

BioWest

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ing these “the pillars of our economic future.”

The state already has one of the better foundations to further grow these pillars, particular in the bio/health-care/med-tech category. Its 400 companies in these areas provide 16,000 jobs, Ritter reported, those jobs providing an average salary of \$70,000 a year (doing the math, that's \$1.12 billion), and adding new companies in these categories at the rate of 30 every year.

A selection of those companies provided interesting exhibitor viewing and conversation at BioWest 2007.

Along with the exhibiting device firms, just as interesting were companies putting their primary emphasis on services to assist emerging biotechs and med-techs, among these **BeamOne** (Denver) and **Quest Product Development** (Wheat Ridge).

BeamOne has taken a page out of Henry Ford's manual of American methodology, though what it provides is not mass production but mass sterilization.

The company is focused on sterilization of single-use devices using electron beam radiation, its system able to provide sterilization of truckload-sized packages of medical devices. Its conveyor systems move large containers, or cases, of various types of devices, and even tissues, through its irradiating system though it is equally able to sterilize an individual cell

The company says the electron beam “is a series of rapid pulses of energy, with each pulse delivering a ‘beam spot’ about 2 inches in diameter.”

The process includes rotation of the cases for complete radiation with what BeamOne calls preliminary Dose Map studies, used to determine the dose ranges for different categories of devices.

Suzie Perlman, director of customer relations, assured *Medical Device Daily* that the system involves no radioactivity and requires no testing or validation of sterility following the procedure.

Its primary benefit is speed, she said, the ability to sterilize a large number of devices quickly, taking this requirement off the hands of the manufacturer. “Most manufacturers aren't in the sterilization business they don't want to be,” she said, adding “we can do one piece of cell or a truckload.”

Perlman explained that electron beam radiation works by “disrupting the DNA of microorganisms.” For different types of devices, she said, “the radiation doesn't change, the dosage changes according to the bioburden.”

Materials that electron beam radiation can't sterilize are those with high water content, she noted, and those with highly variable shapes, such as hip and knee implants.

The company built its first facility in Denver, with operations also in San Diego (the company's official headquarters) and Lima, Ohio, and it is building another facility in Costa Rica, 20 miles north of San Jose. That facility is expected to be operational early next year.

Perlman estimated that BeamOne has about 10% of the electron beam sterilization market with potential for large additional growth via the Costa Rica facility, that country representing another region attempting to emphasize medical device and life science technology, she told *MDD*.

As of now, she said, Costa Rican products must be shipped to the U.S. for sterilization so that the new facility offers a major new benefit for the medical device firms there and creates a major new footprint in Central America for BeamOne.

Among the other positive Colorado “enablers” of the med-tech industry exhibiting at BioWest 2007 were technology transfer organizations.

Quest was one of these, a company offering engineering and consultation services largely growing out of research from the **University of Colorado** (UC; Boulder), while also providing similar services to global clients bringing specific engineering problems to it.

“We're a bunch of real smart scientists and senior engineers that have been together for a long time,” Mitch Houston, mechanical engineer and project manager of **Quest**, told *MDD*, the statement matter-of-fact and not at all boastful.

During a conference poster session, **Quest** presented two of its projects, one a tiny endoscopic device for difficult visualization applications, in 1 mm and 3 mm sizes.

The 1 mm size device is engineered to reach into the torturous areas of the sinuses to treat infection, otherwise not reachable with standard instruments; the 3 mm instrument engineered to provide closer visualization of the lungs – accessed via the esophagus – as an alternative to invasive biopsy procedures through the chest, and often in hit-or-miss fashion, according to Houston.

This tiny technology, interestingly enough, grows out of aerospace research at UC.

Another system that **Quest** was featuring, still at the proof-of-principle stage, offers hope for greatly improving cardiac pulmonary resuscitation.

Noting the high mortality rate from sudden cardiac death, **Quest** says that for about 25% of such patients, “the presenting cardiac arrest rhythm is pulseless electrical activity” (PEA), with survival from PEA only about 4%, though these victims still have some intrinsic cardiac activity.

CPR frequently fails because out of sync with this intrinsic cardiac activity, **Quest** says, and it is developing technology providing synchronization of chest compression geared to what it terms pulse arrival time. Such a system, it says, could provide greater survival and, importantly, greater survival with fewer concomitant deficits.

The company has done first-phase development of the system with an NIH SABR grant and recently submitted its application for funding of the next stage of development, Alan Kopelove, director, technology business development at **Quest** told *MDD* Quest's strength is tech transfer, not manufacturing, and so with the next steps of product development completed, Kopelove said, “we will seek a licensing partner.” ■