

Capsugel® Dosage Form Solutions offers integrated product development from feasibility assessments through clinical trials, and specialized commercial manufacturing of finished dosage forms. This full-service offering helps expedite product development timelines, reduces the risks associated with managing multiple partners, and accelerates speed to clinic and product approval. Co-located product development and manufacturing sites in the US (Bend, OR and Tampa, FL) and Europe (Edinburgh, Scotland and Ploërmel, France) manufacture a full range of solid oral dosage forms in cGMP environments.



- Tablets ranging from bi/tri-layer matrices, osmotics, orally dissolving tablets, and mini-tabs
- Multiparticulate products using various technologies including encapsulation or filled into sachets
- Liquid-filled hard capsules and soft gels utilizing liquid and semi-solid fill technologies
- Encapsulation of multiparticulates, granulations and powders

Capsugel specializes in product and process design to make your compound a commercial reality. Proprietary bench-scale equipment has been designed and installed to facilitate rapid feasibility assessments. Capsugel Xcelodose Precision Powder Micro-Dosing Systems facilitate powder-in-capsule assessments which can reduce product development time by 13-17 weeks. Capsugel CFS 1200™ Capsule Filling & Sealing Systems facilitate lipid-based formulation assessments using liquid fill hard capsule technology.

As a comprehensive solutions provider, our customers look to us for all of their clinical trial material and service needs. We offer primary and secondary packaging services in support of Phase I-V clinical projects, as well as worldwide distribution and storage.

Global Clinical Supplies Packaging Capabilities

Capsugel Dosage Form Solutions supplies a full range of primary and secondary packaging for a variety of dosage forms, including labeling services and clinical kit assembly

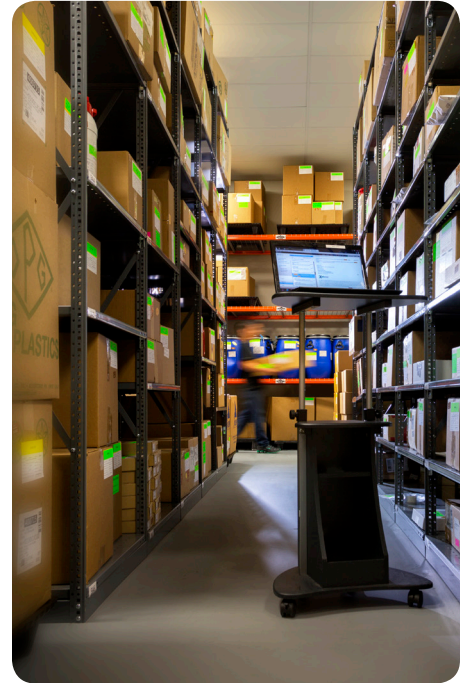


- Blister packaging
- Patient blister card production
- Bottle filling with a wide range of containers and closures, desiccants, induction sealing, in-line printing
- Procurement of clinical labels
- Label production coordination — label proof generation and approval management
- Clinical labeling of trial materials
- Labeling and assembly of kits
- Assembly of ancillary supply kits
- Sourcing and procurement of comparator and rescue medications
- Collaborate with designated IXR providers with upload data and distribution
- Low humidity primary rooms

Global Clinical Supplies Distribution and Logistics Capabilities

All clinical trial material have specific needs, including specialized storage and distribution requirements. Getting packaged investigational materials shipped to the site and dispensed to the patients, on time and correctly, requires orchestrating a myriad of activities. An added benefit is the convenience of having a provider who can manage temperature controlled shipments globally. Capsugel Dosage Form Solutions has the capability to ship temperature controlled products throughout the world and has distribution facilities in the US, UK and an extensive global network of depots.

- cGMP distribution/temperature controlled global warehousing
 - Storage conditions of -20°C, 2°-8°C, and 20°-25°C
 - Controlled drug warehousing for DEA I-V
 - Cold chain distribution
- Retain sample storage, including electronic maintenance
- Clinical site return, reconciliation and destruction services
- Global depot partner network including World Courier and BioCard SMO
- Electronic inventory system with client portals for real-time data retrieval
- Customized reporting capabilities
- Dedicated distribution project management resources
- QP services available in the UK



For more information on our Solid Dosage Manufacturing, Packaging & Logistics contact us at DFSInquiry@capsugel.com, visit capsugel.com, or reach a Capsugel representative directly at:

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