

**THE CHALLENGES OF
CHOOSING A CDMO
OR CMO UNDER THE
BIOSECURE ACT**



The introduction of the [BIOSECURE Act](#) represents a significant shift in the landscape for pharmaceutical and biotechnology companies. This legislation aims to prevent sensitive health and genomic data from falling into the hands of foreign adversaries, particularly those from China. The Act prohibits federal agencies from contracting with biotechnology companies deemed to be of concern due to their ties to foreign governments that pose a national security risk. Companies such as BGI Genomics, MGI, Complete Genomics, and WuXi AppTec are among the entities affected by these restrictions.

As a result, pharmaceutical and biotechnology companies must be more vigilant than ever when selecting Contract Development and Manufacturing Organizations (CDMOs) and Contract Manufacturing Organizations (CMOs) as supply chain partners. In this context, choosing a CDMO or CMO that is the best fit becomes a critical decision that requires careful consideration and strategic planning. Here are the key factors to keep in mind, along with specific actions to take, when choosing a CDMO or CMO in light of [the BIOSECURE Act and its impacts](#).

Understanding Supplier Restrictions

The BIOSECURE Act targets specific biotechnology companies [deemed to pose a national security risk](#), prohibiting federal agencies from contracting with entities that utilize their equipment or services. For pharmaceutical companies receiving federal funding, this means you must avoid these suppliers to comply with the law and carefully vet your suppliers to ensure compliance.

Action Steps:

- 1 Conduct Thorough Due Diligence:** Before engaging with a CDMO or CMO, conduct [comprehensive due diligence](#) to ensure they are not associated with restricted entities. Use public records, industry reports, and intelligence from trade associations to gather information about potential partners.
- 2 Implement Supplier Audits:** Regularly audit current and potential suppliers to verify compliance with the BIOSECURE Act. This includes on-site inspections and reviewing their supply chain to ensure no indirect use of restricted biotechnology services or equipment.
- 3 Contractual Safeguards:** Include clauses in contracts that require suppliers to comply with the BIOSECURE Act and disclose any changes in their supply chain that might affect compliance. This helps mitigate risks and provides legal recourse if a supplier violates the Act.

Implementing Robust Risk Management Practices

Enhanced risk management practices are crucial to ensure compliance with the BIOSECURE Act. Companies must implement robust screening processes to vet their suppliers and partners. This includes conducting due diligence to ensure that potential CDMOs and CMOs do not indirectly use restricted biotechnology services or equipment. Contractual safeguards should also be put in place to prevent inadvertent violations. By [proactively managing these risks](#), companies can avoid potential legal and financial repercussions.

Action Steps:

- 1 Develop a Risk Management Framework:** Establish a comprehensive risk management framework that includes identifying, assessing, and mitigating risks related to the BIOSECURE Act. This framework should be integrated into your overall [supply chain strategy](#).
- 2 Use Technology for Monitoring:** Leverage technology such as supply chain management software and blockchain to [monitor and trace the origin of all materials and services](#) used in your products. This ensures transparency and helps in early detection of compliance issues.
- 3 Provide Regular Training and Updates:** Train your procurement and supply chain teams on the requirements of the BIOSECURE Act and keep them updated on any changes in legislation. Regular training ensures that your team is aware of compliance requirements and can act accordingly.



Addressing Potential Supply Chain Disruptions

The need to switch suppliers could lead to significant disruptions in the supply chain, especially if alternative suppliers are not immediately available or if there are delays in the qualification process. These disruptions could impact the timely delivery of products and services, potentially affecting project timelines and market entry. Therefore, it is crucial to plan for contingencies and develop strategies to mitigate these disruptions. This may include establishing relationships with multiple suppliers and maintaining buffer stocks to ensure continuity of supply.

Action Steps:

- 1 Create Contingency Plans:** Develop detailed contingency plans for potential supply chain disruptions. This includes identifying critical suppliers, mapping alternative supply routes, and maintaining safety stocks of essential materials.
- 2 Engage in Scenario Planning:** Conduct scenario planning exercises to assess the impact of various disruption scenarios, such as the sudden loss of a key supplier. This helps in preparing proactive strategies to mitigate risks and maintain continuity.
- 3 Strengthen Supplier Relationships:** Build strong, collaborative relationships with your suppliers to ensure better communication and coordination in case of disruptions. Long-term partnerships can help in managing crises more effectively.



Diversifying the Supply Chain

Given the restrictions imposed by the BIOSECURE Act, companies need to [diversify their supply chains](#) and find alternative suppliers that are not on the restricted list. This involves identifying and qualifying new CDMOs or CMOs that meet the necessary regulatory and quality standards without using restricted biotechnology equipment or services. Diversifying the supply chain not only ensures compliance with the Act but also mitigates the risk of supply chain disruptions.

Action Steps:

- 1 Identify Alternative Suppliers:** Develop a database of [alternative CDMOs](#) and CMOs that are compliant with the BIOSECURE Act. Use industry networks, trade shows, and business intelligence tools to identify and vet potential partners.
- 2 Qualify New Suppliers:** Implement a rigorous qualification process for new suppliers, including pilot projects, quality audits, and financial stability checks. Ensure they can meet your production requirements and comply with all regulatory standards.

- 3 Geographic Diversification:** Consider diversifying your supply chain geographically to mitigate risks associated with political and economic instability in any one region. This also helps in complying with the BIOSECURE Act by avoiding reliance on suppliers from restricted countries.

Preparing for the Impact on Innovation

The transition away from certain CDMOs or CMOs might slow down innovation, as companies may face delays in finding new partners and ramping up production capabilities. Additionally, [smaller biotechnology firms](#) may find it challenging to secure new, compliant suppliers quickly, which could hinder their development programs. As such, it is essential to assess the potential impact on innovation and develop strategies to mitigate this risk. This may include investing in internal capabilities or partnering with academic institutions and other organizations that can provide the necessary support.

Action Steps:

- 1 Invest in In-House Capabilities:** Consider investing in in-house R&D and manufacturing capabilities to reduce reliance on external CDMOs and [CMOs](#). This can help maintain innovation pipelines while ensuring compliance.
- 2 Collaborate with Academic Institutions:** Partner with academic institutions and research organizations to leverage their capabilities and resources. Such collaborations can provide additional support for innovation while complying with the BIOSECURE Act.
- 3 Focus on Strategic Alliances:** Form strategic alliances with other companies to share resources and capabilities. These alliances can help mitigate the impact on innovation and ensure continued progress in drug development.



Strategic Planning and Communication

Strategic planning and effective communication are vital when navigating the challenges posed by [the BIOSECURE Act](#). Companies need to develop comprehensive plans that address all aspects of compliance, including supplier selection, [risk management](#), and cost control. Additionally, clear communication with stakeholders, including suppliers, regulators, and customers, is essential to ensure a smooth transition and maintain trust and confidence in the company's operations.

Action Steps:

- 1 Develop Comprehensive Plans:** Create detailed plans that address all aspects of compliance with the BIOSECURE Act. These plans should include supplier selection criteria, risk management strategies, and contingency plans for supply chain disruptions.
- 2 Maintain Clear Stakeholder Communication:** Maintain clear and open communication with all stakeholders, including suppliers, regulators, and customers. Regular updates on compliance efforts and changes in supply chain strategies help maintain trust and confidence.
- 3 Prioritize Continuous Improvement:** Regularly review and update your compliance and supply chain strategies to ensure they remain effective and aligned with the evolving regulatory landscape. Continuous improvement helps in staying ahead of potential challenges.

Ensuring Compliance Costs are Managed

Compliance with the BIOSECURE Act will likely increase operational costs due to the need for enhanced screening, legal consultations, and possibly higher costs associated with sourcing from compliant suppliers. These costs could be significant, particularly for smaller companies with limited resources. Therefore, it is important to factor in these additional costs when choosing a CDMO or CMO and to ensure that the chosen partner can help manage these costs effectively.

Action Steps:

- 1 Budget for Compliance:** Allocate a specific budget for compliance-related activities, including due diligence, supplier audits, and legal consultations. This ensures that you have the necessary resources to manage compliance effectively.
- 2 Conduct a Cost-Benefit Analysis:** Perform a cost-benefit analysis to understand the financial impact of switching to compliant suppliers versus the potential penalties for non-compliance. This analysis helps in making informed decisions that balance cost and compliance.
- 3 Leverage Economies of Scale:** If possible, consolidate purchases and negotiate better terms with compliant suppliers to offset the increased costs associated with compliance. Group purchasing organizations (GPOs) can be helpful in achieving this.



Grandfathered Contracts Expiring in 2032

One of the significant aspects of the BIOSECURE Act is the provision related to grandfathered contracts. Contracts that were established before the Act's implementation are allowed to continue under their existing terms until 2032. After this date, all contracts must comply with the new requirements set forth by the Act.

Additional implications include:

- **Transition Planning:** Companies should start planning now for the transition to new contracts that comply with the BIOSECURE Act. This involves identifying which contracts will be affected and developing a timeline for renegotiation or replacement.
- **Supplier Vetting:** Begin vetting current and potential suppliers well before the 2032 deadline to ensure they meet the BIOSECURE Act's requirements. This will help avoid any disruptions when the grandfathered contracts expire.
- **Compliance Audits:** Conduct regular audits of existing contracts and supplier practices to ensure they will be ready to transition to the new requirements without issues.

Looking Ahead

The BIOSECURE Act ushers in a transformative era for [pharmaceutical](#) and [biotechnology](#) companies, requiring an adaptive and proactive approach to [supply chain management](#). While challenging, this legislation offers opportunities to enhance supply chain resilience and ensure compliance through strategic partnerships and innovative practices. Successfully navigating these complexities will not only guarantee regulatory adherence but also reinforce the industry's commitment to safeguarding sensitive data and national security.

Companies that approach this regulatory shift with agility and foresight will thrive in a complex global market. Leveraging technology, strengthening supplier relationships, and fostering innovation through strategic alliances can turn challenges into competitive advantages. The future belongs to those who integrate compliance with operational excellence, maintaining industry leadership while delivering cutting-edge solutions and high-quality products.

For expert guidance on the BIOSECURE Act and its impact on your supply chain, [contact our team](#). We offer [comprehensive consulting services](#) to help you remain compliant and innovative in this evolving landscape. Reach out for personalized advice and turn challenges into opportunities for growth and excellence.

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