

CASE STUDY

Creating a custom solution in China to meet complex microbiology testing requirements

Obtaining approval from several regulatory agencies around the world requires a coordinated effort and a strategic partnership. This case study highlights how Labcorp Drug Development served as a trusted source for a leading pharmaceutical company to support its global clinical trial of an anti-infective—an antibacterial/beta-lactamase inhibitor combination.

Protecting sample stability and aligning to rapidly changing regulatory requirements

With a treatment designed to address significant unmet medical needs from bacterial infections acquired in hospital settings, the sponsor sought to obtain approval from several regulatory agencies, including the U.S. Food and Drug Administration (FDA), European Medicines Agency and National Medical Products Administration (NMPA).

In this global study, the microbiology team had already developed processes to support sample testing that aligned with U.S. FDA requirements and European Committee on Antimicrobial Susceptibility Testing requirements. However, in China, the testing process was more difficult, and several challenges needed to be addressed to meet NMPA requirements.

First, the sponsor had already selected a vendor to provide panels for the minimum inhibitory concentration (MIC) assays used to process patients' samples, but Labcorp found that the vendor's product was not meeting quality standards. Then, an unexpected challenge appeared when the Ministry of Health of the People's Republic of China suddenly changed its rules that prohibited the import and export of biological samples. Before this change, Labcorp had been permitted to ship bacterial isolates collected from patients in China to a U.S.-based Labcorp microbiology testing facility.

Building a custom, in-country laboratory and shipping plates

To address the issue of the sponsor-selected vendor's poorly performing assay, Labcorp worked quickly to manufacture the panels for the MIC assay in-house and validate its quality. The team found that temperature stability of the MIC panels was a crucial factor, requiring a steady temperature of -20°C or colder during shipment. With an unavoidable wait time at customs and an overall travel time of seven to eight days, the team used temperature tracking technology and strategic timing of the shipments to maintain stability of the Labcorp-generated plates and deliver accurate results.



Key Takeaways

- Developed in-house assay and shipment strategies to meet quality control standards for a complex protocol
- Rapidly responded to shifting regulatory requirements overseas
- Launched a new microbiology laboratory in China to provide complex, in-country testing services

Labcorp study directors needed to quickly find a reference laboratory to support the sponsor's testing given the change in NMPA regulations that restricted the export of patient samples to the U.S.

After searching and evaluating all the available laboratories in China, Labcorp found that none of the local reference laboratories were able to support the sponsor's complex testing requirements. With no regional options available, the Labcorp team built its own dedicated microbiology lab in Shanghai.

Applying ingenuity and innovation to keep a complex, global study on track

Developing a laboratory from the ground up was an unexpected challenge, yet after only six months, the Labcorp Drug Development microbiology laboratory in China was established to fully support the sponsor and keep the anti-infective study moving ahead. To provide ongoing quality oversight, the results generated from the Shanghai microbiology laboratory were sent to Labcorp facilities in Indianapolis and Geneva. The team only approved data that met quality standards that would support regulatory submissions. Impressively, the study was completed within the timeline originally established with the sponsor.

As a new facility, Labcorp's Shanghai Microbiology lab had to complete an intense three-day NMPA inspection to continue operations. The key focus of the inspection involved the sponsor's anti-infective protocols. Working together with the team in Indianapolis, the Shanghai Microbiology lab was able to provide all the required information and the lab successfully completed the final NMPA inspection.

After extensive testing of the MIC assay and its requisite shipping conditions, the team learned how to efficiently transfer temperature-sensitive materials overseas. They also adeptly transferred data between global teams to maintain quality and operational processes. Finally, with the recent success of the NMPA inspection, the team in China continues to grow and now supports additional, specialized microbiology testing solutions to help sponsors with their unique, in-country requirements and enable better health outcomes for patients.

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