IMP

Future of CDMO Selection

Beyond Price and Capacity

Industry Intelligence White Paper

CDMO Strategy | Pharma Outsourcing | Supply Chain | Risk Management

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Executive Summary

> ***CDMO selection is no longer a procurement exercise. It is a strategic decision that shapes a company's ability to bring medicines to patients — on time, at scale, and in a world of growing supply chain fragility.***
>
> — IMP Industry Intelligence

The pharmaceutical outsourcing landscape has undergone a fundamental shift. Where selection decisions were once driven primarily by cost and available capacity, sponsors today navigate a far more complex evaluation matrix — one that includes technical capability depth, regulatory track record, digital infrastructure, geopolitical exposure, and cultural alignment with the sponsor's development philosophy.

Industry surveys and market analyses suggest that a majority of pharmaceutical companies have reconsidered at least one CDMO partnership in recent years as outsourcing strategies evolve. At the same time, the number of evaluation criteria applied in CDMO selection has expanded significantly compared to five years ago, reflecting growing concerns around supply chain resilience, regulatory risk, and technological capability.

This white paper examines how CDMO selection criteria are evolving, where legacy evaluation frameworks are creating blind spots, and what both sponsors and CDMOs need to understand about the current market.

A large majority of pharmaceutical companies report having changed at least one CDMO partner in recent years as outsourcing strategies evolve.

61%
cite supply chain risk as top selection factor in 2024

Sources: Pharma IQ / Industry Surveys, McKinsey / Industry Benchmarks, WTW / EY Insights

1. Traditional cost-and-capacity selection frameworks systematically underweight technical depth, regulatory culture, and long-term partnership risk.
2. Geopolitical fragmentation is forcing sponsors to reconsider single-source and geographically concentrated supply models.
3. Digital capability — ELN infrastructure, data sharing protocols, AI-readiness — is emerging as a meaningful differentiator in competitive evaluations.
4. CDMOs that communicate through knowledge-transfer formats rather than capability brochures are winning a disproportionate share of complex projects.

02

The Changing Logic of CDMO Selection

For two decades, the dominant logic of pharmaceutical outsourcing was straightforward: find a partner with the right chemistry capabilities, the right regulatory approvals, and the right price. Capacity was broadly available and risk was manageable. That era is over.

What Changed

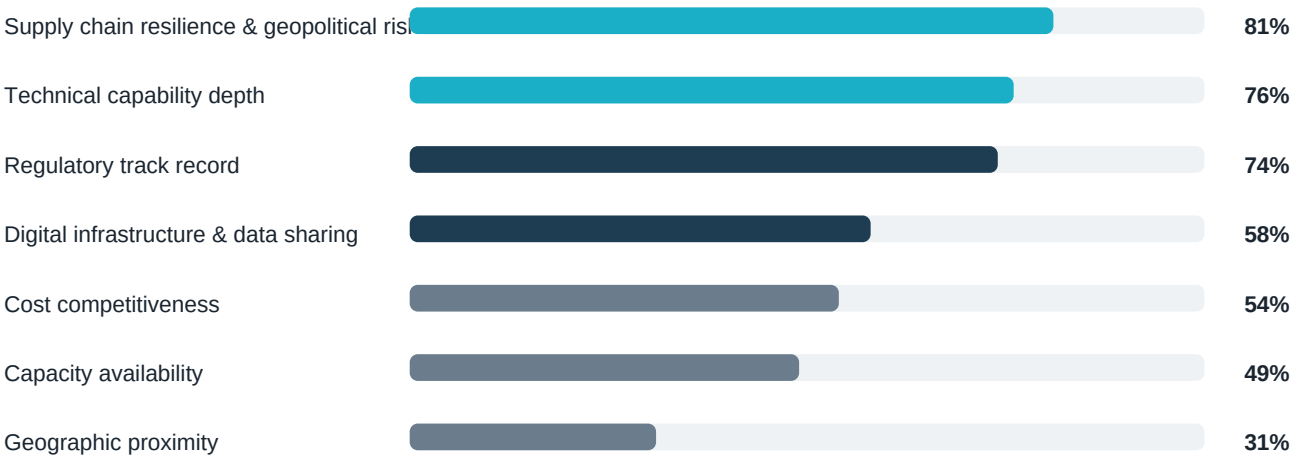
A combination of forces has disrupted the traditional outsourcing model. COVID-19 exposed catastrophic vulnerabilities in geographically concentrated API supply chains. Regulatory agencies intensified inspection regimes and data integrity requirements. And the complexity of drug molecules has increased sharply, with biologics, ADCs, and highly potent compounds demanding specialised manufacturing expertise that cannot be sourced interchangeably.

The New Evaluation Reality

Today's procurement teams are conducting due diligence that looks more like an operational audit than a vendor comparison. Technical capability depth, process development track record, regulatory inspection history, data management infrastructure, and ESG credentials are all part of formal evaluation frameworks at leading pharma companies.

For mid-size biotechs, the challenge is different but equally acute: without large procurement teams, they must make high-stakes CDMO decisions with limited information, often relying on reputation and peer recommendation more than systematic evaluation.

Shift in Selection Priority Weighting



Sponsor-ranked importance in CDMO selection (2024 vs. 2019 trend data — indicative)

03

Capability Landscape: What Sponsors Actually Evaluate

The CDMO market is not homogeneous. Meaningful differentiation exists across chemistry type, scale, regulatory geography, and therapeutic modality. Understanding how sponsors map this landscape is essential for CDMOs positioning their capabilities.

Capability Area	Key Differentiators	Sponsor Priority	Market Gap
Small Molecule API	Complex chemistry, chiral synthesis, HPAPIs	High	Proven scale-up track record
Solid Dose Forms	Particle engineering, modified release	Medium	Formulation-API integration
Biologics / mAbs	Cell line dev., process characterisation	Very High	End-to-end capability
ADCs	Conjugation, containment, analytics	Very High	Specialists scarce globally
Oligonucleotides	Synthesis, purification, formulation	High	Capacity limited
Drug Product (sterile)	Fill-finish, lyophilisation, aseptic	High	Regulatory track record
Analytical Services	Method dev., stability, reference standards	Medium	Integrated with manufacturing

The Integration Imperative

A consistent finding from sponsor evaluations is that integrated capability — the ability to handle process development, scale-up, and commercial manufacture within a single organisation or closely connected network — commands a significant premium in both preference and pricing tolerance. Sponsors have learned, often expensively, that transitions between development-stage and commercial-stage CDMOs introduce technical risk that erodes the apparent cost savings of a modular approach.

04

Where Traditional Selection Models Fail

Despite the sophistication of modern pharmaceutical procurement, a persistent set of evaluation blind spots continues to produce poor outsourcing outcomes. Understanding these failure modes is as important as understanding what to look for.

> ***We selected our CDMO based on a perfect site audit and a competitive price. We did not adequately evaluate their data management culture. Eighteen months later, we had a data integrity finding that delayed our NDA by two years.***
>
> — VP Pharmaceutical Development, mid-size European biotech

01 Audit Theatre vs. Operational Reality

Site audits reveal what a CDMO wants sponsors to see. Systematic review of regulatory inspection histories — including Form 483 observations, warning letters, and EMA inspection reports — provides a more accurate picture of operational culture than any curated site visit.

02 Capacity Confirmation vs. Priority Access

Confirming that capacity exists is not the same as securing access when it is needed. Sponsors frequently discover that a CDMO's 'available' capacity is committed to higher-value or longer-tenured clients when production slots are under pressure.

03 Technical Review vs. Development Culture

A CDMO's technical capabilities are visible and verifiable. Its development culture — the willingness to invest in problem-solving, to communicate challenges early, to allocate experienced scientists to non-flagship projects — is not. This cultural dimension predicts project success more reliably than capability checklists.

04 Cost Comparison vs. Total Cost of Partnership

Unit cost comparisons systematically underestimate the total cost of a CDMO relationship. Technology transfer costs, project management overhead, travel, regulatory support, and the cost of delays attributable to CDMO performance are rarely captured in initial cost modelling.

05 Qualification vs. Scalability

A CDMO qualified for Phase II clinical manufacturing may not be the right partner for commercial launch. Evaluating a CDMO's track record and operational model at the scale and complexity relevant to the intended programme endpoint — not just the immediate need — is a critical and frequently neglected step.

05

Risk, Resilience and Geopolitical Exposure

The geopolitical dimension of pharmaceutical supply chain risk has moved from a theoretical concern to an operational reality. Sponsors that have not systematically mapped their CDMO network's geographic and political risk exposure are operating with an incomplete picture of their programme risk.

Geographic Concentration Risk	Concentration of API manufacturing in a small number of geographic regions — particularly India and China — creates systemic vulnerability. Regulatory shutdowns, natural disasters, and geopolitical incidents have all demonstrated the capacity to simultaneously affect multiple nominally independent supply sources.
Regulatory Geography Mismatch	A CDMO approved by one regulatory authority does not automatically qualify for another. Sponsors operating across US, EU, and Asian markets need partners with multi-agency approval status or explicit plans to obtain it within programme timelines.
Single-Source Dependencies	Critical raw materials, proprietary reagents, and specialised equipment with long lead times create single-source exposures that standard business continuity planning inadequately addresses. Deep supply chain mapping — beyond Tier 1 suppliers — has become a due diligence expectation for leading sponsors.
Partnership Concentration	Sponsors who have consolidated outsourcing relationships to improve efficiency have inadvertently created concentration risk at the partner level. A quality event, capacity crisis, or ownership change at a strategic CDMO partner can simultaneously affect multiple programmes.

06

The Digital CDMO: Technology as a Selection Criterion

Digital capability has emerged as a meaningful and growing differentiator in CDMO selection. Sponsors increasingly expect partners to operate with modern laboratory informatics infrastructure, structured data environments, and the technical foundations required for AI-assisted process development.

Digital Capability	Sponsor Expectation	Current CDMO Maturity
Electronic Lab Notebooks	Structured, searchable experimental records	**High — widely adopted**
LIMS integration	Real-time data access and traceability	**Medium — variable quality**
Data sharing protocols	Secure, auditable sponsor data access	**Medium — improving**
Process analytical tech.	Real-time process monitoring capability	**Low-Medium — specialist only**
AI / ML process tools	Condition optimisation, robustness modelling	**Low — early adoption**
Digital twin capability	Scale-up simulation and risk modelling	**Very Low — emerging**

The Data Ownership Question

Digital capability raises a critical but underexplored issue: data ownership. Process development data generated at a CDMO has strategic value to the sponsor, yet contractual frameworks for data ownership, access rights, and portability remain inconsistent across the industry. Sponsors negotiating CDMO agreements today must explicitly address data governance — including the right to access structured process data in the event of a partner transition — as a standard contractual provision.

07

Industry Signals: How Leading Sponsors Are Adapting

Preferred Provider Networks

Large pharma companies are consolidating outsourcing relationships into tiered preferred provider networks — reducing the number of active CDMOs but deepening integration with those retained. This creates high barriers to entry for new CDMO entrants and intensifies competition for preferred provider status among established players.

Capability-First Selection

Leading biotechs are restructuring selection processes to place technical capability assessment before commercial negotiation. This sequencing — controversial in procurement orthodoxy — is driven by the recognition that capability fit predicts programme outcomes more reliably than price competitiveness.

Real-Time Monitoring Requirements

Sophisticated sponsors are moving beyond periodic site audits to require real-time visibility into manufacturing and quality data. CDMOs that can provide secure, structured data access to sponsor quality teams are winning disproportionate share of high-complexity and high-value programmes.

Programme Continuity Planning

Following several high-profile CDMO failures, programme continuity planning — including qualified backup suppliers, technology transfer readiness, and defined trigger conditions for backup activation — has become a standard expectation in risk-aware outsourcing programmes.

08

Strategic Questions for Outsourcing Decision-Makers

Effective CDMO selection requires structured decision-making that goes beyond the capability checklist. These strategic questions address the dimensions most frequently underweighted in selection processes.

Q1

What is the real risk profile of this programme?

Before selecting a CDMO, have you mapped all critical path dependencies, single-source materials, and regulatory touchpoints? Does your CDMO selection process explicitly address these risk factors, or does it default to the nearest capable supplier?

Q2

What does success look like in five years?

The CDMO that best serves a Phase I programme may not be the right partner at commercial scale. Is your selection process evaluating the partner you need for the programme endpoint, or the partner you need for the next milestone?

Q3

How will you know if it's going wrong early?

What are your leading indicators of CDMO performance deterioration? How frequently do you conduct structured programme reviews beyond formal audit cycles? Do you have defined escalation pathways that are actually used?

Q4

What data rights are you preserving?

Have you explicitly addressed data ownership, access rights, and portability in the CDMO agreement? In the event of a partner transition, can you access structured process development data in a usable format?

Q5

How does this partner communicate?

Communication quality is a leading indicator of partnership quality. How does your CDMO proactively communicate challenges? Do scientists communicate directly with scientists, or is everything filtered through account managers? This cultural dimension predicts partnership outcomes better than most technical metrics.

09

The Communication Gap in CDMO Marketing

CDMO marketing faces a structural problem: the most important decision-makers in the selection process — process development scientists, regulatory directors, quality leaders — are systematically underserved by most CDMO communication formats.

> ***Every CDMO brochure shows the same things: a picture of a reactor, a list of chemistry types, and a claim about 'deep scientific expertise.' None of them tell me what I actually need to know before I pick up the phone.***
>
> — Director of Process Development, European mid-size pharma

What CDMOs Communicate	What Sponsors Need to Evaluate	The Gap
Capability listings	Depth of expertise in specific chemistry	No evidence of complexity handled
Facility descriptions	Operational culture and quality mindset	Surface vs. substance
Client testimonials	Regulatory history and inspection record	Selective, unverifiable
Headcount / scale claims	Scientist-to-project ratios	Irrelevant metric
Technology investments	Data infrastructure quality	Lack of verifiable proof points

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Implications for CDMO Business Development

CDMOs that win disproportionate share of high-value, high-complexity programmes have one thing in common: they communicate in ways that address the real evaluation questions their target sponsors are asking. This requires a fundamental reorientation from product marketing to knowledge transfer.

Technical Case Studies ★★★★★	Detailed descriptions of complex chemistry challenges solved — methodology, decision points, outcomes. Even where commercial confidentiality prevents full disclosure, the structure and depth of a technical case study demonstrates development culture in ways no capability list can match.
Regulatory Intelligence Briefings ★★★★■	Proactive communication about regulatory changes, inspection trends, and compliance developments positions a CDMO as a strategic partner rather than a service vendor. Sponsors with limited regulatory intelligence resources value this significantly.
Process Development Insights ★★★★■	White papers and expert commentary on specific chemistry types, scale-up challenges, or analytical methods demonstrate depth of expertise to exactly the audience that influences CDMO selection — process development scientists and technical directors.
Data Capability Demonstrations ★★★■■	Concrete demonstrations of data infrastructure — how data is captured, structured, and made accessible to sponsors — address the growing digital evaluation criterion directly. Abstract claims about 'digital capabilities' carry little weight; specific examples of data sharing in practice carry significant weight.
Industry Roundtables & Scientific Events ★★★■■	Peer-to-peer scientific dialogue creates relationship capital with technical decision-makers that business development activities alone cannot generate. CDMOs that invest in scientific event organisation build credibility with exactly the audiences that matter most.

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Outlook and Recommendations

The CDMO market will continue to consolidate and specialise. Sponsors will demand deeper integration, better data access, and more transparent communication from fewer, higher-quality partners. CDMOs that invest in technical depth, digital infrastructure, and knowledge-transfer communication will be the consolidation winners.

For both sponsors and CDMOs, the organisations that approach outsourcing as a strategic partnership — rather than a transactional service exchange — will consistently outperform those that do not.

For Pharma Sponsors

- → Map your CDMO network's full risk exposure — geographic, regulatory, and concentration — before the next programme decision.
- → Restructure selection processes to evaluate capability depth and development culture alongside cost.
- → Explicitly address data ownership, access rights, and portability in all CDMO agreements.
- → Define leading indicators of partner performance and monitor them between formal audit cycles.

For CDMOs

- → Replace capability brochures with evidence — technical case studies, regulatory track records, data infrastructure demonstrations.
- → Invest in scientific content that reaches process development scientists, not just procurement teams.
- → Build digital infrastructure that enables real-time data access for sponsors as a competitive differentiator.
- → Position programme continuity planning as a service, not a liability.

For CDMO Business Development & Marketing

- → Audit your content against the real evaluation questions your target sponsors are asking.
- → Develop technical content that demonstrates depth in your specific chemistry capabilities.
- → Build relationships with technical decision-makers through scientific dialogue, not sales calls.
- → Measure engagement with technical content as a leading indicator of pipeline quality.

About IMP InterMediaPartners

IMP InterMediaPartners GmbH specialises in B2B marketing and content strategy for complex industrial and technology markets — including pharmaceutical manufacturing, chemical R&D;, and laboratory technology.
We help organisations translate technical expertise into market authority through structured demand architecture, knowledge-transfer content, and precision media deployment.

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