

## Finding right site for drug device

### Tech seeking Ariz. facility to produce auto-injector systems

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Tech Group plans to establish another Tempe, Ariz., facility for volume production of the new ConfiDose auto-injector system for parent company West Pharmaceutical Services Inc.

Tech seeks space in the range of 30,000-40,000 square feet and plans to select a site in the first quarter of 2009, said Eric Resnick, Tech vice president and general manager for drug-delivery devices.

Commercial manufacturing and assembly should start in the second half of 2009.

The device has 12 injection molded components, two metal springs and a standard 1-milliliter, prefilled syringe with a barrel of either glass or plastic. Resins in parts of the power-pack and clear-window-tube subassemblies include polycarbonate, Delrin-brand acetal, Ryton-brand polyphenylene sulfide compound with two-shot moldings of PC and a thermoplastic elastomer.

All tools are hot-runner, hot-tip or valve-gated except for a few hot-to-cold runner systems.

Either traditional glass or Daikyo Crystal Zenith-brand cyclic olefin polymer can form the syringe barrel.

"ConfiDose will be the only auto-injector to take a 1-mL needle (with a syringe barrel) of CZ material," Resnick said. Nippon Zeon Co. Ltd. manufactures CZ and, in 1995, granted Daikyo Seiko Ltd. and West exclusivity to use CZ in pharmaceutical and medical devices.

Tech's Scottsdale, Ariz., engineering center builds ConfiDose prototype and production molds.

West said the single-use ConfiDose system avoids preparation steps and makes delivery easy for its user.

"There are auto-injectors out there, and people are not happy with them," Resnick said.

West and Tech went



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through “painstaking detail” in the early stages as part of “what it takes to develop a device that is new,” Resnick noted.

Auto-injectors have become a preferred delivery method and, soon, will be a standard, said Glenn Thorpe, vice president and general manager for advanced injection systems for Lionville, Pa.-based West.

That kind of thinking led to West’s acquiring Pharma-Pen Inc. of Athens, Texas, in February 2007.

Pharma-Pen developed a type of automatic injector and received Food and Drug Administration premarket clearance in July 2006. Subsequently, that design was abandoned, but its patented technology gained attention.

“We started looking [at ConfiDose] as a contract business from Pharma-Pen,” Resnick said.

Tech, a business segment of West, started ConfiDose engineering tests in late 2007, produced several iterations and tweaked the design to reflect trial-identified human factors.

The research-and-development Athens site, which employs 11, is making initial ConfiDose units for design, verification, testing and regulatory purposes.



Resnick

A ConfiDose syringe contains an individual dose for a self-administered injection for a chronic disease such as rheumatoid arthritis, multiple sclerosis and anemia.

A user presses a button causing a needle to extend, deliver a dose and retract. Post-use, the system permanently shields the needle.

West showed the product at a Parenteral Drug Association conference on prefilled syringes and injection devices, held Oct. 6-7 in San Diego.

With ConfiDose, West and Tech began on the ground floor with the mechanical design, tooling, material selection and development processes.

This continuous collaboration streamlined the process and allowed West and Tech to work through challenges to create a system that increases ease of use for patients and reduces bulkiness — issues that Pfizer Inc. faced with the design of the Exubera inhaler.

New York-based pharmaceutical giant Pfizer discontinued production of the inhalable insulin device in October 2007 after the medical community reported the bulky Exubera device was difficult to use. Exubera inhaler contract manufacturing ceased at facilities of Tech in Tempe and Consort Medical plc in Milton Keynes, England, with costly consequences.

West acquired the business assets of Tech Group Inc. in May 2005.



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