LIFECYCLE SUPPORT FOR MEDICAL DEVICE

PART 1: The specialized skills of contract manufacturing organizations play a vital role in supporting the work of serial medtech innovators.

By Eric King

For most medical device and diagnostic companies, whatever their size or area of clinical specialization, technological innovation is central to their identity. But continuously working to develop increasingly sophisticated technologies can create challenges for both the designers and manufacturers of medical devices. Even for the largest and best-funded medtech companies, it can be difficult to maintain a base of employees with talent and experience in all the technology fields now being applied to the development and manufacturing of next-generation medical devices.

To maintain their grasp on the latest technologies needed to develop new products, both established and startup companies benefit from the expertise of contract manufacturing organizations (CMOs) that have long been a hallmark of the medical device industry. CMOs with varied scope and specialty provide the medtech sector with vital services that can augment or even take the place of a manufacturer's in-house operations.

This two-part paper looks at a successful outsourcing partnership that adopted a lifecycle approach to product innovation, resulting in the creation of many successful generations of surgical catheters and specialized products for vascular access, and generating more than $10 billion in end- customer sales. Here, Part 1 examines the role of specialized contract manufacturing organizations in supporting innovative medical technology companies. Part 2 will look at how medtech manufacturers and contract manufacturing organizations can apply a product lifecycle model to support ongoing innovation.

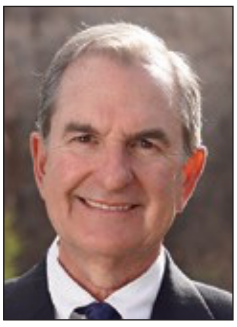
Eric King, vice president for product development in the Salt Lake City facility of Flexan, a contract manufacturing organization specializing in medical technologies.

OUTSOURCING ADVANCES MEDTECH INNOVATION

"For medical device companies, having the ability to innovate is very important," says Eric King, vice president for product development at the Salt Lake City facility of Flexan, a CMO specializing in product development and cleanroom manufacturing of silicone and thermoplastic components for medical technologies. "Without design innovation and associated intellectual properties, product lines can become commoditized very quickly—and at that point, the only permissible innovations are often limited to those that reduce costs, so that the product can remain competitive."

King should know. A product developer and medtech innovator for nearly three decades, he is the holder of a number of patents related to vascular access devices including peripherally inserted central catheters (PICCs) and associated accessories. Beginning in the 1990s, teams led by King played a vital role in the successful development of several market- leading vascular access product lines commercialized by Bard Access Systems (BAS), a division of longtime device manufacturer C.R. Bard (acquired by Becton Dickinson and Company in 2017).

As the manufacturer of record, BAS initiated the market and clinical research that led to its work with Flexan (then called Medron).



Former BAS executive Kelly Powers, now an adjunct assistant professor and entrepreneur in residence in the department of surgery at the University of Utah College of Medicine.

"When I was the head of R&D, my emphasis was on capturing and maintaining the initiative in the marketplace," says Kelly Powers, who was BAS vice president and senior vice president for

research and development from 1993 through 2013, before taking on the role of corporate vice president for science and technology at C. R. Bard.

“When companies acquire externally developed products, they typically have little uncertainty about market demand and expected revenues,” notes Powers. “However, products developed by others often arrive with gaps in user experience, errors in design control, or design and manufacturing problems that need to be addressed.

Figure 1. A novel catheter designed by BAS and Medron (Flexan), taking advantage of better bifurcation techniques for multilumen access.

“By contrast, the development of new product introductions (NPIs)—products that are new to the world—involve more unknowns and risks, arising in areas such as design characteristics, clinical use, market demand, design tradeoffs, potential failure modes, and the application of unproven solutions,” says Powers. “But if done well, using the right processes, organically developed products can cost much less in development, solve previously unsolved problems in novel ways, and deliver products that precisely meet the needs of customers.

“As companies become larger and more successful, however, there is a natural deterioration that affects most companies’ ability to innovate,” says Powers. “They become bureaucratic, more risk averse, and less creative, resulting in changed alignments of incentives that inhibit new product development. At Bard, we found ways to preserve the entrepreneurial spirit, but it required constant vigilance to preserve the team culture and its alignments.”

To move products toward commercialization efficiently, says Powers, it is important for manufacturers to partner with medtech CMOs that provide full-service support for product research and development (R&D), verification and validation testing, process engineering, supply chain management, manufacturing, distribution, and many other tasks. Engaging a full-service CMO as a product development partner can reduce a manufacturer’s time to market, while ensuring compliance with applicable regulatory requirements and best practices.

“Acquisitions can keep a medtech company’s market initiative going, but in our work with Medron (Flexan), we preferred to be working on new product introductions because that was where we could grow the business and add the most value,” says Powers.

“Innovation was critical for our project to develop PICC lines that could be used in novel vascular access applications,” King recalls. “This was true for the catheter materials, features, accessories, and equipment needed for clinical catheter placement” (Table 1).

A PICC OPPORTUNITY

In a sector as competitive as the medical device industry, even large companies with specialized field expertise and established market dominance can rarely afford to rest on the strength of their current product portfolio. Patient diagnostics and input from healthcare professionals often reveal unmet clinical needs that are crying to be addressed, and technological advances frequently lead to ideas for new products that can outcompete and displace existing devices (Figure 1).

Taking on the work of innovating in a competitive market involves more than just waiting for the light bulb to go on, says King.

Category	Silicone	TPE	PVC
Healthcare classification	FDA and USP Class VI, implantable	FDA and USP Class VI	FDA, USP Class VI, and NSF
Biocompatibility	Excellent	Good	Good
Toxicity	Negligible	Low	Low
Flexibility	Excellent	Fair	Fair
Feel	Excellent	Good	Fair
Color	Excellent	Good	Fair
Type	Thermoset elastomer	Thermoplastic, recyclable	Thermoplastic, flexible with plasticizers, recyclable
Sterilization	Yes	Yes	Yes
Resistance to oils	Good	Poor	Poor
Resistance to acids	Good	Excellent	Good
Resistance to bases	Good	Excellent	Excellent
Temperature range (°F)	–58 to 446	–50 to 210	–30 to 200

Table 1. Flexan is experienced in materials selection for vascular access and surgical specialty products, and specializes in silicone rubber and thermoplastic extrusion for a wide variety of medical devices, including catheters, wound drains, and irrigation tube sets. Here, a comparison of silicone, thermoplastic elastomers (TPE), and polyvinyl chloride (PVC), showing the superiority of silicone across a wide range of characteristics.

"When undertaking product innovation, challenges include finding the formula for identifying previously unrecognized clinical needs and ensuring that the envisioned product will meet those clinical needs."

"Of course, we served clinicians and patients, so we were very focused on doing things that were meaningful to them," says Powers. "This was only possible with constant effort to gain and maintain an intimate clinical connection and customer insight.

"Our product development teams included not only R&D engineers and marketing managers but also quality engineering and regulatory affairs colleagues," Powers adds. "This was not only more fun and engaging for members of the team but bringing in different perspectives results in better products. And as a group, we all spent time reading the relevant literature, observing cases, conducting interviews and surveys, and analyzing market data—all done in a systematic and reproducible way."

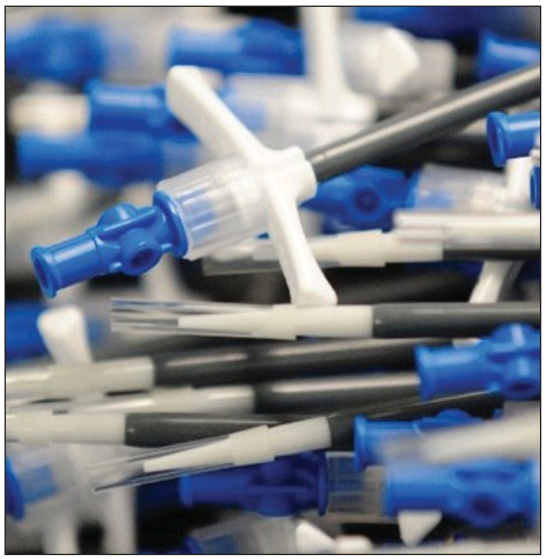


Figure 2. Flexan Split Sheath Introducers feature a smooth tip transition that facilitate placement by the physician.

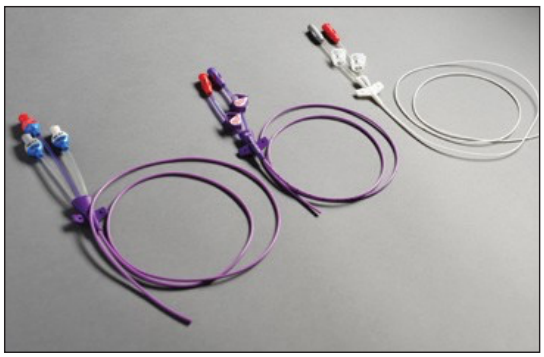


Figure 3. The development cycle, staying ahead of the curve with next-generation products.

Finding a Fit

Device manufacturers can benefit from the specialized manufacturing capabilities of outsourcing firms with experience in a wide range of medical technologies. But when a company is seeking to develop new products for a competitive sector, selecting a partner with all the right tools can be a critical first step.

In its work developing surgical catheters and vascular access products for BAS, Medron (Flexan) brought to bear extensive experience in molding and extruding components for a wide array of cutting-edge devices including implantable cardiac rhythm devices, implantable neurostimulation devices, and orthopedic implants. The firm's experience in producing silicone and thermoplastic components for such devices provided the essential capabilities needed to take on the development and manufacturing of BAS products. Key catheter manufacturing processes offered by Medron (Flexan) include:

- Extrusion
- Bump extrusion
- Multilayer extrusion
- Multilumen extrusion
- Compression molding
- Insert overmolding
- Liquid injection molding
- Micromolding
- Transfer molding
- Bonding
- Braiding
- Hole drilling
- Laser marking
- Inkpad printing
- Low-friction radiofrequency tipping
- Tip forming
- Component assembly
- Finished device assembly
- Packaging
- Sterilization

Medron (Flexan) engineers work with clients to determine the optimal molding process, to design appropriate tooling and processing equipment, and to produce components and finished devices that meet all quality and reliability standards. The company offers manufacturing in Class 7 and 8 cleanroom facilities as well as 100% inspection of all components prior to shipment.

"In just that way, we identified a number of important unmet needs and developed whole families of very successful products and insertion tools," Powers adds. In the case of BAS's successful PowerPICC product (Figure 2), he says, "once we understood the user needs and product requirements, we were able to leverage our relationship with Medron (Flexan) and especially the company's skill in developing a product designed for manufacturing, to bring resources to bear and develop the product quickly."

"Understanding the problem was the critical step but having a relationship with Medron (Flexan) enabled us to immediately develop a product that would solve the problem," says Powers. "Because the companies had already worked together frequently—sharing such things as design controls, data collection practices, and process validation requirements—it was a straightforward step to seamlessly integrate our internal processes with theirs.

"For the PowerPICC product line, the insight of user needs addressed by new product performance was the key innovation; in most instances, engineering was not the greatest barrier. One exception was an issue of moldability while providing a fluidic pathway. In fact, it was Medron's Eric King who figured out how to prevent such issues by developing a high-pressure catheter connector—a device for which he still holds the patent," Powers notes.

A MODEL FOR SUCCESS

"Involving Eric and his team from the outset helped us to speed the development of this new product while simultaneously designing the processes that would be needed to manufacture it," says Powers. "The upshot was that we were able to launch the product a little more than a year after the clinical need was first identified, capturing a first-mover advantage in the marketplace that the product has never relinquished."

The long-term success of the partnership between BAS and Medron (Flexan) offers a model for other companies seeking to innovate in the medtech sector, says King. "Based on the success of our PICC projects and others like them, I think that all device companies can benefit from having strong relationships with contract design and development firms under a spirit of true partnership."

"Medron (Flexan) was an important part of our agility equation, enabling BAS to take actions quickly and sure-footedly, and then to move forward to the next opportunity," agrees Powers. "Together, we worked very hard to

develop and launch a new product, and six months later we would be talking about developing the next-generation product that would replace it" (Figure 3).

In its work with BAS, Medron (Flexan) demonstrated that it could provide the essential services that made it a good fit for vascular access projects (see sidebar above). "Flexan offered experience with a wide range of materials and catheter manufacturing processes including thermoplastic component molding, insert overmolding, inkpad printing, low-friction radiofrequency tipping, bonding, and assembly, as well as tooling and processing equipment design," says King.

"Bringing this expertise to bear on BAS projects resulted in several new and innovative processing and tooling combinations for maximizing manufacturing efficiency."

Next Up

Part 2 of this paper looks at how medtech manufacturers and contract manufacturing organizations can apply a product lifecycle model to support ongoing innovation. Visit Part 2 at *https://www.medicaldesignbriefs.com/ei21/flexan-pt2.*