

Focused on Faster



Our company was founded with the vision of being a contract development and manufacturing organization (CDMO) that would fill the gaps in the drug development process and focus on getting patients the treatments they need faster. Our shorter lead times, dedicated team of experts, and single site location mean your project will receive focus and speed while never compromising quality, whether you are a virtual or large pharmaceutical company.



Our team of experts at Singota is here to collaborate with you, customizing our services to meet your needs and hit your milestones. We welcome the opportunity to show you how we can get your products to patients *faster*.

CONTACT US

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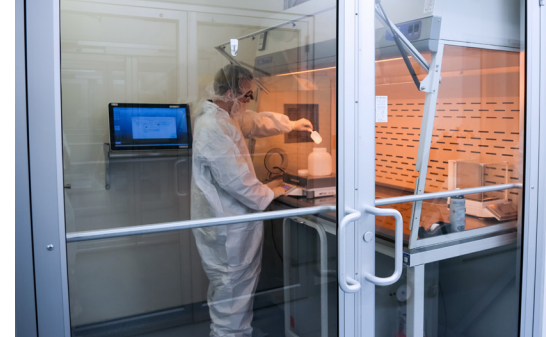
Your CDMO
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MANUFACTURING

Aseptic Filling & Finishing

Our gloveless, robotic, aseptic filling workcell provides a state-of-the-art filling process for manufacturing injectable therapies. Singota can fill your parenterals into ready-to-use vials, syringes, or cartridges. Our manufacturing process ensures freedom from in-process human intervention by not only removing the impact of operators from the initial aseptic environment but also by removing operator variability from the filling process. We also offer customized finishing services, specializing in small-volume clinical batches.

Advantages of our aseptic filling service include reduced line losses and rapid access to our line with standard, ready-to-use components. Contact us to see how Singota can get your product through the development pipeline faster.



QUALITY CONTROL AND DEVELOPMENT LABORATORY

Development & GMP Testing

Our laboratory services include formulation development, process development, and analytical testing. We work with clients in the early phases of development all the way through to post-manufacturing support, including release testing and ICH stability programs.

Singota's development and QC testing capabilities allow us to tailor a solution to a specific need in a streamlined and efficient manner. Our on-site lab saves valuable time on client projects by working seamlessly with our comprehensive services to ensure client milestones are met. Visit our website for more information on our capabilities and equipment.



SUPPLY CHAIN MANAGEMENT

SCM & Cold Chain

Singota manages a diversified group of materials from APIs and excipients to finished products. We have the capability to handle toxic, potent, flammable, and hazardous materials. Our secure cGMP warehouse offers storage conditions including controlled room temperature (15–25°C), cool (2–8°C), and frozen (-20°C, and -80°C). Singota also manages distribution of clinical trial materials, as well as cold chain solutions for temperature-sensitive products.

Our unique sampling and dispensing services are available to aliquot specified weights or volumes of materials into appropriate containers for testing, development, and manufacturing purposes. Visit us for a tour of our facility located in central Indiana, just 90 minutes from major FedEx and UPS hubs.

CLIENT SERVICES

Singota Solutions is a client-focused organization that operates with a project-based structure to deliver services at a high level. Project managers who work within the client services team are responsible to lead and oversee all aspects of project execution. Our project management team is integral to the success of Singota's service model, providing a single point of contact and supporting a high-trust, high-accountability, collaborative experience for our clients.

QUALITY

Singota's quality management system (QMS) has been designed to achieve Singota's mission, vision, and core values, by implementing processes and procedures that conform to cGMP. QMS components, such as validation, supplier management, training, deviation and CAPA management, internal assessments, and change control management, have been created to align with 21 CFR (Parts 210 & 211) and EU requirements. Singota's QMS is routinely evaluated via numerous client audits, regulatory inspections, and internal audits.