at attractive costs to customers. The starting point is to evaluate the company's key capabilities and differentiators, and then develop an overarching strategy.

2. Becoming a trusted partner for MAHs and CDMOs provides a competitive advantage. Growing MAHs and CDMOs prefer a strategic partnership model, enabling them to expand together with successful products. Internal preparation is the key to forming strategic partnerships.

3. MAHs need to develop a strategic view on which services and production technology to outsource, identify the right partners, and build lasting relationships to generate a competitive advantage.

Our study sample

In this study we analyzed data from 150 of the world's major CDMOs from a revenue perspective in terms of the services they offer along the value chain (*see Exhibit 2*).

EXHIBIT 2
Study key figures

 Sample size	~150 companies out of >1,000 CDMOs	 Countries	CDMOs from 29 countries mainly in Europe (41%) and Asia (43%) while 16% from North America	 Revenues	The majority is ranked as mid-size with annual revenues ranging from €250mn to €1bn (58%)
 Type of player	Mainly Pure play (35%) and PharmaCo CDMOs (37%) – less Generics manufacturing (15%) and Pharma affiliate CDMOs (13%)	 CMO/ CDMO	79% of the 150 companies are offering development services	 End-to-end services	More than 1/3 of companies are offering fully integrated end-to-end services from development to packaging and beyond

Source: Strategy& analysis

SECTION 1

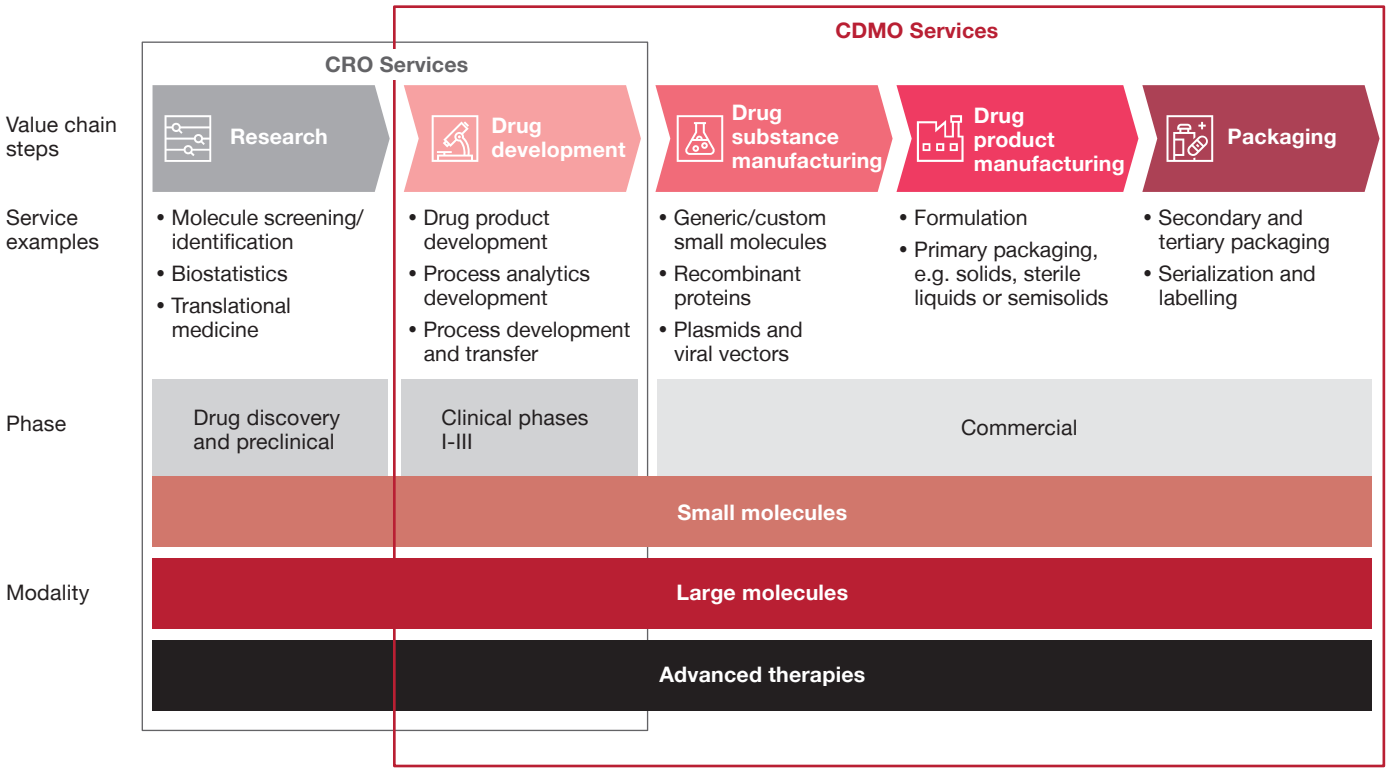
The MAH and CDMO ecosystem

More than 1,000 CDMOs provide a diverse range of services to marketing authorization holders (MAHs), the pharmaceutical companies at the apex of the industry. MAHs seek and obtain approvals for drugs from medical authorities and are formally responsible for their efficacy.

This study focuses on the companies that supply MAHs with small molecules, large molecules and ATx[2] under contract. Their services range from drug development to packaging, and include additional services such as logistics, but our survey excludes pure contract research organizations, which focus on identifying potential treatments (*see Exhibit 3*). Some CDMOs are niche suppliers, specializing in a particular product or process. Others offer a full range of services.

2 In the study we are focusing on gene therapies, cell therapies and RNA therapies

EXHIBIT 3
Overview of CDMO services



Source: Strategy& analysis

Who does what?

To gain insights into today's pharmaceutical manufacturing ecosystem we classified 150 major players according to the nature of their core business, identifying four main CDMO archetypes serving MAHs (*see Exhibit 4*).

EXHIBIT 4
The pharmaceutical manufacturing ecosystem and relevant CDMO players

	Pure play	PharmaCo	Generic	Pharma affiliate
Innovator (I) or Generics (G) MAH	X	I	G	X
Primary focus on CDMO business	✓	X	X	X
Primary focus on pharmaceuticals	✓	✓	✓	X

Source: Strategy& analysis

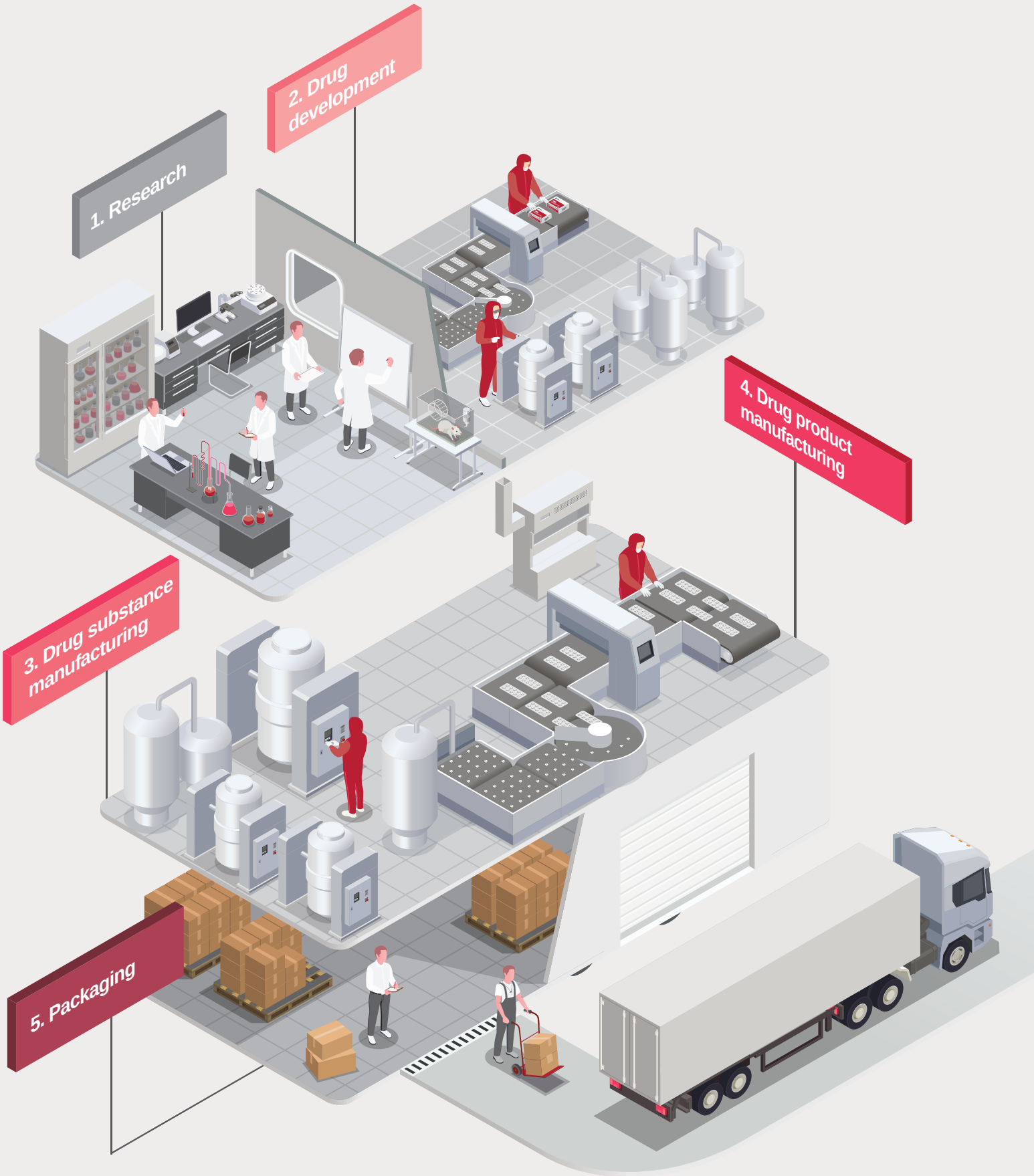
Marketing authorization holder (MAH): A pharmaceutical company that primarily focuses on commercialization of its own-developed or acquired (blockbuster) drugs.

Pure play CDMO: These are drug development and/or manufacturing service providers that primarily focus on supplying pharmaceutical companies/MAHs or other CDMOs. This activity is sometimes combined with another business, such as basic chemicals.

PharmaCo CDMO: Some pharmaceutical companies contract out part of their manufacturing capacity to other MAHs. This can help spread the cost of in-house products by augmenting production volumes, which may be advantageous in a particular geographical market.

Generics manufacturing CDMO: These focus on producing large volumes of generics and biosimilars for generics MAHs and typically offer idle capacities combined with deep expertise in producing chemical compounds.

Pharma affiliate CDMO: These companies, which originally focused on pharma-adjacent industries such as chemicals or fast-moving consumer goods, offer CDMO services across the entire ecosystem, mostly focusing on intermediate products complementary to their main industry.


1. Research
2. Drug development
3. Drug substance manufacturing
4. Drug product manufacturing
5. Packaging

SECTION 2

Six findings of our study

Here, we will look in detail at the six key messages coming from the fast-changing pharmaceutical manufacturing and supply market.

1. MAHs are expanding strategic collaborations with CDMOs

Marketing Authorization Holders are increasingly forming strategic partnerships with CDMOs to the benefit of both. This is because multi-sourcing is becoming the new normal for key products to reduce the risk of supply-chain interruptions and because collaboration shares the costs and risks of developing and producing new treatments. Typically, MAHs pursue three types of partnership:

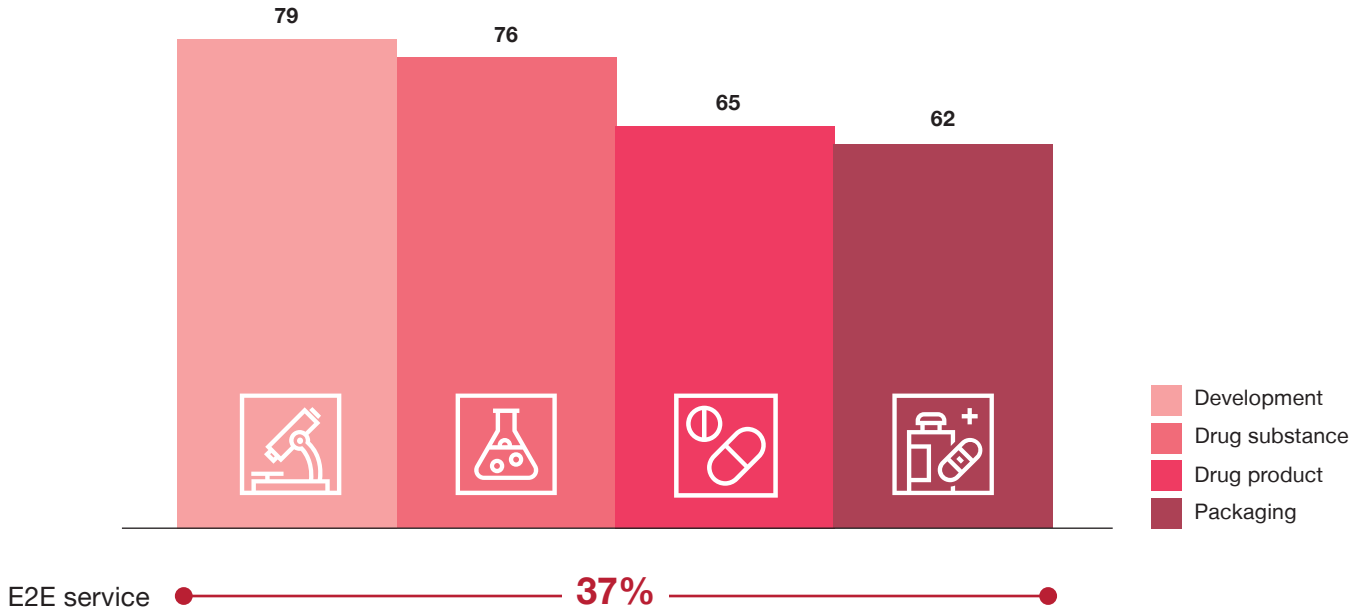
Strategic Partners	are key collaborative partners (centers of excellence by production technology or region, for example), preferred providers, and the default choice for growth products. MAHs and CDMOs provide visibility to each other's pipeline and development process to ensure alignment between internal decisions and the strategic partner's capabilities and investments. A high degree of transparency is needed. Cross-functional teams drawn from both partners exchange information on running orders, production status, and potential orders. CDMO integration is accompanied by operational transparency into the MAH's planning systems, and the MAH may also share knowledge about how to achieve operational excellence, with the partners acting as equals.
Niche Partners	are preferred providers for individual or low-value supply-chain steps, as MAHs aim to consolidate their footprint over time to aggregate volumes and improve costs. Cross-functional teams comprising MAH and CDMO representatives are regularly in touch to exchange information on running orders and production status.
Transactional Partners	have a purely transactional relationship based on small volumes and non-focus products. MAHs manage these CDMOs mainly via purchase orders, and information is exchanged yearly, or when there are problems such as delivery delays or quality issues.

Strategic alliances are often preferred by MAHs over a larger number of transactional relationships because they provide increased transparency, greater flexibility, faster transactions, and shared incentives.

MAHs can benefit from having a pool of strategic CDMO partners. In particular, they can leverage the capacities of CDMOs in technologies they lack in-house, and can add to their internal capacity if sales exceed expectations.

From the CDMOs' perspective, those that become strategic partners with MAHs can benefit from increased transparency, greater flexibility, faster transactions, and common incentives. Offering end-to-end services increases the chances of becoming a strategic partner to MAHs. As a result, 37 percent of CDMOs studied offer services spanning the entire value chain, from development, to commercial drug substance and drug product manufacturing, to packaging (*see Exhibit 5*).

EXHIBIT 5
Services offered by CDMOs studied

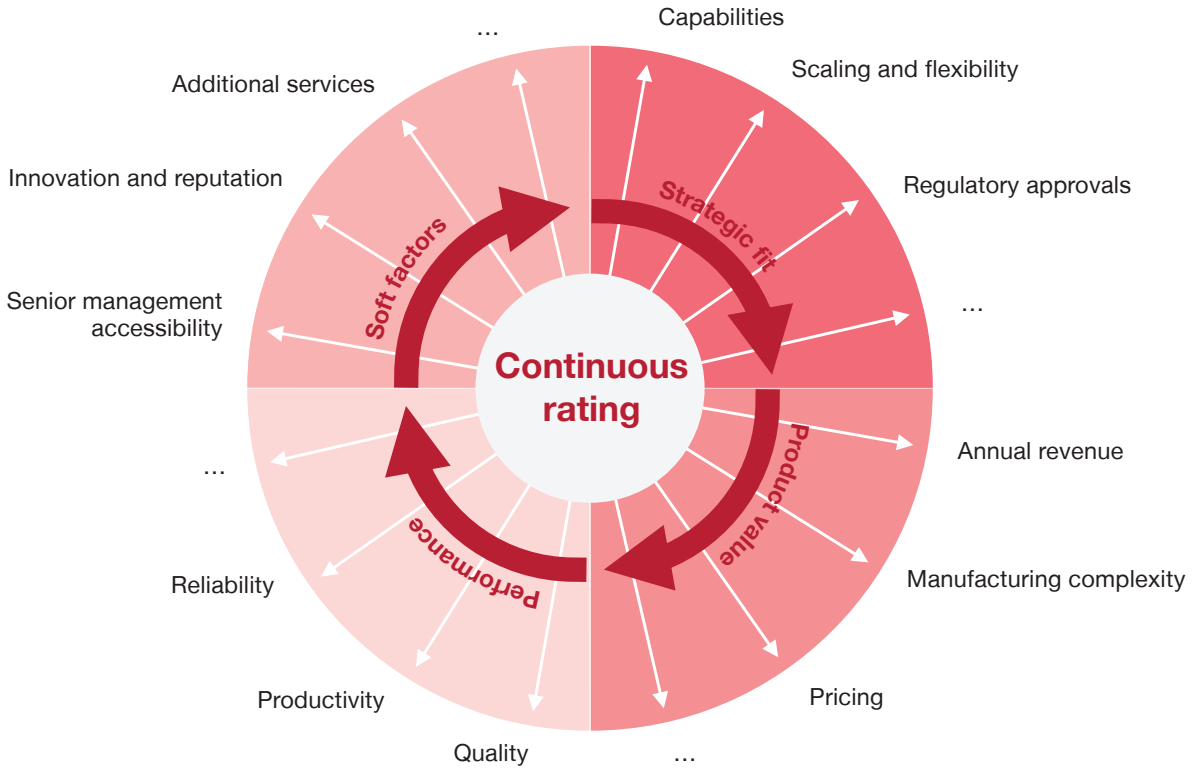


Source: Strategy& analysis

> 37 percent of CDMOs studied offer services spanning the entire value chain, from development, to commercial drug substance and drug product manufacturing, to packaging."

MAHs should evaluate what categories their CDMO relationships fall into, based on the following criteria (*see Exhibit 6*), recognizing that this may vary between different locations. Of course, some MAH-CDMO partnerships may fall outside the three categories as stated above, typically when launching innovative technologies, or where the product value is uncertain and there is no performance history for the treatment. Such situations are an opportunity for niche players to form a strategic partnership on potential blockbuster drugs.

EXHIBIT 6
CDMO evaluation criteria



Source: Strategy& analysis

2. Professionalized CDMO management is needed to ensure collaborative success

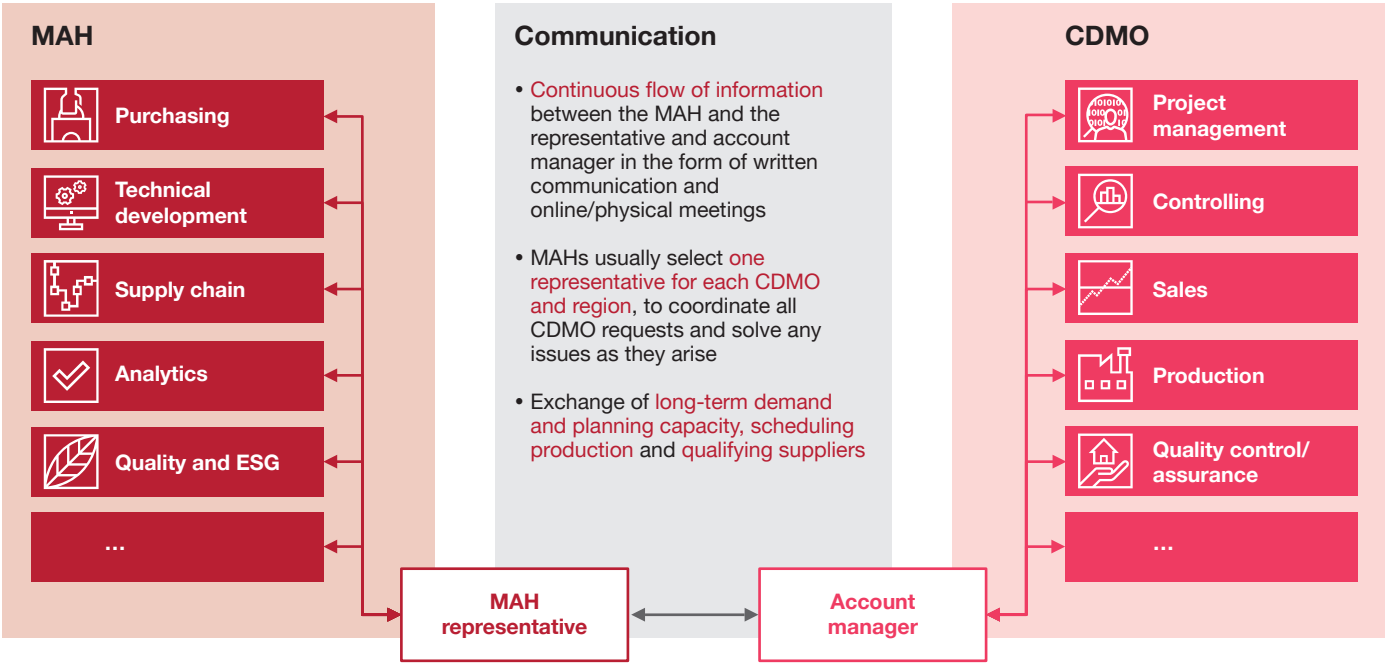
Strategic partnerships with CDMOs offer a lasting competitive advantage. But to set the foundation for a successful long-term collaboration, the relationship has to be carefully managed. MAHs usually select a representative for each CDMO and region, to coordinate all CDMO requests and solve any issues as they arise.

This representative is typically supported by an internal cross-functional team drawn for example from the purchasing, technical development and supply chain department, which support the CDMO, including on-site. The representative liaises with the CDMO, develops closer alignment between the partners, monitors its performance on quality, productivity, and reliability, oversees review meetings, and reports internally to management. Within the CDMO there is an account manager coordinating activities with each MAH.

Professionalizing the relationship between MAHs and CDMOs includes integrating long-term demand and planning capacity, scheduling production, qualifying suppliers, and ensuring supply-chain transparency. Once reserved for strategic partners, these features are also being extended to niche and transactional partnerships on a smaller scale to help the MAH achieve its strategic objectives. At the same time, working in this way secures the place of CDMOs.

The strengthening focus on sustainability is also reinforced within partnerships: most MAHs now have dedicated environmental, social and governance (ESG) experts involved who collect sustainability performance KPIs from CDMOs (*see Exhibit 7*).

EXHIBIT 7
Professionalized communication between MAHs and CDMOs



Source: Strategy& analysis

3. MAHs increasingly act as CDMOs, offering spare capacity to the market to absorb costs

In our study, we found that

56%

of the largest MAHs offer contract manufacturing

1/3

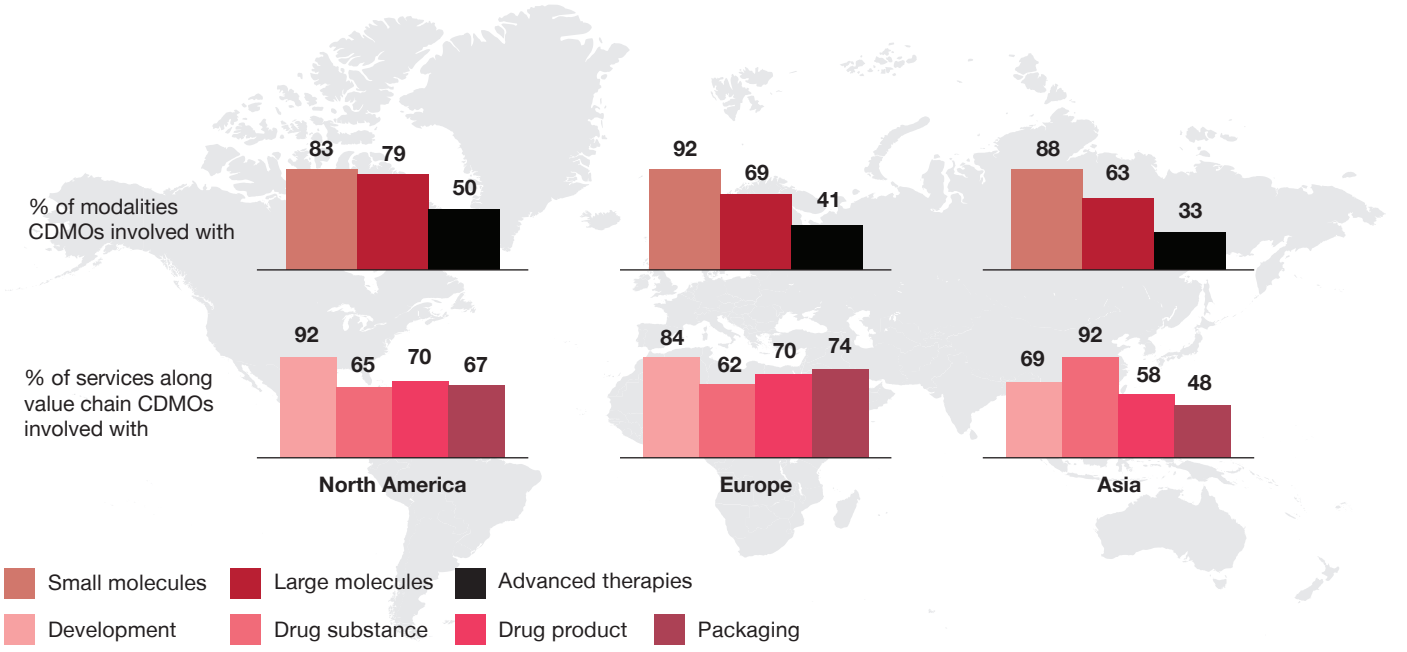
of smaller MAHs also act as CDMOs

Many well-established MAHs offer idle capacity to the market, from early-stage R&D and clinical supply, to launch and operational commercialization. The trend accelerated during the pandemic as companies sought to rapidly increase vaccine development, production, and distribution. The benefits of acting as a CDMO include additional revenue at potentially higher margins, committed volumes, and stable production volumes e.g., as an authorized generics maker after patent expiry. Much MAH third-party medicine production stems from historic agreements, divested portfolios, or opportunism. But the growing CDMO market offers ample growth potential for MAHs: pure play CDMO players need to be prepared for intensifying competition as MAHs bring their deep manufacturing experience to this market.

Looking at what CDMOs do, and where (*see Exhibit 8*), offers insights into how MAHs could offer spare capacity: 92 percent of CDMOs in North America and 84 percent of those in Europe offer development as a service, while in Asia only 69 percent do. On the contrary, 65 percent of CDMOs in North America and 62 percent in Europe offer drug substance services, while in Asia, drug substance manufacturing is still the most prevalent service, offered by 92 percent of CDMOs.

Expanding service portfolio is not only important for CDMOs, who want to remain competitive in the market, but also for MAHs, who can strategically select for which services outsourcing makes most sense. Some PharmaCo CDMOs, however, are still offering their idle capacity opportunistically. They need to combine their services into larger offerings and find their right to win in the market, because cost-efficiency is no longer enough to stay competitive.

EXHIBIT 8
Geographic differences among CDMOs across major markets



Source: Strategy& analysis

4. CDMOs are becoming end-to-end service providers

As we outlined in our previous study, Current Trends and Strategic Options in the Pharma CDMO Market,[3] CDMOs facing limits to their growth are looking at integration opportunities both vertically (along the value chain) and horizontally (via different technologies such as dosage forms or drug types). Becoming one-stop-shop solution providers can also strengthen their market position.

However, CDMO market growth has also created greater competition across types of treatments and value-chain steps, forcing players to differentiate via their capability and technology ambitions. The pandemic has turbo-charged pressure to shift toward more local manufacturing of essential drugs. As a result, CDMOs are building up their end-to-end services in the following ways:

- Pure play CDMOs are striving to drive technology standards with best-in-class manufacturing and highly integrated services
- Generics manufacturing CDMOs and pharma affiliate CDMOs are trying to add new mainstays to their core business by developing specific capabilities such as customized synthetics and investing into best-in-class manufacturing technologies

3 https://www.pwc.de/de/gesundheitswesen-und-pharma/studie-pharma-cdmo-market.pdf

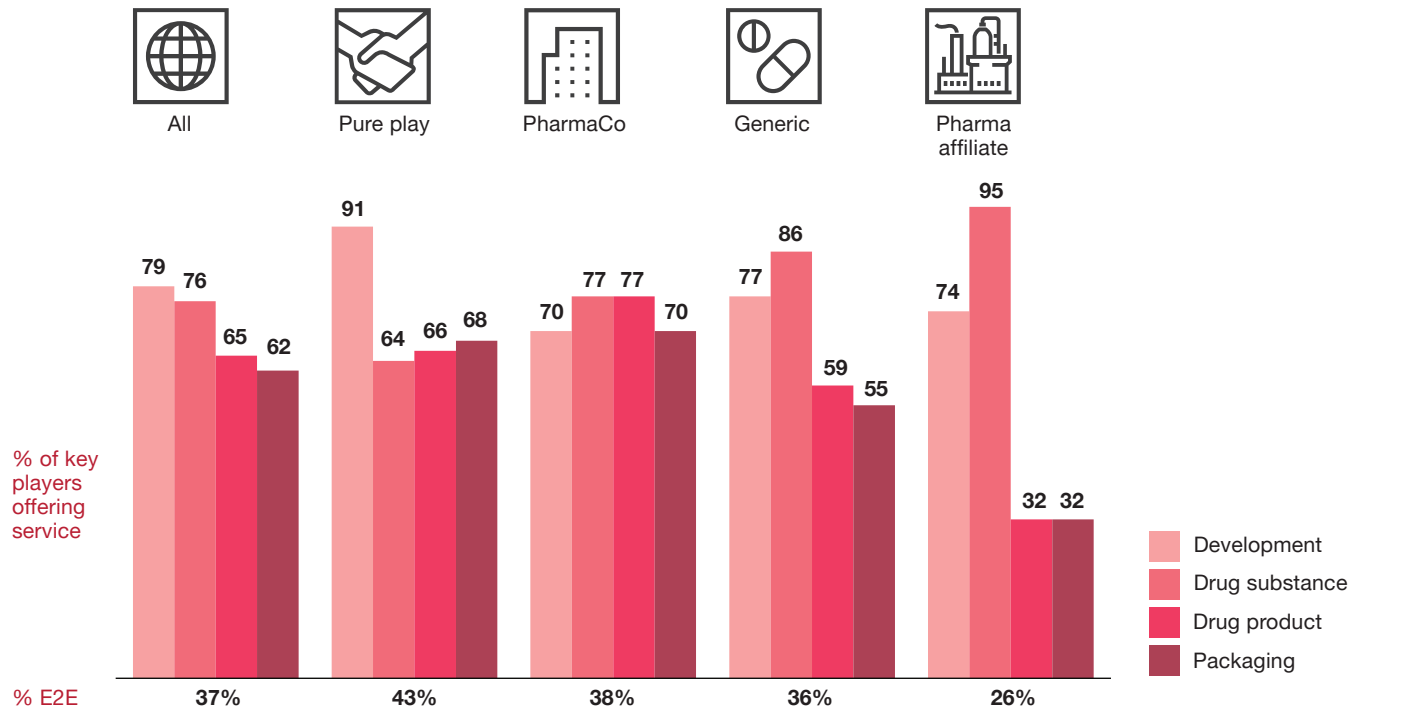
As *Exhibit 9* shows, the CDMOs' drive for vertical integration is clear: across all four CDMO categories, 79 percent now offer development services. Yet pure play CDMOs are out in front in this respect, with 91 percent offering development services. They can leverage their in-depth expertise and leading market position to dominate attractive market segments early on.

While pure play CDMOs are positioning themselves as early-stage development partners, PharmaCo CDMOs are more focused on the manufacturing stages. Generics manufacturing CDMOs and pharma affiliate CDMOs are particularly focused on drug substance manufacturing (86 percent and 95 percent respectively).

Pure play CDMOs also lead the way on building end-to-end services – from drug development to packaging – with 43 percent doing so. Only 17 percent of them are focusing on a single value-chain step. PharmaCo CDMOs and generics manufacturing CDMOs are hot on their heels, with 38 percent and 36 percent respectively offering end-to-end manufacturing services. To become MAH strategic partners, pharma affiliates may be reluctant to expand their range of services to offer more, but the others might explore this option.

To thrive today, we believe CDMOs must go further and become full-service providers for MAHs to mark themselves out from competitors. Already, most of pure play CDMOs offer such services, with regulatory support, logistics or project management, for example, becoming everyday add-ons.

EXHIBIT 9
Average services offered by key players



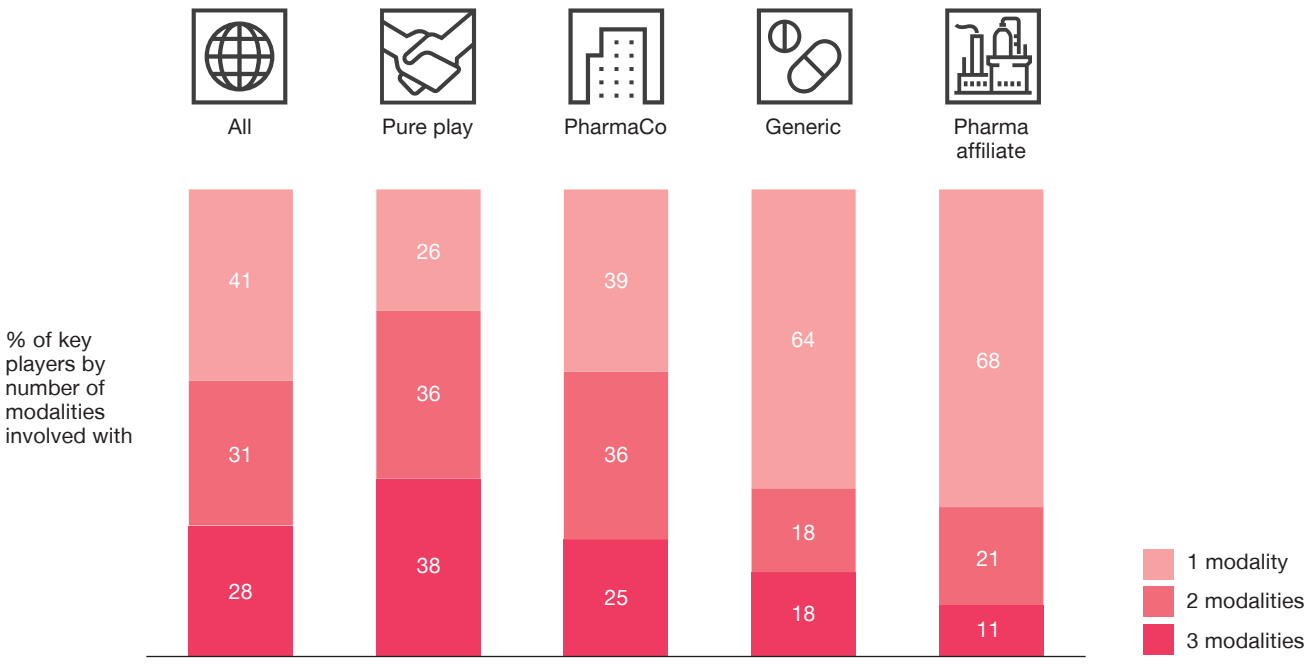
Source: Strategy& analysis

5. CDMOs are expanding beyond their traditional technology portfolios

Pure play CDMOs are carving out a new role as strategic partners and uncovering new growth opportunities, simultaneously making themselves indispensable by expanding their service offering across different drug types – small molecule, large molecule, and ATx. Some 38 percent of pure play CDMOs are involved across all three areas, but that falls to 25 percent of PharmaCo CDMOs, 18 percent of genetics manufacturing CDMOs, and 11 percent of pharma affiliate CDMOs (*see Exhibit 10*).

Meanwhile, around two-thirds of generics manufacturing CDMOs and pharma affiliate CDMOs are involved in a single production technology type only, exceeding the average of 41 percent across all companies within our study.

EXHIBIT 10
Average number of modalities of key players



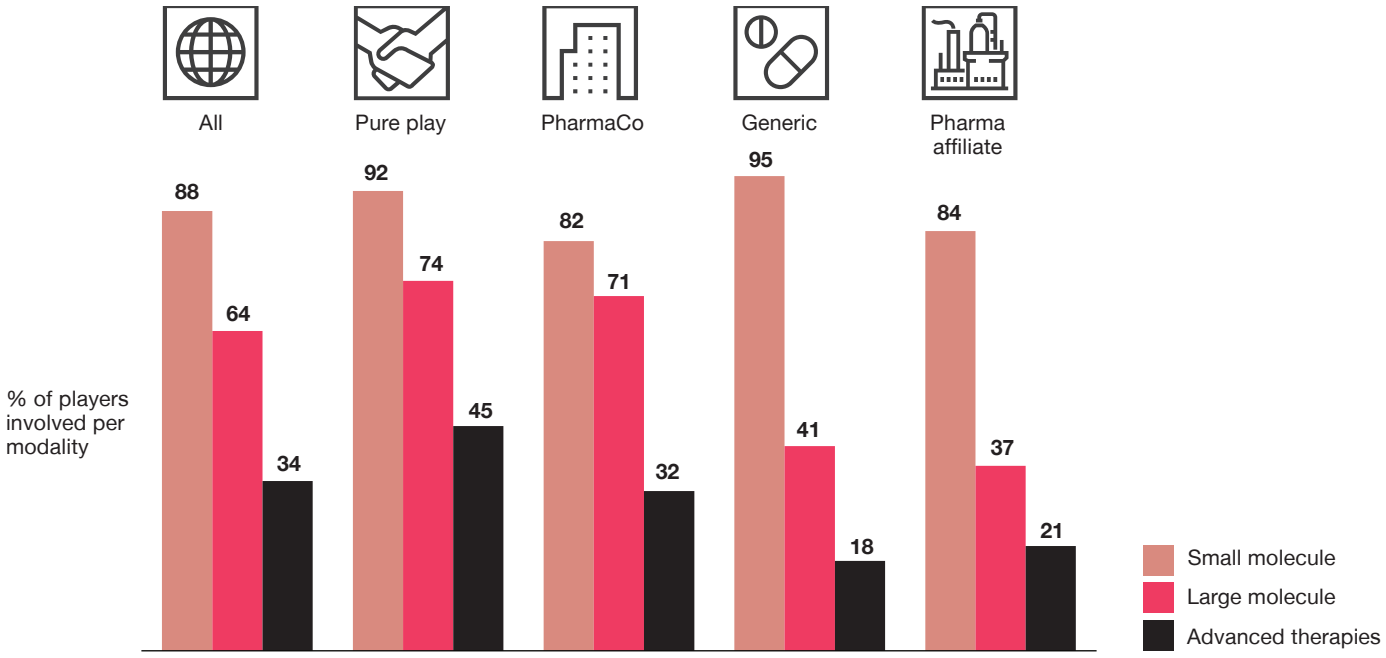
Source: Strategy& analysis

Despite their development and technology leadership, 92 percent of pure play CDMOs are still involved with traditional small molecule manufacturing (*see Exhibit 11, next page*), highlighting the need to maintain a risk-balanced portfolio of traditional and novel modalities.

Expanding into new drug types requires investment, expertise, and reputation building. For example, manufacturing and services linked to complex ATx are mainly driven by pure play CDMOs – 45 percent offer services around ATx, compared with 32 percent of PharmaCo CDMOs, 18 percent of generics manufacturing CDMOs, and 21 percent of pharma affiliate CDMOs.

MAHs, currently at the top of the pharmaceutical food chain, increasingly rely upon pure play CDMOs for specialist expertise when it comes to these new production technology. This puts CDMOs in pole position to dominate the fastest growing markets in the future. Yet, there are risks for both sides: MAHs will have to assess which value-chain steps they want to own, then integrate selected CDMOs from an early stage. But trailblazing CDMOs will take on higher technology risks.

EXHIBIT 11
Production technology types offered by players



Source: Strategy& analysis

> MAHs, currently at the top of the pharmaceutical food chain, increasingly rely upon pure play CDMOs for specialist expertise when it comes to these new production technology. This puts CDMOs in pole position to dominate the fastest growing markets in the future."

6. CDMOs are producing advanced therapies, turning visionary hype into operational reality

ATx, including cell, gene and RNA therapies, now make up a major share of products within pharmaceutical pipelines. More than 1,000 cell and gene therapies are in development. The market is entering a new era in which commentators expect growth in such ATx to exceed that of small and large molecule therapeutics. Some ATx have the potential to replace existing therapies; others are complementary to them, or offer new approaches for unmet medical needs.

However, the curative character of these therapies makes the race to market an opportunity to gain market share, because they may replace some existing treatments. The Covid-19 pandemic has expedited the growth of RNA therapies, for example, simultaneously shaping and accelerating regulatory pathways.

We see four different ways in which MAHs are currently participating in the shift towards ATx (*see Exhibit 12*). These depend upon their ATx ambitions, differences in their target operating model and upon the extent of their partnerships with external CDMOs.

EXHIBIT 12
MAH ways to play in advanced therapies

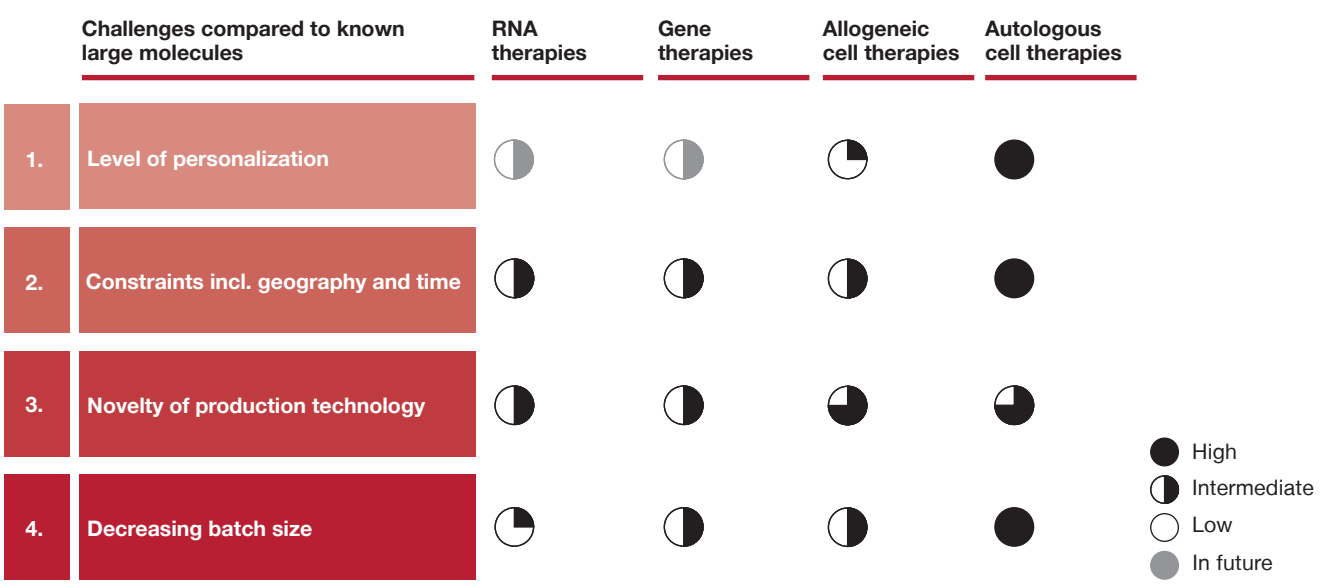
Ways to play	ATx ambition	Target operating model
Full vertical integration	• Coverage of full value chain from R&D to manufacturing • Large ambition to become ATx leader potentially for multiple indications or tech platforms	• Global manufacturing capacities to build hub and spoke network spanning over one or multiple ATx modalities • More than 50% in-house capacities, maintain control over quality and processes, volatilities balanced via CDMOs
ATx tech platform ownership	• Ambition to build tech specific portfolio for multiple therapeutic areas • Become leading expert offering platform manufacturing services	• Robust ATx specific in-house CDMO hubs and logistics allowing for efficient (local) supply chains and technology leadership • Manufacturing partner of choice for multiple ATx biotechs
TA-focused leadership	• Leveraging strong position in selected therapeutic areas for development of ATx including partnerships • Often ATx unspecific play for defending market share	• Rare, central production sites in combination with regional partnerships • >50% clinical and commercial manufacturing via CDMOs, including development
Disruptive partnership	• Focus on development of cutting-edge ATx tech (e.g. gene editing, RNA vaccines) • Development of novel therapies with highest unmet need	• Partnership of or investment into innovative biotech with/ from large MAH • Production mainly via external CDMOs and in-house capacities of MAH

Source: Strategy& analysis

However, manufacturing ATx is radically different from making traditional drug compounds. Some new treatments are personalized, requiring proximity to both patients and production, and batches are small – down to a lot size of one. Allogeneic cell therapies rely upon cells from a generic donor, while autologous cell treatments are especially demanding, requiring cells from patients as input material.

Exhibit 13 below shows four ways in which manufacturing of ATx differs from that of established large molecule treatments. Some MAHs are starting to develop deep expertise in these new manufacturing technologies. Others are forgoing vertical integration, betting instead on strategic partnerships with CDMOs that are experts in the technology needed to produce a particular treatment.

EXHIBIT 13
Changes in manufacturing of advanced therapies compared to large molecules



Source: Strategy& analysis

MAHs are thus outsourcing many of the challenges brought by these rising technologies (*see Exhibit 14*), such as small batch numbers (often associated with personalization) and two-way supply chains, turning costly novel technologies into large-scale production. When MAHs step back, CDMOs benefit, leveraging their capacity and developing into full-service providers by extending their business model.

These trends benefit both MAHs and CDMOs. MAHs can reduce risk and increase opportunities to establish themselves in the fastest growing markets via strategic partnerships. This also compensates for the high risk that they may fail to find a new blockbuster small or large molecule. CDMOs, meantime, can lead the way into a new pharmaceutical industry era which will rely upon small-batch production of precision medicines. This era will require moderate investments compared to conventional mAbs, giving CDMOs a growing chance to participate in high-margin business.

EXHIBIT 14
Selected challenges of manufacturing advanced therapies

Quality/QC

- Quality of end product determined by patient cells
- Unknown correlation of analytical testing with quality of end product
- Integration of QC testing in light of time constraints and small/individual batch sizes
- Seamless tracing and careful tracking and adherence to stability requirements (cryogenic conditions)
- …

Production process

- High complexity of manufacturing network comprising multiple stakeholders
- Availability and maturity of specific automated equipment
- Selection and development of different cell lines for each virus
- Costly cell growth monitoring/procedure and adapted cell media composition/ costs
- High degree of manual processes to be conducted by skilled labor
- …

Scale-up/automation

- Single batch production, parallelization instead of automation due to lack of automated equipment (scale-out)
- Availability of trained/experienced operators
- Challenging/low yield production of complex, large viral vectors
- Cost-intensive development of stable cell lines for large-scale production while huge number of viral particles per patient required
- …

Source: Strategy& analysis

SECTION 3

Act now to stay or grow more successfully in the fast-changing CDMO market

The race for ATx has already begun, but the ecosystem of the future is yet to be defined. CDMOs are achieving their competitive advantage by expanding their key capabilities and their portfolios across treatment types and value-chain steps, to deliver optimized solutions to their MAH customers.

Already, 37 percent of CDMOs provide end-to-end services across the value chain, while 28 percent offer a portfolio across all three modalities: small molecules, large molecules and ATx.

For MAHs and CDMOs, becoming a trusted partner provides a competitive advantage, enabling both sides to introduce new products and grow. To pave the way toward value generation through strategic partnerships, MAHs and CDMOs should follow this blueprint.

Steps toward value generation through strategic partnerships for MAHs and CDMOs

	MAHS	CDMOs
1.	Assess your own existing key capabilities and differentiators to understand what is possible: which capabilities are available internally, and which are better accessed through partnerships or other external arrangements?	
2.	Assess partner landscape, offerings and requirements.	Assess market trends and partner requirements to ensure future growth.
3.	Evaluate your company's overall strategy and ambition: this analysis considers the value chain as well as production technologies, services, locations, and technologies. The goal is to refine the overall strategy and ambition, then align on key strategic pillars.	
4.	Evaluate in detail and seek the strategic partners needed to fill emerging gaps in capabilities. Communicate internally about the future direction to everyone affected.	Prepare the organization for strategic partnership models, communicate internally about the future direction to everyone affected. Getting people on board and on the same page is crucial.
5.	Focus on building the right partnerships for outsourced activities.	Build the required in-house capabilities iteratively. Quick wins can be implemented right away, but when developing manufacturing capacity for new production technologies, companies will need to recruit to enhance their internal capabilities.
6.	Position your company to be a trusted partner.	

After enhancing their capabilities, both MAHs and CDMOs must learn to take full advantage of their new and ideally unique value proposition, and strengthen and build strategic partnerships. To accelerate growth, but sides need to invest into building a fertile operational ground such as dedicated organizational structures, more digitally integrated collaboration platforms or globally acting control towers. As the pharma manufacturing ecosystem evolves, companies should reinvest in continued growth across and beyond their portfolio, to gain further market share.

Sources

Primary research based on Strategy& network/project insights, company websites, and other databases as indicated, reviewed by internal and external subject matter experts (SMEs).

Secondary research based on other publicly available materials such as investor presentations, annual reports, press releases, industry databases.

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