

# GET \$SMART:

## AVOIDING COSTLY PHASE 1 INJECTABLE TRIAL MISTAKES

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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.*

Every drug development journey is filled with exciting milestones, but also plenty of hurdles. The key to success? Avoiding the ones that cost you time, money, and sanity. That's exactly why Singota Solutions hosted its Get \$mart: 1 Year Out from Phase 1 Injectable Trials, Avoid 3 Expensive Mistakes webinar, an event designed to help early-stage drug developers steer clear of costly pitfalls as they prepare for clinical trials.

If there's one thing the experts at Singota know, it's that drug development is as much about strategy as it is about science. In this insightful session, Singota's scientific leaders broke down the top three mistakes that can derail an injectable program, and more importantly: how to avoid them. Whether it's underestimating the scale-up process, neglecting robust analytical methods, or choosing the wrong CDMO partner, these issues can mean the difference between a seamless transition to Phase 1 or an expensive, frustrating delay.

For those who missed it, don't panic! Here is a recap of the key takeaways, plus, why these lessons could be game-changing for your early-phase drug development program.

### The Three Costly Mistakes You Really Don't Want to Make

Singota's experts took attendees on a deep dive into the three most common (and expensive) mistakes that early-stage injectable drug developers make when preparing for clinical trials. Let's break them down:

#### 1. Assuming Scale-Up is a Simple Copy-Paste from the Lab

If only it were that easy! Just because your formulation works perfectly at the benchtop doesn't mean it will seamlessly transition to GMP manufacturing. The shift from small-scale R&D batches to clinical-scale production introduces a host of new challenges; solubility, stability, sterility, and supply chain logistics, to name a few.

Singota's experts emphasized that one of the most common pitfalls is assuming that what works in the lab will automatically work in larger volumes. Factors like API solubility, excipient compatibility, and even the equipment used for mixing and filtration can lead to unexpected challenges. Without careful planning, what seemed like a stable formulation at 10mL might fall apart at 1000mL.

Key takeaways? Anticipate potential formulation adjustments early, conduct feasibility studies, and ensure your manufacturing partner has the flexibility and expertise to adapt to scale-up hurdles before they become roadblocks.

#### 2. Cutting Corners on Analytical Method Development

A strong analytical method isn't just nice to have. It's the backbone of your stability program. If your testing methods aren't optimized early, you risk inaccurate data, compliance issues, and potential regulatory delays.

The experts at Singota broke down why analytical method development needs to be tailored to your molecule's unique properties. Early-phase injectables often have complex formulations, meaning a one-size-fits-all approach to testing simply won't cut it. Without proper method validation, you could end up chasing false stability trends or struggling with unexpected degradation issues.



Our experts (Ryan Memmer: Manager, Product & Process Development and Quality Control & Robert Sleiman, PhD.: Business Development Manager) also highlighted the importance of method robustness, ensuring that your analytical strategy can withstand the transition from R&D to GMP testing. Poorly designed methods often result in failed stability studies, repeat testing, and wasted resources - all things that can derail your timeline and add significant cost to your program.

Bottom line? Investing in method development upfront will save you time, money, and regulatory headaches down the road.

### 3. Choosing the Wrong CDMO (Based Solely on Price)

We get it. Budgets matter. But choosing a CDMO partner based on cost alone can lead to larger (hidden) expenses, unexpected delays, and a lot of unnecessary stress.

Memmer & Sleiman stressed that a CDMO should be more than just a vendor. They should be a true partner in your success. Too often, small biotech companies choose a provider based purely on a low bid, only to find themselves at the bottom of a long priority list, waiting weeks (or months) for answers to critical questions.

Some essential questions to ask when evaluating a CDMO:

- Will they prioritize your project, or will you be just another number?
- Do they have expertise in early-phase injectable development?
- Are they flexible and communicative, or will you be left in the dark?

Singota's approach focuses on client-centric collaboration, transparency, and flexibility, ensuring that early-phase teams have the scientific and operational support they need to hit Phase 1 on time and with confidence.



#### Why Singota's Approach to Early-Phase Development Stands Out

The Get \$mart event wasn't just about identifying problems. The event was about providing solutions. Singota Solutions has spent over 20 years refining its approach to small-batch injectable drug development, setting itself apart from large, impersonal CDMOs.

#### What makes Singota different?

- Expert-Driven Formulation & Analytical Method Development: Our scientists work hands-on with clients to optimize formulations and testing strategies tailored to unique molecules.
- Flexible, Small-Batch Manufacturing: Unlike larger CDMOs, small biopharma teams aren't pushed to the back of the line. Singota prioritizes emerging innovators.
- End-to-End Support: From early development to aseptic filling, cold storage, and logistics, Singota offers a seamless pathway from preclinical work to Phase 1 trials.
- Proven Track Record: With an industry-leading 99.99% on-time operations rate, Singota ensures your project moves forward without costly delays.

It's certainly clear: for teams working on early-phase injectables, having the right CDMO partner can be the difference between a smooth clinical transition and a logistical nightmare.

#### Missed the Event? Here's Your Next Move

If you didn't make it to Get \$mart, don't worry! You can still access all the insights from the webinar by watching the on-demand recording [HERE](#).

And if you're looking for a CDMO partner that understands the complexities of small-batch injectable drug development, Singota Solutions is here to help. Let's be real - nobody wants to learn these costly mistakes the hard way. Skip the headaches, save the budget, and get to Phase 1 smarter, faster, and more efficiently.

Your future self will thank you.

**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](http://Singota.com) to explore how Singota has established itself as a one-stop solution for all your developmental needs.

Contact [solutions@singota.com](mailto:solutions@singota.com) to schedule a meeting with our business development team to further discuss your current or future projects.