Baxter

BioPharma Solutions

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
- 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

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

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

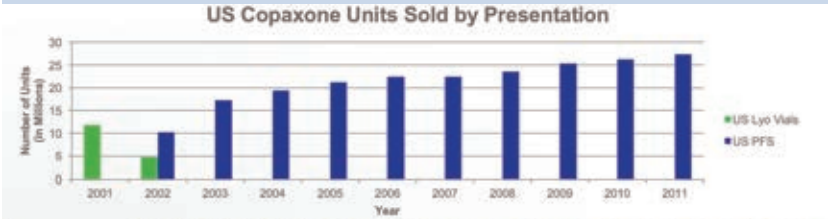
Stability

- 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



	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Lyo vial price (in $US)	$25.28	$26.02	$25.73	$25.81	$25.87	$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%

Work with an experienced, award-winning CMO:

- 2018, 2017, 2015, 2012, 2011, 2010: Best Contract Manufacturing Organization, Vaccine Industry Excellence Awards (6-time winner)
- 2017, 2016, 2015, 2013, 2012: CMO Leadership Awards (Life Science Leader publication), winner in multiple categories (5-time winner)

10th Annual ViE Vaccine Industry Excellence AWARDS

CMO LEADERSHIP AWARDS 2018

Contact us via *email* today:
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