STRATEGIC GUIDANCE FOR SEAMLESS US MARKET INTEGRATION

Life sciences manufacturing onshoring and reshoring

Expanding operations across the US is a complex endeavor that requires meticulous planning and guidance. At DLA Piper, we understand the challenges businesses face in this process – whether establishing new manufacturing facilities, optimizing existing operations, or seeking a comprehensive review of best practices. Our tailored solutions help businesses navigate regulatory landscapes, streamline supply chains, and enhance operational efficiency.

By leveraging our experience, we empower businesses to mitigate risks, reduce costs, and achieve sustainable growth in the dynamic US market.

The challenge

Expanding across the US can significantly shape the strategy of life sciences companies and often introduces complex regulatory and operational considerations. For organizations with existing US operations, scaling and optimizing activities can present substantial challenges. Companies engaged in commercialization without US-based manufacturing **may face significant hurdles in establishing production facilities, including navigating FDA and other regulatory requirements, managing life sciences supply chains, and recruiting and retaining a qualified scientific and technical workforce**. Additionally, life sciences companies that already manufacture and commercialize products in the US may benefit from a comprehensive review of current practices to better position themselves for sustained growth, compliance, and long-term success in a highly competitive and regulated market.

The impact

These expansion and optimization challenges can have far-reaching implications for operational performance, compliance posture, and growth potential. Without informed guidance, life sciences companies may encounter delays, increased costs, and operational inefficiencies. **Missteps in regulatory compliance can result in inspections, enforcement actions, and financial penalties.** Ineffective supply chain management may disrupt manufacturing continuity and product distribution, negatively affecting patients, customers, and revenue streams. For organizations seeking strategic renewal, outdated operating models and practices can inhibit innovation and scale, leaving them exposed to more agile and better-positioned competitors.

Life sciences, including pharmaceutical, biopharmaceutical, and medical device companies are increasingly re-assessing global manufacturing footprints amid geopolitical shifts, tariff changes, national security priorities, Food and Drug Administration (FDA) enforcement trends, and federal and state incentives for US production.

Onshoring manufacturing – whether through acquisition, greenfield development, or strategic partnerships – can present both opportunities and complex regulatory, tax, workforce, and supply chain challenges.

DLA Piper provides end-to-end, cross practice counsel to help companies design and execute US manufacturing strategies that are compliant, cost efficient, and operationally resilient – while accelerating time to market and protecting long term enterprise value.

Onshoring and the operational equation

Manufacturing decisions in the life sciences sector are no longer driven solely by cost. A single shift in manufacturing location can impact regulatory approvals, tax structures, workforce planning, and supply chain continuity. In today's environment, a holistic, integrated, and execution focused approach can support the development of onshoring strategies.

FDA readiness

New or relocated US facilities trigger current good manufacturing practice (cGMP) obligations, inspection readiness requirements, and potential re-qualification of products, processes, and suppliers – often under tight timelines.

Supply chain re-configuration

Changes to active pharmaceutical ingredient (API) sourcing, intermediates, or finished dosage manufacturing may require regulatory filings, re-validation, and coordination across FDA and global regulators.

Tax and incentives

Federal, state, and local incentives can offset capital costs. However, companies are encouraged to align incentives with international tax, transfer pricing, and intellectual property (IP) strategies to avoid unintended exposure.

Workforce and site selection

Labor availability, training incentives, union considerations, and immigration planning can directly impact operational feasibility and scalability.

End to end privileged solutions for onshoring manufacturing

DLA Piper delivers global, multi-disciplinary solutions tailored to life sciences manufacturing investments. Our team integrates deep experience across the FDA regulatory, tax, corporate, employment, real estate, environmental, trade, and government affairs spaces – supporting legal privilege, execution, and policy insight.

Our integrated capabilities include:

- Manufacturing strategy and feasibility analysis
- FDA regulatory readiness and inspection strategy
- Site selection and incentive negotiation
- Tax incentives and international tax alignment
- Transactional execution (buy, build, or partner)
- Supply chain, trade, and national security counseling
- Workforce, employment, and immigration planning
- Environmental, health, and safety compliance
- Dispute resolution and enforcement defense

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Life Sciences: Multi-Jurisdictional
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Life Sciences: Nationwide
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Healthcare: Pharmaceutical/ Medical Products Regulatory District of Columbia
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Real Estate: Nationwide
Chambers USA 2025

Top Ranked
Tax: Multi-Jurisdictional
Chambers Global 2026

Top Ranked
Corporate/M&A: Nationwide
Chambers USA 2025

How DLA Piper can help

Strategy and diagnostics

- Assess onshoring feasibility across cost, regulatory risk, incentives, workforce, and speed to market considerations
- Evaluate build versus buy options, including acquisition of FDA regulated facilities and contract development and manufacturing organizations
- Design phased transition strategies to help minimize regulatory and supply disruption

FDA and regulatory execution

- Advise on cGMP compliance, quality systems, and inspection readiness for US facilities
- Guide FDA re-qualification and regulatory filings triggered by manufacturing changes
- Support regulatory diligence in manufacturing acquisitions and facility transitions
- Manage inspection response, remediation planning, and enforcement risk

Site selection and incentives

- Lead multi state site selection processes aligned with workforce, infrastructure, and logistics needs
- Negotiate state and local incentive packages, including tax credits, grants, property tax abatements, and workforce programs
- Advise on compliance obligations, claw-back exposure, and reporting requirements

Tax and international structuring

- Structure federal, state and local tax incentives tied to manufacturing investments
- Align onshoring strategies with international tax, transfer pricing, and IP planning
- Support audit defense and long term tax compliance

Transactions and development

- Represent buyers in acquisitions of pharmaceutical manufacturing facilities and contract manufacturing organizations
- Structure joint ventures, strategic alliances, and contract manufacturing arrangements
- Advise on real estate acquisition, development, leasing, and construction for regulated facilities

Workforce and operations

- Counsel on large scale hiring, employment compliance, and labor considerations
- Support strategies for scientific and technical talent
- Develop executive and workforce incentive structures tied to operational milestones

Impact

Our onshoring solution enables life sciences and pharmaceutical companies to:

- Accelerate US manufacturing readiness
- Reduce regulatory and execution risk
- Capture and protect incentive value
- Build resilient, compliant supply chains
- Align operational decisions with long term enterprise strategy

By combining legal privilege, industry depth, and cross practice execution, we help businesses move manufacturing onshore without losing momentum or value.

Key differentiators

End to end manufacturing lifecycle coverage
Provide integrated support across strategy, site selection, incentives, transactional execution, regulatory compliance, workforce issues, and operational readiness

FDA and life sciences regulatory insight
Leverage extensive experience advising on FDA inspection readiness, cGMP compliance, quality systems, and regulatory risk management for new and transitioning US manufacturing facilities, including implications of FDA's evolving pre check and inspection initiatives

Incentives and tax alignment
Develop coordinated federal, state, and local incentives strategies – integrating tax credits, grants, property tax abatements, workforce incentives, and infrastructure support with international and domestic tax planning

Global supply chain and trade perspective
Help re-shape global supply chains, advising on import and export controls, tariffs, trade remedies, and national security considerations affecting pharmaceutical inputs and APIs

Transactional flexibility (buy, build, or partner)
Structure acquisitions of existing facilities, greenfield developments, joint ventures, and contract manufacturing relationships

Policy aware, forward looking guidance
Advise on US industrial policy, healthcare security initiatives, and legislative trends impacting domestic manufacturing incentives, pricing pressures, and government procurement

One firm, many disciplines
Collaborate across the firm's Life Sciences Regulatory, Tax, Corporate, Real Estate, Supply Chain, Employment, Government Affairs and Public Policy, Site Selection and Incentives, Construction, Environmental, and Litigation teams – delivering practical, coordinated advice

For more information

To learn more about DLA Piper, visit dlapiper.com or contact:

Emilio Ragosa
Partner
Global Co-Chair, Life Sciences and Healthcare
T +1 973 307 3004
emilio.ragosa@us.dlapiper.com

Joshua Kaye
Partner
Global Co-Chair, Life Sciences and Healthcare
T +1 305 423 8521
joshua.kaye@us.dlapiper.com

Marco de Morpurgo
Partner
Global Co-Chair, Life Sciences and Healthcare
T +39 06 68 880 1
marco.demorpurgo@dlapiper.com

Steven Davis
Partner
Supply Chain Tax
T +1 212 335 4890
steven.davis@us.dlapiper.com

Elyssa Kutner
Partner
International Trade
T +1 202 799 4373
elyssa.kutner@us.dlapiper.com

Vernessa Pollard
Partner
Chair, FDA Regulatory Practice
T +1 202 799 4212
vernessa.pollard@us.dlapiper.com

David Pope
Partner — State and Local Tax
T +1 212 335 4650
david.pope@us.dlapiper.com

Stacie Trott
Partner
Co-Chair of Global Real Estate Practice
Chair of New York Real Estate Practice
T +1 212 335 4860
stacie.trott@us.dlapiper.com

Stephanie Yarbrough
Partner — State and Local Incentives
T +1 212 335 4635
stephanie.yarbrough@us.dlapiper.com

About us

DLA Piper is a global law firm with lawyers located in more than 40 countries throughout the Americas, Europe, the Middle East, Africa, and Asia Pacific, positioning us to help companies with their legal needs around the world.

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