



Capsugel® offers integrated product development from feasibility assessments through clinical and specialized commercial manufacturing of finished dosage forms. This integrated, full-service offering helps expedite product development timelines, reduces the risks associated with managing multiple partners, and accelerates speed to clinic and product commercialization. Product design, development and manufacturing sites in the United States (Bend, Oregon and Tampa, Florida) and Europe (Edinburgh, Scotland and Ploermel, France) produce a full range of oral dosage forms in cGMP environments for clinical and commercial supply.

Comprehensive Clinical Supplies Solutions

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.

Tablets ranging from bi/tri-layer matrices and osmotics to orally dissolving tablets and mini-tabs

Encapsulation of multiparticulates, granulations and powders

Multiparticulate products using a range of technologies, with the option of encapsulation into capsules or filled into sachets

Liquid-filled hard capsules and soft gels utilizing liquid and semi-solid fill technologies

A wide range of steady-state release rates is possible in addition to zero order

Modifications to the platform technologies such as immediate, delayed and custom release profiles — as well as fixed-dose combination therapies — can be designed into the finished dosage form

Our integrated product development includes full preformulation, formulation development and analytical services. We provide clients with clinical trial and commercial manufacture of innovative dose forms, and have isolation capability for highly potent compounds at each stage of the product development and supply process.

Extensive Packaging Capabilities

Capsugel 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 assortment of containers and closures, as well as desiccants, induction sealing and in-line printing

Clinical label procurement

Label production coordination, including label proof generation and approval management

Clinical labeling of trial materials

Kit labeling and assembly

Assembly of ancillary supply kits

Sourcing and procurement of comparator and rescue medications

Collaboration with designated IXR providers for data upload and distribution

Low-humidity primary rooms



Solid Dosage Manufacturing, Packaging and Distribution

Global Distribution and Logistics

All clinical trial materials have specific needs, including specialized storage and distribution requirements. Getting packaged investigational materials shipped to the proper sites and dispensed to the appropriate patients, all at the right times, requires orchestrating a myriad of activities — and having a provider who can manage temperature-controlled shipments globally. Capsugel is experienced at delivering these kinds of products throughout the world, utilizing distribution facilities in the US and UK, and a widespread global network of depots.

cGMP distribution and 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

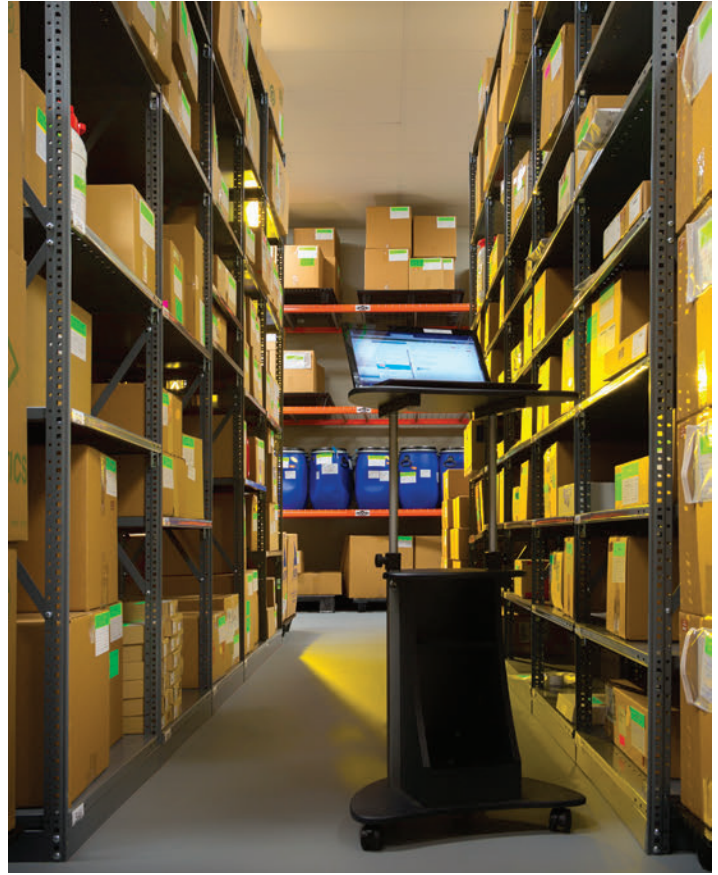
Global depot partner network including World Courier and BioCard SMO

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



Learn more about how Capsugel's Clinical Supply Solutions can support and accelerate your clinical studies.

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