

US IND vs. EU Clinical Supply Path

Your US supply chain may already be deciding whether Europe is possible.

There is no US equivalent to a Qualified Person.

In the US, release runs through a QA function. In the EU, a named individual must personally certify each batch before it can be used in a clinical trial. It's a different release model, not extra paperwork.

	US IND Path	EU Clinical Trial Path
Who releases	The sponsor's Quality Assurance function	A Qualified Person (QP) with defined training and experience requirements
Accountability	No single accountable individual role built into the process	One named, accountable individual
Release standard	Manufactured and tested per GMP and the protocol	Certified per EU GMP and the clinical trial authorization
What release requires	Internal review and sign-off	Direct visibility into batch records, analytical data, and often the site itself
Manufacturing site	Any qualified CDMO	An EU GMP-certified site, or import of US-made product with added QP release and import documentation
Agreements	Cover US release criteria	Must give the QP access to records, data, and sites. Relying on another QP's confirmation requires a written agreement in advance
Stability & labeling	US storage conditions and US-required label elements	May need additional climate zone conditions and multilingual, country-specific labels

A US biotech runs Phase 1 domestically. 18 months later, a partner wants EU sites for Phase 2. The technical agreement never addressed QP access, the CDMO has no EU-certified facility, and stability data wasn't scoped for EU conditions. None of it was a mistake at the time. Together, it's a 6–9 month delay.

6–9 months

lost when EU readiness is discovered late

6–12 months

for comparability when manufacturing moves to a second, EU-capable site

- EU capacity:**

Does your CDMO have EU GMP-certified capacity, or a credible path to it?
- QP provisions:**

Do your agreements allow for QP documentation and site access?
- Stability design:**

Can you add climate zone conditions without restarting the study?
- Labeling:**

Is there room for additional country requirements?

You don't need to build EU infrastructure now. You just need to avoid closing the door.

How Syner-G Helps

Syner-G's integrated CMC360 model brings regulatory, quality, and CMC expertise together so your US IND decisions preserve global options, without overbuilding for markets you don't have yet.

Plan for Europe before Europe plans for you.
Connect with our team.