

Clinical Manufacturing, Packaging & Labeling

Once a drug has been formulated, Bilcare has a manufacturing facility that can provide fast, efficient and agile manufacturing, packaging and labeling of the test product. Our unique approach enables us to support customer requirements for short-term studies as well as large-volume ongoing projects.

Manufacturing and Packaging

Solid, Semi-solid and Liquid manufacturing and packaging are completed using the following equipment:

- + Bottle packaging
- + Blister packaging
- + Liquid/Semi-solid filling
- + Blending
- + Granulation - wet and dry
- + Pouch packaging
- + Capsule filling
- + Powder filling
- + Tablet manufacturing and coating
- + Liquid/semi-solid manufacturing
- + Controlled environmental chambers
- + Scales and balances
- + Label application and kit assembly
- + Refrigerated and frozen packaging capabilities

The products are manufactured exactly to the specified formulation keeping parameters such as quality, GMP, humidity, temperature and moisture within control limits.

We can provide flexible manufacturing ranging from small to large high-speed production in accordance with GMP manufacturing standards.

Controlled Substance Management

Bilcare is registered with the DEA as a Manufacturer, Distributor, Exporter, Importer and Analytical Laboratory of Controlled Substances.

Packaging

Our extensive experience makes us uniquely qualified to design and prepare your clinical supplies. We help you select the right packaging solutions, complete production and deliver a final product that meets your high standards with:

- + Clinical study design, protocol interpretation and consultation
- + Packaging design and engineering
- + Complete line of thermoform and coldform blister packaging
- + Bottle filling for solid and semi-solid dosage forms
- + Label application and kit assembly for randomized and non-randomized labels
- + Blister card sealing/walleting
- + Clinical label design and generation
- + Pouching
- + Controlled substances Schedule I-V
- + Refrigerated and frozen packaging capabilities
- + Sourcing of comparator drugs

Labeling

The third and final operation in our manufacturing area is labeling. Being critical to the clinical trials supply chain, we are very careful in the label design and generation, specifically:

- + Label size
- + Label content
- + Regulatory requirements (Global)
- + Randomization
- + Printing

We have the capability to produce labels that are:

- + Open
- + Randomized
- + Variable text
- + Single and multi panel
- + Multilingual

To produce the labels we have the following equipment:

- + PRISYM software for label design
- + Zebra printer

Benefits of an Integrated Process

- + A single point of contact
- + A single audit for you to complete and sustain
- + Single format and management of batch records and documentation
- + Minimized manufacturing timeline, risk and documentation delays that can occur when transferring materials between multiple vendor strategies
- + Elimination of the technology transfer process that is required when moving product from one location to another

Our Quality Process Ensures that We have Produced

- + The right product
- + In the right container
- + With the correct label

Service and Quality Beyond Compliance.

www.BilcareGCS.com