Recreating an Off-Patent Product Critical to the Development of Pharmaceuticals

A global biopharmaceutical company that focuses on the development of complex small-molecule and macro-molecule compounds for treating chronic illnesses experienced a significant supply chain issue when they received word that a key component used in their development process would no longer be made by their supplier. The component was a polymeric resin known as “milling media” used to break pharmaceutical compounds into nanoparticles. The technology had recently come off patent and served as a cleaner alterative to YTZ, a grinding media produced from yttria-stabilized zirconia powder.

To make matters worse, the company not only used the media in their own processes, they also processed the media to meet FDA requirements for cleanliness and then relicensed it to other pharmaceutical companies—who depended on it to produce their proprietary compounds as well. The production and availability of billions of dollars’ worth of pharmaceuticals for treating prevalent chronic diseases depended upon this product—and it would not be available in a short period of time.

Although they were provided a large stock of the media from the current supplier, they had to ensure long-term security of supply to the customers that relied on them.
After researching the ion exchange and polymeric resin market, Purolite was the most obvious choice for being able to reproduce the proprietary technology. Known for our competency in manufacturing polymeric resins, strong commitment to research and development, ability to customize resin technologies and speed to market, the customer asked Purolite to manufacture, purify and package the media.

A feasibility study was conducted and Purolite agreed to help them out. The two companies entered into an agreement to develop a product with the same characteristics and specifications as the current milling media. Purolite would both make the polymer as well as complete the purification process and product packaging so that the customer would only need to ship the final product to their customers.

The initiative included the following main steps:

- Undertake a research and product development program
- Make a capital investment to build a new cGMP manufacturing and packaging plant
- Develop a bench-scale process
- Scale-up the manufacturing process
- Produce and approve a successful equivalent product
- Develop an FDA compliant purification process
- Establish a packaging process to maintain purity
- Detail a protocol for full regulatory compliance—including writing a Drug Master Files (DMF)

Purolite built a cGMP manufacturing site to purify and package the media. Purolite also perfected manufacturing monodisperse beads through jetting technology—improving on the original process.

An equivalent final product was successfully produced long before the customer's supply reserves ran out or expired. Purolite ensured the continuity of their supply agreements, while also enabling them to to shut down their purification facility and utilize that space for processes relevant to their biopharmaceutical medicine production.

Why Purolite?

- Focused on doing whatever it takes to get tasks done—and done correctly
- Thorough yet fast with decision making, contracts and agreements
- nsurpassed competency in manufacturing polymeric media to a desired specification
- Proficient in regulatory compliance documentation and processes
- Specialized experts for R&D and production of resin technology
- Extensive state-of-the art laboratory equipment for product analysis

If you are in need of a manufacturer for a highly specialized, resin-based product—and don't know where to turn—contact the Purolite technical experts in your region.