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# How A Sample/Dispense Service Streamlines Drug Development

By **Alice Levis**, Singota Solutions

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Biopharma organizations often require aliquoting of materials to support their projects, but can be burdened by the timelines, costs, and risk of compromising materials. Not all contract development and manufacturing organizations (CDMOs) have the capability to aliquot clients' material via sample (non-GMP use) and dispense (GMP use) for further processing.

In response, Singota has developed sample/dispense services with an array of options to accommodate client needs. Often, pharmaceutical companies may not be aware this service exists. We strive to communicate clearly with clients' project managers to help them understand the most appropriate option(s) to meet their project's need, since every request is unique:

- ***Manufacturing/Aseptic Filling —*** Singota formulates product on behalf of some clients, who send us their API and, in some cases, excipients. We also carry common excipients in our inventory to support formulation needs. We can then conveniently aliquot materials for formulation. Other clients send us drug substance (DS) ready to be filled into different presentations.
- ***Quality Control and Development —*** Singota may perform formulation development or analytical testing. Client materials can be aliquoted to support this work at Singota or shipped, per client request, to a third-party laboratory.
- ***Supply Chain Management —*** A client with materials stored at Singota's warehouse has 24/7 visibility of their inventory via our E-Transparency system. In our system, clients can make sampling/dispensing requests to support shipments, analytical testing, and/or manufacturing processes on-site or elsewhere.

Clients utilizing Singota's supply chain management service (e.g., storage) benefit by using our sampling/dispense service. For example, they are saved the burden and cost of sending unnecessarily large containers to testing sites and having to pay for storage fees at those destinations. Deliberately modest material amounts are easier to ship, care for, and track, in addition to allowing the shipment of multiple samples/dispenses to different locations.

This approach minimizes waste of client materials. APIs generally are quite precious, so sending only what is necessary reduces associated risk and bolsters product quality security. Finally, some materials might have special properties. For example, they may be hydroscopic or respond negatively to oxygen, so they must be dispensed within a nitrogen-filled "glove box." Or, the material may require dispensation into amber-colored vials because it is light sensitive. We are able to handle highly potent materials as well. Our request forms allow clients to add special in-

structions to ensure their materials' integrity (e.g., how a frozen material is meant to be thawed, or concerns about its time out of refrigeration).

In terms of capabilities, the lowest aliquot we can typically handle is 50 mg. We can accommodate same-day aliquoting requests in some instances. Our standard lead time is three to five days. Highly potent materials may take extra time for cleanroom and sampling/dispensation setup due to additional safeguards associated with their handling.

Timelines usually are our clients' most significant concern, followed by regulatory and documentation safeguards. Singota has U.S. and EU certifications for our aliquoting services. Materials in our warehouse are evaluated by our environmental health and safety (EHS) team, which identifies proper storage and handling conditions. Additionally, with our team's extensive expertise, we ask questions to reduce risks and optimize client requests as needed.

Everything we do is driven by robust standard operating procedures (SOPs). Our sample/dispense suites feature one-time through air in exhaust, with monitor and control of differential pressure, temperature, and humidity, and entry/exit is tightly managed. We use electronic documentation for weigh and dispense and have procedures in place to prevent and reduce cross-contamination risks.

To learn more, visit us at https://singota.com/ and follow us on Twitter (@SingotaSolution).

## About The Author

Alice Levis is a Client Services Supervisor at Singota Solutions. She has over seven years of experience in the pharmaceutical and biotechnology industries. Alice enjoys helping clients meet their project needs and mentoring teammates.

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## About Singota Solutions

Singota Solutions is a contract development and manufacturing organization (CDMO) focused on helping clients in the pharmaceutical, animal health, and biotechnology industries move their products through the drug development pipeline faster by being agile, accountable, and transparent.