FAQ

Q | Where are you located?

A | Singota's facility is in Bloomington, IN, we are 90 minutes from major FedEx & UPS hubs. Please note we also offer International supply chain services.

FAQ

Q

What type of clients do you serve?

A

Serving 200+ clients with active projects, including but not limited to: Large Pharma, Virtual Pharma, Consulting Firms, & Animal Health

FAQ

Supply Chain

Q What storage conditions do you offer?

A

- 15-25°C
- 2-8°C
- -20°C
- -80°C
- Hazardous storage
- Open bonded warehouse location in Switzerland
- We offer temperature, relative humidity, and differential pressure monitoring where applicable
- We do not offer liquid nitrogen, cell bank, human tissues, beta-lactams, or cephalosporins storage currently

FAQ

Supply Chain

Q Are you FDA registered?

A Yes, Singota is FDA registered to handle storage of controlled substances (Scheduled CIII-CV).

FAQ

Supply Chain

Q What are your licenses, registrations and accreditations?

A

- FDA Registration
- EU GMP Certificate
- Drug Distributor Accreditation
- Japanese PMDA
- DEA Licenses (Analytical, Distributor, Manufacturing)
- 3PL Licenses

FAQ

Supply Chain

Q What is your current capacity?

A Singota is a 72,000 ft² facility with a range of storage options. We have domestic and international partnerships to meet our client's logistics and storage needs. Please contact us for specific open capacity and capability

FAQ

Supply Chain

Q Can you perform sampling and dispensing?

A

- Single use-disposable product contact items
- Utilize electronic documentation for weigh & dispense
- Sampling and Dispensing services cover:
  - -Powders and liquids
  - -Flammable, toxic, and potent materials
  - -Light, humidity, and static sensitive materials

FAQ

Aseptic Manufacturing

Q What filling technology does Singota use?

A

- Cytiva (formerly Vanrx) SA25 workcell, an automated filling, stoppering, and capping process integrated within a gloveless isolator
- No human exposure to Grade A areas, no human intervention
- Pre-sterilized single use flow path, component sterilizations

FAQ

Aseptic Manufacturing

Q What size components can you fill?

A

- Pre-sterilized, nested, Read-to-Use (RTU) components
  - -Syringes: 1mL Long, 1mL – 3mL standard
  - -Vials: 2R-30R
  - -Cartridges: 1.5mL
  - -We do not fill bags or bottles currently

FAQ

Aseptic Manufacturing

Q What is your capability?

A

- Aqueous based, parenteral aseptic filling
- We have experience from Pre-clinical to Phase 3
- Batch Sizes: <100 to 10,000 units
- Fill volumes: We have flexibility of formats and fill volumes

FAQ

Aseptic Manufacturing

Q What is your open capacity?

A We have a flexible schedule; We can work with our clients to meet their timeline(s).

FAQ

Development & Testing

Q | Do you perform formulation development?

Yes! | A

FAQ

Development & Testing

Q Do you perform microbiology testing in-house?

A

- Yes - Sterility Testing USP <71>
- Bacterial Endotoxin Testing USP <85>
- Microbial Enumeration/Bioburden USP <61>
- Specified Microorganism Testing USP <62>

FAQ

Development & Testing

Q | Do you have stability testing?

Yes, ICH storage conditions and excursion capabilities | **A**

FAQ

Development & Testing

Q What type of analytical support do you offer?

A

- For full list of services, please download our Service Offering fact sheet
- API and Drug Product release testing
- Raw material testing
- Infusion and material compatibility studies
- Container closure integrity testing (CCIT)
- Reconstitution studies
- Post packaging ID

FAQ

Finishing Services

Q Can you perform labeling and kitting?

A

- Yes, we support development and clinical trial labeling and kitting needs.

Services we offer:

-Labeling/De-labeling

-Re-labeling

-Kitting

-Blinded

FAQ

Quality Status

Q What are the various Quality Status Categories used at Singota to classify materials as to their quality classifications, according to Singota's Quality Management System?

A

QOH – Quantity on hand / released status; this is the only status that permits material transactions (aliquot, ship, etc.)

QC – Quarantine status

QR – Quality hold status

REJ – Reject status; this is for materials deemed unacceptable for use and/or destined for disposal.

RESEARCH – Non-GMP status; this status indicates the material is only for non-GMP/not for human use.

RETAIN – Retention status; designates the material is part of the retention program at Singota.

STAB – Stability status; designates the material is part of a stability study at Singota.