Baker McKenzie.

Client Alert

January 2026

International: Manufacturing Site Divestitures

Best practices for successful execution

In brief

Pharmaceutical companies are increasingly outsourcing complex manufacturing activities to contract development and manufacturing organizations (CDMOs). This enables pharmaceutical companies to streamline their operations and redeploy capital toward research and development activities. At the same time, the CDMO industry is booming, with many analysts predicting continued rapid growth. CDMOs need more capacity, and they need it quickly. As a result of these trends, many pharmaceutical companies are engaging in an increasing number of transactions in which they divest manufacturing sites to CDMOs.

Contents

Recommended actions

These site divestitures — whether to a CDMO or any other buyer — are complex and require careful planning, analysis, and implementation. This article highlights some best practices that can help make your next site divestiture a success.

In more detail

1. **Define the perimeter**

At first glance, defining the perimeter of a manufacturing site may seem simple — the seller is divesting the site and everything in the site. In practice, however, determining exactly which assets transfer as part of "the site" requires in-depth analysis of the site's operations and how the assets used by the site overlap with those of the seller's broader organization. Key areas to consider include:

- **Supply and services contracts:** The seller needs to determine whether raw materials, consumables, and facility-related services are provided under contracts used only by the site or under contracts used by other seller-operated sites. If contracts are shared across sites, the seller will need to determine whether the site-related portion of the contract can be assigned to the buyer without adversely affecting the seller's retained businesses – e.g., as a result of minimum purchase commitments, volume-based pricing or discounts, or the risk of the supplier placing conditions on its consent to splitting the contract.
- **Intellectual property:** It can be challenging to delineate between know-how for general site operations and know-how for manufacturing specific products. The seller may be hesitant to transfer general know-how because it is difficult to define and, if not addressed precisely, could result in unintended loss of product-specific know-how. In some cases, the seller may be able to get the buyer comfortable with the seller keeping general know-how if the buyer receives a non-exclusive license sufficient to operate the site and manufacture the relevant products.
- **IT systems and assets:** The buyer often expects the site to be "ready to go" on day one, including having all necessary IT assets and systems in place. The seller, by contrast, may prefer to remove existing servers or other IT assets, to protect the information thereon, and have them replaced by the buyer. Some sellers don't consider this until integration planning, but it should be assessed as part of the initial planning.
- **Books and records:** The buyer will expect to receive records related to historical site operations, including manufacturing, quality, and regulatory documentation. These records may be commingled with those related to the seller's retained products or other operations, which the seller would not want to provide. Separating these records can be very time-consuming. The seller can lessen this work by limiting the records that the buyer gets (e.g., site-related records for a certain number of years prior to closing).

- **Who is involved:** Defining the perimeter with precision often requires input from people with in-depth knowledge of site operations. This can be a challenge if the seller desires to restrict who is “under the tent” to corporate-level personnel. The seller should think strategically about which site personnel to consult about the transaction and whether to implement retention arrangements to incentivize their future services.

2. **Analyze and plan for transition requirements**

Transitioning a site’s operations from the seller to a third party requires careful, multi-functional analysis planning, particularly with respect to regulatory and supply-chain matters.

a. **Regulatory matters**

From a regulatory perspective, a site divesture typically triggers a change in ownership process (CHOW). This may require pre- or post-closing notifications to or approvals from federal and state regulatory authorities, such as FDA, state health departments, and state boards of pharmacy. State laws vary in how they define and interpret CHOWs. In some states, a CHOW occurs only when the site’s federal taxpayer ID is changing, whereas in other states, even a 5% change in controlling ownership in the site may constitute a CHOW. In such cases, a new license under the buyer’s name (or a new application disclosing the updated ownership structure) may be required to ensure continuous operation from day one post-closing.

However, a site divestiture involves more than a CHOW; it often requires careful coordination to ensure continued compliance with applicable regulatory requirements and uninterrupted manufacturing authorization. The seller should assess early whether regulatory approvals, licenses, registrations, and filings are site-specific or entity-specific, and whether they can be transferred, referenced, or must be re-issued or supplemented following closing.

Regulatory considerations frequently intersect with operational timing. CHOW, quality system responsibility, or manufacturing oversight may trigger notifications, supplements, or prior approvals, depending on the jurisdiction and product type. These requirements can affect the timing of closing, the scope of interim operating arrangements, and the sequencing of technology-transfer activities.

Before pursuing a site divestiture, it is essential to identify and address any outstanding compliance issues related to the current Good Manufacturing Practices (cGMP). Recent regulatory inspections and transactional due diligence increasingly emphasize manufacturing quality, making cGMP compliance a critical factor for both FDA and prospective buyers. Unresolved deficiencies or uncertainty around regulatory timelines can pose significant transactional risk, including delays or deal termination. Taking proactive steps to resolve cGMP concerns not only helps mitigate regulatory exposure, but also preserves deal value and ensures a smooth transition post-closing. In addition, the seller should consider how responsibility for regulatory compliance will shift during any transition period. Interim or transition services arrangements, quality agreements, and technology-transfer documentation often play a central role in allocating responsibility for regulatory interactions, inspections, deviations, and corrective actions until the buyer is fully operational under its own quality systems.

In addition to regulatory considerations, the newly enacted BIOSECURE Act (Section 851 of the National Defense Authorization Act for Fiscal Year 2026, P.L. 119-60) imposes restrictions on US government contracts, grants and loans involving entities that use equipment or services from designated “biotechnology companies of concern” for national security reasons. These restrictions may extend to downstream service providers including CDMOs. For companies divesting a site to a CDMO or continuing services under long-term supply agreements, such restrictions could impact their ability to maintain or transfer site operations if the CDMO is designated as a “biotechnology company of concern” under the BIOSECURE Act, with the official list expected to be published by the US Office of Management and Budget by December 2026. As a result, it is crucial to stay informed on upcoming updates and thoroughly assess service providers against BIOSECURE criteria to avoid potential disruptions in contractual relationships.

b. **Supply chain impact**

From a supply-chain standpoint, one of the earliest and most important considerations in a site divestiture is understanding how the divested site will function within the post-closing supply chain. Following closing, the acquiring CDMO becomes an integral part of the seller’s manufacturing and sourcing network, and the transaction must be structured so that this new configuration operates without disruption.

Once ownership of the site changes, the site’s position within the supply chain is effectively re-wired. Supplier relationships that were historically managed within the seller’s broader enterprise may need to be re-established or re-qualified at the site level, particularly where regulatory qualifications or quality agreements are tied to the seller’s legal entity or quality system. Allocation rights, lead times, and pricing structures that were previously supported by enterprise-wide volumes may no longer apply, potentially exposing the site to shortages or increased costs if these issues are not addressed in advance.

Additionally, a facility that previously operated as an internal manufacturing node may become an external supplier, subject to different release processes, regulatory oversight expectations, and performance metrics. This shift can affect forecasting accuracy, inventory strategies, batch release timing, and logistics flows, particularly where regulatory approvals or quality-system transitions constrain flexibility during the early post-closing period.

Supply-chain resilience during the transition period also depends on how effectively operational responsibilities are sequenced between the parties. Interim operating support, technology-transfer activities, and changes to quality oversight can all influence whether materials continue to flow as expected. If these activities are not tightly coordinated with the transaction documents — including the asset purchase agreement, any interim or transition services arrangements, technology-transfer documentation, quality agreements, and the supply agreement — gaps can emerge that disrupt supply even where each agreement appears reasonable in isolation.

Finally, site divestitures often introduce new dependencies and constraints that must be actively managed. Long-lead materials, single-source suppliers, and site-specific or regulator-dependent qualifications can limit flexibility during the early post-closing period. Proactive planning around inventory buffers, supplier engagement, and escalation mechanisms can help mitigate these risks and preserve continuity while the buyer integrates the site into its broader manufacturing network.

3. **Consider long-term supply arrangements**

Pairing the sale of a manufacturing site with a multi-year manufacturing or supply contract is often a “win-win” for the seller and buyer. The seller benefits from extra time to establish an alternative manufacturing site (if needed), and the buyer benefits from temporary utilization of the site’s manufacturing capacity until the buyer can start using the site to manufacturing other products. These types of manufacturing agreements often raise heavily negotiated issues, such as:

- Forecasting and scheduling: Supply agreements often address multiple forecasting layers, including long-range forecasts, rolling forecasts, and binding production schedules. Clear rules around forecast updates, forecast accuracy, and the point at which forecasts become binding are critical to capacity planning and continuity of supply.
- Minimum purchase/take-or-pay Commitments: Buyers may require aggressive and/or long term minimum purchase or take-or-pay commitments to support the economics of the site acquisition. Sellers should assess these commitments in light of realistic demand projections and alternative sourcing options, particularly during the transition period.
- Materials, inventory, and obsolescence: Agreements should clearly allocate responsibility for raw-material procurement, inventory ownership, safety stock, and obsolescence risk. Ambiguity in these areas can lead to disputes and production delays, particularly where demand changes or products are discontinued.
- Pricing structure and change management: Pricing mechanisms often include pass-throughs for materials, labor, or utilities, as well as assumptions regarding yields, scrap factors, or process efficiency. Clear change-order processes are essential to manage deviations from these assumptions without disrupting supply.
- Quality integration and release: Supply agreements must align with applicable quality agreements and address batch release, acceptance criteria, deviation handling, investigations, and recalls. These provisions are central to ensuring regulatory compliance and uninterrupted supply.
- Failure to supply: Typically, if a manufacturer is unable to supply product, it risks cancellation of orders, financial penalties, or even termination of the manufacturing and supply agreement. But, what if a post-closing failure to supply was caused by a condition or issue at the site that existed prior to closing? Should the buyer still risk liability or termination? The seller often says yes – if there was a pre-closing issue, then Buyer’s remedy is a claim under the purchase agreement, not an exception from liability under the manufacturing agreement. However, this is sometimes a difficult position for the buyer to accept. In practice, the parties should address this tension by using targeted risk-allocation mechanisms rather than broad carve-outs from supply obligations. These may include clearly defining when a failure to supply is deemed attributable to legacy site conditions versus post-closing operational decisions, aligning cure periods and escalation processes across the asset purchase agreement and supply agreement, and calibrating remedies to reflect the underlying cause of the disruption. Related provisions governing delivery terms, risk of loss, acceptance, and non-conforming product can also be structured to reinforce this allocation of risk, helping ensure that supply disruptions are addressed through the appropriate contractual framework without creating overlapping or inconsistent remedies.

4. **Take a holistic review of the economics**

Every site divestiture should start with a clear strategic rationale and an understanding of the alternatives. Pharmaceutical companies often divest sites in lieu of shutting them down. This creates an unusual benchmark for what constitutes a “good” deal from an economic perspective. The seller has to understand how much it would cost to shut down the site and determine whether that is more or less expensive than the amount of the buyer’s offer.

The economics of any long-term supply arrangements must also be taken into account in evaluating whether a site divestiture makes economic sense for the seller. If the buyer requires premium pricing or higher volume commitments than the seller expects it can meet, then this could erode the value provided by the upfront purchase price.

Conclusion

Pharmaceutical site divestitures are not just transactional — they are strategic levers for optimizing manufacturing networks, reducing fixed costs, and accelerating innovation. Successful site divestitures require careful analysis, transition planning, and evaluation of value. By prioritizing the best practices discussed in this article, pharmaceutical companies can achieve these goals.

Contact us

Michelle Carr
Partner
michelle.carr
@bakermckenzie.com

Xin Tao
Partner
xin.tao
@bakermckenzie.com

Daniel Garcia
Counsel
daniel.garcia
@bakermckenzie.com

Lois Sheng Liu
Associate
loissheng.liu
@bakermckenzie.com

© 2026 Baker & McKenzie. **Ownership:** This site (Site) is a proprietary resource owned exclusively by Baker McKenzie (meaning Baker & McKenzie International and its member firms, including Baker & McKenzie LLP). Use of this site does not of itself create a contractual relationship, nor any attorney/client relationship, between Baker McKenzie and any person. **Non-reliance and exclusion:** All information on this Site is of general comment and for informational purposes only and may not reflect the most current legal and regulatory developments. All summaries of the laws, regulation and practice are subject to change. The information on this Site is not offered as legal or any other advice on any particular matter, whether it be legal, procedural or otherwise. It is not intended to be a substitute for reference to (and compliance with) the detailed provisions of applicable laws, rules, regulations or forms. Legal advice should always be sought before taking any action or refraining from taking any action based on any information provided in this Site. Baker McKenzie, the editors and the contributing authors do not guarantee the accuracy of the contents and expressly disclaim any and all liability to any person in respect of the consequences of anything done or permitted to be done or omitted to be done wholly or partly in reliance upon the whole or any part of the contents of this Site. **Attorney Advertising:** This Site may qualify as "Attorney Advertising" requiring notice in some jurisdictions. To the extent that this Site may qualify as Attorney Advertising, PRIOR RESULTS DO NOT GUARANTEE A SIMILAR OUTCOME. All rights reserved. The content of the this Site is protected under international copyright conventions. Reproduction of the content of this Site without express written authorization is strictly prohibited.