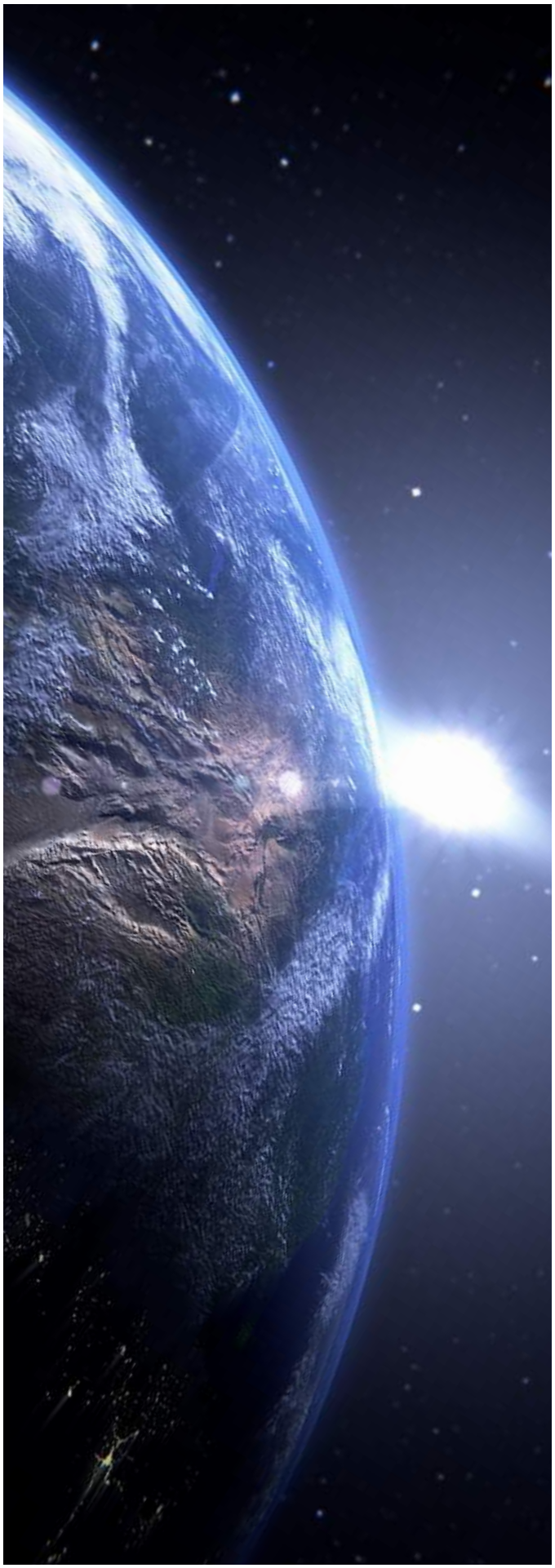
GLOBAL INJECTABLE INNOVATION:
LEVERAGING SINGOTA'S EUR AND US CAPABILITIES



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Singota® Solutions is a CDMO located in Bloomington, Indiana, USA that specializes in Parenteral, Early Phase Drug Development and Aseptic Filling projects.

Not All CDMOs Speak Global Fluently. We're Bilingual in Biotech

Imagine this: you've just finished developing a promising injectable therapy. You've got the data. You've got the vision. But now you need to get it there - and by "there," we mean everywhere: from Bloomington to Basel, from Boston to Balerna. You're not just racing against time, you're navigating tariffs, timelines, tech transfers, and the tender art of keeping your molecule stable and compliant across borders.

Welcome to the crossroads of pharmaceutical ambition and global execution. Most CDMOs can get your project somewhere. But what happens when "somewhere" isn't good enough?

At Singota Solutions, we've spent over two decades perfecting our blend of scientific precision and supply chain finesse, not just within U.S. borders but across the Atlantic too. With one foot firmly planted in Indiana and three others sprinting ahead in Balerna and Basel, Switzerland, and Rovello Porro, Italy, we've become a rare breed in the CDMO world - one that combines agility, strategy, and international reach to serve clients developing injectable therapies across continents.

But before we get to how we make it all happen, let's look at why it matters more than ever.

The Stakes of Going Global in Injectable Drug Development

Global development isn't a luxury in 2025, it's a necessity. Oncology assets, rare disease biologics, cell and gene therapies - all of them are being advanced by biotech innovators operating in complex, multicountry ecosystems. Add to that the post-pandemic restructuring of global trade, persistent tariff concerns, and new regulatory dynamics between the U.S. and EU, and the message becomes clear: cross-border CDMO support isn't a nice-to-have - it's make or break.

For injectable drug products in particular, the logistics can be daunting. These therapies demand pristine handling, cold-chain integrity, and tight regulatory synchronization - often in real-time. A mislabeled batch, a misaligned timeline, or a misinterpreted regulatory nuance in one country can derail an entire development program.

That's where having a global yet nimble partner changes everything.

Built for Molecules That Move

Unlike large-scale CDMOs that silo their services and take months to align international operations, Singota has designed its model around early-phase injectable programs that need movement - between labs, timelines, and time zones.
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Here's what makes it all possible:

- Strategic EU Sites: Our facilities in Balerna and Basel (Switzerland) and Rovello Porro (Italy) are more than geographic assets, they're pharmaceutical accelerators. These GMP-compliant locations offer temperature-controlled warehousing at 15–25°C, 2–8°C, -20°C, -40°C, and -80°C, supporting international storage, 3PL logistics, and cross-border distribution for clinical trials. Whether you're prepping for an IND, managing an IMPD, or tech-transferring a fill/finish batch, we've got the infrastructure and fluency to get it done.

- Seamless Tech Transfers: Our team doesn't just speak science, we speak regulatory dialects.

- Our decades of experience navigating FDA, EMA, and other regulatory frameworks ensures your drug product maintains continuity, quality, and compliance throughout tech transfers. Whether it's formulation handoff, batch certification, or stability bridging, we reduce friction, not add to it.
- Agile U.S. Expertise: Based in Bloomington, Indiana, our headquarters remains a hub for formulation development, aseptic filling, and analytical testing, all performed with speed and transparency. But what truly sets us apart? We've never missed an operational timeline, with a 99.99% on-time track record and a back-up manufacturing date always available within 30 days. That's not just rare - it's Singota rare.
- Integrated Supply Chain Philosophy: Global injectable development is about more than shipping. It's about planning. Our supply chain metrics (like a decade-long 99.77% deviation-free performance and 100% on-time operations since 2020) don't happen by accident. They happen because we bake resilience, clarity, and collaboration into every phase of the project, from Phase I to global clinical deployment.

Where Global Isn't Just a Buzzword, It's a Buildout

While many CDMOs advertise "global capabilities," what they're really offering is a collection of disjointed services scattered across time zones with limited cross-functional communication. The result? Long delays, lost-in-translation errors, and molecule momentum that's more start-and-stop than seamless.

Singota is different. Our global footprint is designed with continuity in mind. A client developing an injectable drug in the EU can transfer development or fill/finish operations to our U.S. team without recreating documentation, repeating validation, or fearing miscommunication. And vice versa. It's one team, one system, and one mission: to get your molecule across borders, and across the finish line.

Closing Act: One CDMO, Many Countries, Zero Compromise

At the end of the day, injectable innovation doesn't care about borders, but regulatory bodies, clinical timelines, and cold-chain stability certainly do. That's why your CDMO shouldn't just have a passport. It should have a plan.

Singota Solutions is that plan. With unmatched early-phase injectable expertise, a clean digital operation that reduces error and accelerates insight, and global capabilities rooted in real infrastructure (not marketing slides), we're built for biotechs with global ambitions.

So if you're advancing your injectable drug across continents (or planning to) don't settle for a CDMO that's big on buzzwords but short on follow-through. Reach out, plug in, and let's make global development feel like local delivery.

Because when it comes to injectable success, borders should never be barriers.

Singota Solutions is a US based CDMO in Bloomington, Indiana. Singota specializes in formulation development and aseptic fill finish for injectable projects. Once a formulation is established, Singota utilizes state of the art robotic filling technology and focuses on smaller batch size requirements. For more information, visit Singota.com to explore how Singota has established itself as a one-stop solution for all your developmental needs.

Contact **solutions@singota.com** to schedule a meeting with our business development team to further discuss your current or future projects.