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â??A core problem for Chinese companies entering Western markets is regulatory translationâ?•

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Chinese biopharma companies are expanding their focus beyond domestic approvals to seek market access in the United States, Europe, and other regions. Veristat reports increased engagement from Chinese sponsors pursuing regulatory submissions and commercialisation abroad. In this interview, Daphne Smyth, Vice President of Global Regulatory Affairs, Veristat outlines how companies are approaching agencies such as the US Food and Drug Administration (US FDA) and the European Medicines Agency (EMA), the challenges involved in preparing data for these markets, and the role of CROs in supporting regulatory strategy, submission, and clinical development across regions.



We’re seeing China move much more aggressively to bring innovative therapies beyond its borders. From your vantage point, what is driving this shift toward seeking approvals in Western markets?

China's biotech industry is very active, as market approval processes in China have improved. As such, the National Medical Products Administration (NMPA) pipeline is increasingly crowded, particularly in oncology while National Reimbursement Drug List pricing negotiations have negatively impacted domestic returns. Now, companies with strong intellectual property can no longer continue to grow inside China alone. Chinese research & development has also pivoted. We are seeing first-in-class assets now, not just ‘me-too’ molecules chasing domestic market share. Investors, including global crossover funds, are increasingly building Western approval into their return expectations, adding pressure on Chinese sponsors to go outside of China.

Chinese biotech companies historically focused on domestic approvals. What regulatory strategy changes are you seeing as they now prioritise filings with agencies like US FDA and EMA?

Historically, Chinese sponsors developed their assets to achieve NMPA approval first and delayed Western filings. But that is changing. Many companies are designing trials for global submission from the start with ICH-aligned protocols, statistical analysis plans written for both FDA and EMA review, and global data safety monitoring board structures. Type B meetings with the FDA and scientific advice at EMA are happening pre-IND from sponsors who had no prior relationship with either agency a few years ago. The Marketing Authorisation Holder model in Europe has also opened commercial opportunities by allowing Chinese companies to sell into European markets without standing up a full subsidiary, which used to be a real obstacle.

What are the biggest hurdles Chinese drug developers face when preparing therapies for regulatory review and commercialisation in Western markets?

Companies who develop their assets in China either need western or global site participation in pivotal studies, or they need to make a rigorous scientific case for why data from Chinese patient populations extrapolates to EU or U.S. patient populations. That case is harder to build than most sponsors expect and is very dependent on the drug being developed.

Manufacturing can also be an issue. The chemistry, manufacturing and controls documentation and inspection standards for the EMA and FDA market approvals are different from NMPA requirements. Companies that moved smoothly through domestic approval, can face significant hurdles when faced with strict FDA and EMA guidelines.

Finally, there's a lack of regulatory talent: Constructing a marketing authorisation submission that lands with an FDA or EMA reviewer requires a different approach than with NMPA, and that expertise is still scarce among Chinese sponsors that don't have a seasoned global partner.

As Chinese innovators begin launching therapies in Europe and North America, how might this reshape competitive dynamics for U.S. and EU biotech companies?

Chinese sponsors are arriving in EU and US markets with late-stage assets in the same indications where U.S. and European companies are competing, but built at substantially lower development cost. Large pharmaceutical companies are noticing. They are accessing those assets directly, which shrinks the licensing window for mid-sized biotechs that used to sit in that space. The pressure is sharpest in high-volume oncology, antibody-drug conjugates and bispecifics, where Chinese pipelines are deepest. Western companies in those spaces need differentiation at the level of mechanism or indication. Cost and speed are no longer available as competitive levers.

What role do CROs like Veristat play in bridging regulatory, cultural, and operational gaps for Chinese sponsors entering Western markets?

A core problem for Chinese companies entering Western markets is regulatory translation. A data package that satisfies NMPA may have serious gaps when read by an FDA or EMA reviewer. Those gaps need to be found and addressed before a New Drug Application (NDA) submission to the FDA or a Marketing Authorisation Application (MAA) submission to the EMA submission. Veristat works with sponsors to do that assessment honestly: to analyse what the existing data actually supports in the EU or US context, where the holes are and what it takes to close them before filing. For sponsors without Western regulatory experience in-house, that work shapes whether the first FDA or EMA interaction is productive or corrective. Beyond the submission mechanics, experienced CROs like Veristat bring a rich understanding of what EMA and FDA regulators find persuasive – i.e., clinical framing, efficacy and safety profile, risk-benefit narrative, risk management, and what it takes for exposure across many programmes. and positioning of the new asset in the relevant regulatory environment

Which therapeutic areas or modalities from China’s biotech ecosystem are most likely to gain approval in Western markets over the next 3–5 years (e.g., cell therapy, bispecific antibodies, ADCs)?

Antibody-drug conjugates (ADCs) are furthest developed. Chinese companies have built novel linker-payload combinations with strong early clinical data, and several programmes have accessed FDA expedited pathways. Bispecific antibodies in oncology are close behind. Cell therapy is compelling science but the manufacturing and supply chain demands for Western commercialisation are a real constraint and approval timelines there will be longer. Outside oncology, metabolic disease is moving fast. Chinese sponsors have been aggressive on GLP-1 adjacent mechanisms and novel obesity targets. Rare disease is also tractable. Smaller patient populations and tools like orphan drug designation and accelerated approval suit sponsors that are still building their Western infrastructure rather than working against them.

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