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Reducing Risk in U.S. Market Entry: The Case for a Single Partner from Manufacturing to Clinical Supply

By Matthew Mollan, Ph.D., Chief Executive Officer, Experic

The U.S. and E.U. pharmaceutical markets are major targets for international drug companies looking to grow their global sales. Geopolitical uncertainty and the push to improve supply-chain resiliency are driving onshoring efforts and making the importation of drug products, particularly from Asia, increasingly challenging. Partnering with a contract development and manufacturing organization (CDMO) that provides end-to-end services with compliant production, packaging, and distribution capabilities in the U.S. and a point of entry into the European market can avoid import issues while reducing program timelines and risk. In addition to these capabilities, Experic is an agile and flexible, specialized solutions provider with the ability to rapidly grow and expand to meet changing client needs and focused on getting products to the clinic and ultimately patients.

Why Manufacturing in the U.S.?

International drug companies looking to grow their global sales cannot ignore the U.S., as it accounts for nearly half of the global pharmaceutical market.[1] In addition, the spend per capita in the U.S. is one of the highest in the world. Importing drug products and active pharmaceutical ingredients (APIs) into the US has become increasingly challenging, however, particularly for companies based in China.

- The U.S. Food and Drug Administration (FDA) has expanded unannounced inspections of foreign facilities manufacturing drug products, APIs, and medical devices for import into the U.S., with a focus on firms supplying high-risk products and critical components in regions with a history of non-compliance, including China and India.[2]
- The supply-chain disruptions created by the COVID-19 pandemic have created concerns over reliance on raw materials and active pharmaceutical ingredients (APIs) from outside the U.S., particularly Asian countries.[3]

- Ongoing geopolitical instabilities have heightened interest in onshoring production.[4]
- Passage of the BIOSECURE Act adds further question marks for any Chinese companies that could potentially be designated as "biotechnology companies of concern (BCCs).[5]
- Section 232 national security tariffs of 100% on specific branded imported biopharmaceutical products and APIs (excludes generics, biosimilars, and certain specialty drugs) made outside the United States in non-ally countries (to which a 15% duty applies), except generics, biosimilars, and certain orphan drugs and specialty products will be in full effect at the end of September 2026.[6]

Foreign companies that are not considered allied trading partners can, however, reduce their Section 232 tariffs to 20% through early 2030 if they have a Department of Commerce-approved onshoring plan or even to 0% through the beginning of 2029 if they have an approved onshoring plan and have established a Most Favored Nation (MFN) pricing agreement with the Department of Health and Human Services.

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Why Partner with a CDMO for US Manufacturing?

Establishing in-house manufacturing capacity is an expensive, time-consuming, and resource-intensive proposition, whether purchasing an established facility or building a greenfield site. Talent shortages can pose significant hurdles, particularly with respect to finding skilled workers with highly specialized technical expertise. Forging positive relationships with regulatory authorities, which are essential to success, requires significant time and effort.

Partnering with a US-based CDMO avoids these myriad issues. In addition to eliminating the need for large capital outlays, projects can be initiated more quickly. Careful selection of the right CDMO partner also provides access to specialized capabilities and ensures regulatory compliance. Furthermore, outsourcing to a CDMO can reduce overall program costs due to economies of scale and access to efficient and optimized processes. For foreign companies with early-stage projects and/or anticipating increases in demand over time, CDMOs that offer flexible, scalable capacities and the ability to grow with customers help streamline process development and reduce time to the clinic and the market.

Finally, partnering with a U.S. CDMO that has connections with both China and the U.S. offers even more benefits. Such partners have solutions for overcoming language and time-zone differences. They also support a more sustainable approach to entering the U.S. pharmaceutical market, contribute to improved supply-chain resiliency, and can increase the competitive advantage of Chinese drug companies.

Why Is an Integrated CDMO Partner Even Better?

Bringing a drug to market anywhere in the world is a complex process that involves several development stages and requires multiple regulatory filings. In the past, sponsors have needed to engage with outsourcing partners specialized in different phases – preclinical, early clinical, later clinical, and commercial, often separately for the drug substance and drug product, and then contract packaging and logistics companies to produce and distribute final products. Managing relationships with that many partners is challenging, and the need for numerous handoffs from one to the other creates significant risk. There are many hidden costs associated with this fragmented approach in terms of coordination gaps, split accountability, and delays.

Partnering with a single CDMO offering end-to-end support from preclinical through final

Today international drug companies looking to enter the U.S. pharmaceutical market have another alternative: partnering with a single CDMO offering end-to-end support from preclinical through final product packaging and distribution, dramatically reducing complexity, risk, and cost. Regulatory expertise is built in, not bolted on, reducing regulatory exposure due to lack of comprehensive ownership. Eliminating the need for technology transfers saves time and cost with fewer surprises and gaps, streamlining the development and commercialization process and further reducing risk. Truly integrated CDMOs with in-house analytical testing, packaging, and regulatory expertise magnify the benefits.

With effectively integrated CDMOs, a dedicated project manager serves as a single point of contact across development and clinical and commercial supply. The ability to establish consistent relationships helps overcome time zone, language and cultural differences.

What Are Key Attributes of an Optimal Single US CDMO Partner?

An optimal end-to-end U.S-based CDMO partner does more than manufacture products for its international partners. Of course, a strong track record of quality and regulatory compliance performance and the completion of projects on-time and in full is essential. So are an excellent industry reputation and credibility. Expertise and capabilities in the technologies and processes required for production of the client's specific drug substances and drug products are also a must. That includes chemical synthesis to tablet/

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capsule filling and final product packaging, warehousing, and supply-chain coordination. The ability to both provide clinical trial materials and support commercial manufacturing adds significant competitive and operational advantages.

Beyond these baseline attributes, the best CDMO partner for a Chinese drug developer looking to expand into the U.S. market understands the cultural divers, needs, and expectations of Chinese companies. This understanding should be coupled with transparency, open communication, and strong project management capabilities. A commitment to building long-term relationships combined with agility and flexibility to grow with clients are equally important. In addition to immediately available capacity, the ideal CDMO will have the ability to expand its existing footprint and scale as needed by leveraging already permitted, physically adjacent grey space. Emphasis on risk identification and mitigation help ensure ongoing quality, safety, and regulatory compliance.

Why Partner with Experic?

With a manufacturing location in the U.S. and an Ireland-based depot to support European clinical trials, Experic is an optimal CDMO partner for Chinese sponsors entering the US and EU markets. Our cGMP facility in Cranbury, New Jersey, has immediate capacity and 40,000 square feet of customizable expansion space for dry powder inhalation, highly potent and low-dose powder filling, complex capsule filling, spray drying, and clinical trial supply programs.

Experic seeks to be a true partner, developing long-term relationships with our clients. We are a specialized solutions provider by design. Dedicated project management with a single point of contact and frequent, regularly scheduled, in-depth project meetings ensure ongoing alignment. Direct access to technical leadership and a team that treats your program as a priority rather than a production slot are woven into the organization.

Importantly, Experic is structured to support growing, international companies entering new markets with more responsive communication and rapid decision-making. In addition to immediately available capacity, we have the ability to expand within the sites' existing footprint, including building bespoke production suites in support of specific client needs. Fast onboarding and tech transfer capabilities and flexible batch sizes provide additional competitive advantage.

Experic has extensive experience supporting FDA-regulated programs and strong CMC and quality alignment. Our smaller size ensures speed, agility, and client-focused operations, while our New Jersey location provides a logistical advantage, and our end-to-end services, including development, analytical testing, manufacturing, packaging, and distribution, enable global clinical supply with reduced complexity and timelines.

We know that every product Experic manufactures, tests, or packages ultimately reaches a patient. We are passionate about improving patients' lives and committed to meeting and exceeding our clients' expectations.

If you are evaluating U.S.-based CDMO partners for a dry-powder inhalation, encapsulation, or clinical supply program, contact us.

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Matthew Mollan, Ph.D., brings more than 30 years of leadership experience across pharmaceutical development, manufacturing, and clinical supply. A strategically focused operations executive, he is known for driving growth, operational excellence, and high-performing teams.

Prior to Experic, Matthew served as Vice President of Operations, Early Phase, at Catalent, where he led a multi-site U.S. and UK network supporting Phase I–III programs. He expanded capabilities, strengthened quality systems, and advanced key growth initiatives. Earlier, he led Catalent's Drug Delivery Solutions business in Kansas City, transforming it into a core strategic site with expanded capacity, enhanced technologies, and a strong reputation for scientific rigor.

Matthew has also held leadership roles at Aptuit, Pfizer, Warner-Lambert/Parke-Davis, and Carter-Wallace, building deep expertise in drug product development and novel dosage forms. He holds a Ph.D. in Pharmaceutical Science and a B.S. in Pharmacy from Rutgers University.