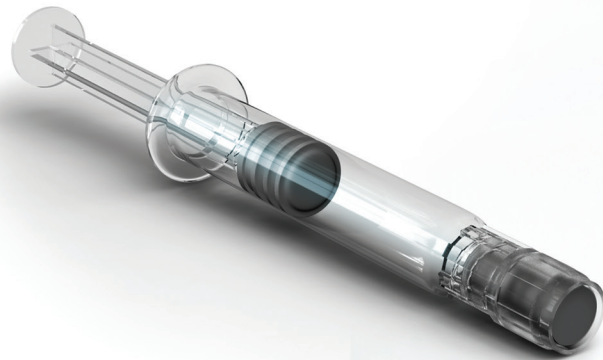


Move Your Molecule From a Vial To a Prefilled Syringe

Why Move?

- **Convenience:** Less materials, less steps, less time to administer
- **Safety:** Reduced risk of needlestick 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
- Like-in-kind high speed syringe lines located in different buildings with separate water and HVAC systems, creating a built-in risk mitigation strategy to help assure product availability
- Prefilled syringe sizes ranging from 0.5 mL to 20mL
- Sterile plastic or glass syringes ready-to-fill in a nested tub configuration, double-bagged

Product 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
- Serialization capabilities

Full-Service R&D Support

- Syringe evaluation with laboratory fill and development stability studies
- Silicone and/or tungsten evaluation
- Piston or Peristaltic Pump evaluation studies
- Analytical method development and validation
- Retention studies

Stability

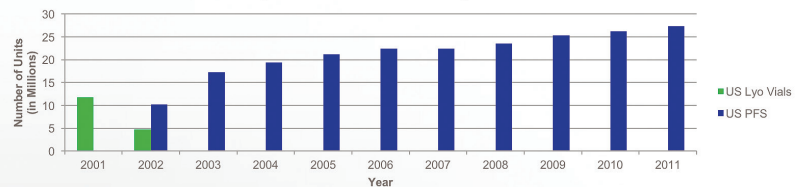
- Storage
- Testing at various time points

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



	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Lyo vial price (in \$US)	\$25.28	\$26.02	\$25.73	\$25.61	\$25.67	\$24.97	N/A	N/A	N/A	N/A	N/A
PFS price (in \$US)	N/A	\$28.04	\$29.42	\$33.20	\$37.83	\$42.59	\$48.01	\$55.62	\$65.69	\$83.14	\$104.77
PFS Price Premium	N/A	7.8%	14.4%	29.6%	47.4%	70.5%	N/A	N/A	N/A	N/A	N/A

Source: IMS Data

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 PFS increased to 70.5%



BioPharma Solutions offers more than just fill finish of sterile injectables.

Strong organizational capabilities and broad parenteral resources help us align with your company’s commercialization objectives and our shared goal of moving patient care forward.

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