

Move Your Molecule From a Vial To a Prefilled Syringe

Why move?

- **Convenience:** Less materials, less steps, less time to administer
- **Safety:** Reduced risk of needle stick injury, greater dose accuracy, and less risk for contamination
- **API Cost Savings Per Unit:** Less overfill required for a prefilled syringe (PFS) vs. a vial = less API waste = increased units filled/batch = increased revenue/batch
- **Lifecycle Management:** A new delivery platform has the potential to provide market differentiation, extension of your product's exclusivity beyond patent expiry, and a price premium/increased revenue



BioPharma Solutions can help you “move”!

As one of the fastest-growing choices for unit dose medication, the advantages of prefilled syringes help to improve healthcare in many ways. As a global leader in prefilled syringe contract manufacturing, BioPharma Solutions offers clinical through commercial high-volume sterile manufacturing. We can increase your production potential and help ensure on-time delivery to meet product demand.

Manufacturing

- Experience manufacturing products sold worldwide including: North America, South America, Europe, and Asia
- Expertise in handling a variety of drug categories, including biologics, vaccines, and small molecules
- Three (3) like-in-kind high speed syringe lines located in three (3) different buildings with separate water and HVAC systems, creating a built-in risk mitigation strategy to help assure product availability
- Can fill/finish syringe sizes ranging from 0.5 to 20mL
- Can fill/finish plastic or glass syringes that are received clean, sterile, and ready-to-fill in a nested tub configuration double bagged

Options/Customization

- Option for manual or fully automated Eisai inspection
- Choose from a variety of secondary packaging options and product enhancements including plunger rod, finger flange, product insert, carton, and blister
- Option to design custom label

Full-Service R&D Support

- Silicone and/or tungsten evaluation
- Container feasibility study
- Extractables and leachables testing (outsourced)
- Analytical method development and validation
- Laboratory stability studies

Stability

- Storage
- Testing at various time points

Regulatory

- Author Module 3 submission section of the application
- Reference to established Drug Master Files
 - Facility
 - Syringe container closure

Case Study: Teva changes the presentation of COPAXONE from a lyo vial to a prefilled syringe

US COPAXONE Units Sold by Presentation



Source: IMS Database

Results:

- COPAXONE PFS achieved rapid uptake in the US with 64% of patients switching within the first three months, and over 99% switching within six months of launch.
- The average prep time for patients was reduced from 235 seconds (vial) to 38 seconds (PFS), saving patients 20+ hours per year
- Although the price of the vial presentation remained stable from 2002 to 2006, the price premium for the PFS increased to 70.5%

Work with an experienced, award-winning CMO:

- **2015, 2012, 2011, 2010:** Best Contract Manufacturing Organization, Vaccine Industry Excellence Awards (4-time winner)
- **2013:** CMO Leadership Awards (Life Science Leader) winner in all 5 categories: Quality, Reliability, Productivity, Innovation, Regulatory



Contact us via email today:
biopharmasolutions@baxter.com

Visit our website for additional services/information:
baxterbiopharmasolutions.com