

Solid-state and HPAPI: the advantage of a European supply chain

RFP comparison of timelines, containment and compliance (AIFA and FDA) against Asian solid-state R&D providers.

	PCL Research & Manufacturing	Asian providers (offshore model)
Timelines	• EU-based laboratory: samples and APIs move within the EU, with no non-EU customs • Same time zone as European clients: technical discussions in real time • Site visits and audits can be arranged at short notice	• Non-EU shipping with customs procedures; for HPAPIs and controlled substances, also import/export authorizations • Time zone 6 hours ahead of Central Europe (7 in winter) • A re-test or a non-conformity triggers a new shipping cycle
Containment	• HPAPIs up to OEB5 handled on site, with dedicated expertise • Controlled substances handled under Italian authorization • Chain of custody entirely within the EU	• OEB4/OEB5 capability claimed by several players • The issue is verifiability and transport: highly potent material on intercontinental routes, with risk of delay or customs holds
AIFA and FDA compliance	• AIFA-authorized site, within the EU GMP framework • References: EU GMP and FDA data integrity expectations (ALCOA+) • Client audits and authority inspections under the same legal system as the European client	• Primary authority is NMPA; FDA and EMA compliance is declared site by site • To be verified by scope: research screening and GMP manufacturing are not the same • Supplier qualification falls on the client, with more travel and longer lead times

US context: BIOSECURE Act (status as of 1 October 2026)

- In force since 18 December 2025 (FY2026 NDAA, sec. 851): restricts US federal procurement, contracts and funding involving “biotechnology companies of concern”.
- The official OMB list is due by 18 December 2026; the prohibitions take effect after the FAR revision (likely in 2027), with a 5-year transition for existing contracts.
- The June 2026 1260H list includes five Chinese biotech companies, among them WuXi AppTec and BGI: the first step toward designation.

What it means for your program

The law does not ban Asian CROs as such: it targets designated entities. If a provider were designated mid-program, changing site would cost time and data. A European provider removes this uncertainty, especially in programs involving US federal agencies.

Proximity, verifiable containment and European compliance: less supply-chain risk and less time lost between one cycle and the next.

Sources: BIOSECURE Act text (FY2026 NDAA, sec. 851); analyses by Baker McKenzie, Arnold & Porter and Hogan Lovells (2026).