# Lifecycle Support for Medical Devices

## Part 2: *Team integration enables manufacturers and suppliers to use each project as a springboard to the next, keeping the R&D pipeline full—and profitable.*

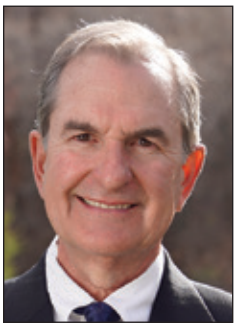
Beginning in the 1990s, several market-leading vascular access product lines were developed and commercialized by Bard Access Systems (BAS), a division of longtime device manufacturer C.R. Bard (acquired by Becton Dickinson and Company in 2017). The company's approach to product innovation resulted in the creation of many successful generations of surgical catheters and specialized products for vascular access, generating more than $10 billion in end-customer sales.

### Square One

*Part 1 of this paper examines the role of specialized contract manufacturing organizations in supporting innovative medical technology companies. Read Part 1 at https://www.medicaldesignbriefs.com/ei21/flexan-pt1.*

To achieve such long-lived market success, BAS partnered with Flexan (then called Medron), a contract manufacturing organization (CMO) specializing in product development and cleanroom manufacturing of silicone and thermoplastic components for medical technologies.

This two-part paper looks at how the outsourcing partnership between BAS and Medron (Flexan) was able to achieve and maintain its market dominance for more than a decade. Part 1 examined the role of specialized contract manufacturing organizations in supporting innovative medical technology companies. Here, Part 2 looks at how medtech manufacturers and contract manufacturing organizations can apply a product lifecycle model to support ongoing innovation.



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.

### Building a Relationship

"The value that the BAS team brought to the table centered on a clear understanding of what was needed by the customer," 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. "That understanding opened the door to all sorts of innovative possibilities that might address problems and provide solutions to unmet needs.

"For any given project, we would typically share our customer insights with our partners at Medron (Flexan) and then we'd work together to devise solutions. We established particular design specifications, performance characteristics, and cost targets as starting points for the development of a new product.

"We treated Medron (Flexan) as an extension of our own group," says Powers. "We couldn't hire experts in every single process, so for the processes Medron (Flexan) had—such as molding and tipping—we worked with them just as though they were colleagues from our own company."

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

"The working relationship between BAS and Medron (Flexan) was not typical in the sense that it was a true partnership, with mutual support and transparency on both sides," says Eric King, vice president for product development at the Salt Lake City facility of Flexan. "Medron (Flexan) was not viewed as one of many suppliers of components or materials but as a stakeholder in the project. BAS was not viewed as one of many customers but as a key to future growth. When a design or manufacturing issue arose, both teams worked together to arrive at a solution. In turn, this required the teams to integrate with one another's communications and reporting structures."

Interactions between BAS and Medron (Flexan) were usually handled in accord with what each project required at any given time, says Powers. "My personal attention was often only necessary at the outset. Day-to-day management of the programs was done directly by the R&D program managers and Medron (Flexan) leadership.

"The interaction of BAS directors and project managers with Medron (Flexan) was frequent and sometimes daily. In some cases,

| BAS | Medron (Flexan) |
|---|---|
| Identification of need | Prototyping |
| Design inputs, design requirements | Process development |
| Design and analysis | Design for manufacturing |
| Failure mode and effects analysis | Tool development |
| Design validation | Operator training and documentation |
| Cost targets | Raw materials sourcing and process efficiencies |
| Design verification and validation | Process validation |
| Regulatory processes | Manufacturing |
| Packaging and sterilization | Regulatory documentation |
| Launch and sales | Quality assurance |

Table 1. Full integration between a device manufacturer and an outsourcing partner requires careful delineation of responsibilities across teams from both companies.

we would have BAS people report to the Medron (Flexan) facility in the morning and remain there for an extended period—sometimes all day or all week. Because no supplier has every possible capability, we would sometimes supplement the Medron (Flexan) force with our own people, who would essentially make the Medron (Flexan) facility their base of operations for a time."

The product development partnership also benefited from frequent informal communications. On a day-to-day basis, routine meetings were most often attended by the R&D and quality engineering staff. But one of the benefits of having co-located team members is that teams don't have to hold so many meetings, says Powers. "When team members occupy offices or cubicles near one another, a lot of communication can be conducted quickly and informally," he explains.

"Nevertheless, at certain phases of the projects—and certainly for formal design reviews—it was necessary for our quality, regulatory, and R&D staff to meet with members of the Medron (Flexan) team and those meetings took place sometimes in our offices, and sometimes in theirs.

"The more we worked with Medron (Flexan), the better we all became at doing it," says Powers. "The more projects the companies' teams completed with one another, the more seamless it became to take on additional projects for the future, because people learned to know and like each other and to understand one another's processes" (Figure 1).

Collaboration generated the cumulative effect of technical understanding between the teams, says King (Table 1). "By understanding the technical requirements of the device, the Flexan team was able to support and enhance the design rather than just receiving the design. And by understanding the manufacturing challenges, the BAS team was able to incorporate design features that would facilitate manufacturing."

Working out the details of an integrated product development partnership required effort on both sides, says Powers. "Very early on—as soon as Medron (Flexan) became our go-to catheter development partner—we made a point of transferring Bard's design control system to them. This made our terminology consistent, made quality audits easier, and made our collective development processes more seamless."

Because of industry standards and federal regulations, the fundamentals of the quality systems at Medron (Flexan) and BAS were similar at the start, says King. "There were some aspects of the Medron (Flexan) quality system that were adjusted to better align with the BAS quality system—especially with regard to validation requirements. The adjustments helped to specify test methods, inspection equipment, and data analysis techniques, which all together facilitated the customer's review and approval processes for validation reports."

To assist Medron (Flexan) in fine-tuning its quality systems, BAS sent people over to train the company's employees, says Powers. "We sent environmental control people to help the company assess its use of filtration and to confirm its water and airborne particulate counts. We sent people from the quality department to make sure that the company had a training program equivalent to our own and to ensure that its documentation practices were consistent with ours.

"Our goal in taking these steps was to make it as seamless as possible to transfer operations and documentation between

Figure 1. At Flexan's vascular access center of excellence in Salt Lake City, an automated assembly line designed by the company improves manufacturing capacity for its customers.

| End-to-End Capabilities |
|---|
| Certified project management support |
| Design for manufacturability |
| Rapid prototyping |
| Process validation (installation, operational, and performance qualification) |
| Certified cleanroom manufacturing |
| Primary manufacturing operations (molding, extrusion) |
| Secondary manufacturing operations (bonding, hole drilling, laser marking) |
| Assembly |
| Packaging |
| Sterilization coordination |
| Logistics and distribution |
| Import/export management |
| Manufacturability and lifecycle sustainability |
| Lean and Six Sigma methodologies |

Table 2. An FDA-registered and ISO 134585-certified global CMO specializing in product development and cleanroom manufacturing of silicone and thermoplastic components for medical technologies, Flexan also offers a complete range of end-to-end manufacturing capabilities, including finished device assembly, logistics, and distribution.

the two companies but also to make certain that Medron (Flexan) would be able to pass its quality systems audits without any problems.

"All of this was a little painful in the beginning, because BAS tended to be extremely conservative, applying standards for quality and environmental controls that were much stricter than those used by most companies," says Powers. "But once Medron (Flexan) had these new systems in place, our supplier quality audits raised zero issues. Once a company has put in place all the necessary investments in systems and training, it gets easier and easier to just keep meeting those expectations. Ultimately, Medron (Flexan) used these conservative controls and buttoned-up processes as a competitive differentiator with other customers."

## Matching Interests and Capabilities

"Developing products in a large company always requires overcoming internal frictions and misaligned incentives that slow everything down and make projects more difficult and expensive," says Powers.

"In many cases, it is easier and faster to work with a CMO than to struggle against those frictions. Doing so can also provide greater independence and control of the operations being outsourced. Throughout the period we worked with Medron (Flexan), my decisions about outsourcing were always based on what arrangements provided the fastest, lowest risk, and least expensive way to get something done," says Powers.

"There were certain internal capabilities that BAS considered critical to keep proprietary, including certain materials, simulated use testing, biocompatibility, and packaging engineering," says Powers. "On the other hand, we had many products that involved elastomeric extrusions of either silicone or polyurethane that had to be insert overmolded followed by other operations, such as inkpad printing or tipping, and some final assembly. BAS didn't have those kinds of capabilities in-house, so it was natural that we decided to work with Medron (Flexan), which did have those capabilities. For me, that was a fast and easy decision to make, because Medron (Flexan) had more agility than BAS when it came to extrusion and molding."

Working together, the product development partnership enabled BAS to maintain its market leadership by accelerating the company's design and development cycles, producing novel tooling to maximize manufacturing capacity, and developing validated manufacturing processes to support regulatory submissions (Figure 2).

## Supporting the Product Lifecycle

Identifying opportunities to address unmet clinical needs while also keeping an eye on the competition requires manufacturers and their outsourcing partners to adopt a structured approach that supports the development of new technologies. The new product development model that BAS and Medron (Flexan) pursued successfully for more than a decade took this strategy to the next level by incorporating a lifecycle approach.

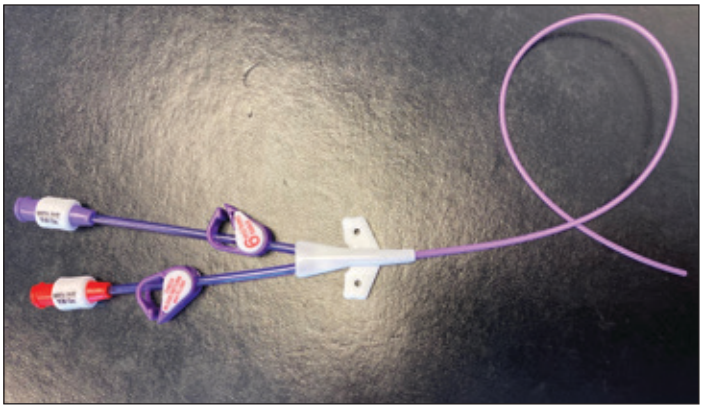


Figure 2. Provena Midline catheters from BAS occupy a smaller portion of the target vessel than the company's larger PowerMidline catheters of the same lumen configuration.

Figure 3. A robust product development process starts with having members of the development team involved in visiting local area hospitals and speaking with clinicians. Here, Eric King, Flexan vice president for product development (center), leads a team from BAS and Medron (Flexan) on a site visit to confer with clinicians and identify clinical needs.

"Medron (Flexan) was our development partner for a whole class of products," says Powers. "As we replaced products with next generations, they were the obvious choice to help us develop successor products. It was a synergistic relationship, because Medron (Flexan) was willing to invest in adding the talent and capabilities that we needed and they trusted that we would follow through on our commitments to make use of those capabilities.

"From a manufacturing standpoint, for instance, we didn't just develop products, run up the volume, and then take over production in our own facilities. In some cases, production might be moved out of our facilities to take advantage of capabilities at Medron (Flexan) or we might retain production in-house in order to take advantage of investments we made to support the growth of the product line.

"In most cases," says Powers, "Medron (Flexan) got to hold on to manufacturing for a period of time and for many products, Medron (Flexan) retained manufacturing indefinitely."

Full product lifecycle support requires extraordinary capabilities from both manufacturers and their outsourcing partners (Table 2). "Once the product is launched, Flexan support activities fall in line with and are tracked according to four types of operational metrics in order of importance: safety, quality, delivery, and cost," says King. "Lean manufacturing principles (eliminating waste, optimizing processes, and cutting costs) are important but can sometimes be difficult to implement in high-mix, low-volume specialty device projects."

"I can't emphasize enough the importance of having an independent supplier relationship," Powers adds. "When a company brings a development project in-house, all of its incentives change. That transfer alone can muddy a lot of waters, because corporate requirements can take priority over development requirements, making it less clear whether the new product is meeting its design expectations or is being produced as efficiently as possible.

"But when the development team is working independently with a supplier, there is a very clear relationship that avoids internal bureaucratic complexities and misalignments. Since the development team controls the budget, the incentives of both sides are clear and simple.

"Our goal was always to develop new products that would enable us to capture and maintain the initiative in the marketplace and essentially to stay in front of the competition," says Powers. "Having Medron (Flexan) as an outsourcing partner enabled us to do that across an entire class of products.

"After we established that relationship in the late1990s, it just got better and better," says Powers. "By the mid 2000s, the partnership was producing as many as five new products every year and that level of production continued for more than a decade (Figure 3). In the end, the products we developed with Medron (Flexan) resulted in well over $10 billion in end-customer sales."

## Lessons Learned

"BAS was a large company with a long history in the medtech marketplace. During my time with the company, we built on this foundation by developing a very robust recipe for innovation," says Powers. "That recipe was based on our close connections with customers and our understanding of their needs but it also relied on the supplier relationships we had with companies such as Medron (Flexan).

"Working with Medron (Flexan) enabled us to recapture and maintain our agility for new product development and to overcome the inertia that often plagues large companies. There was no way to do that by relying exclusively on our internal resources, so this was a very important relationship. Other large companies can likely benefit similarly from working with outside suppliers."

"Establishing a true development and manufacturing partnership was key to the success of the BAS PICC product line" agrees King. "The partnership provided a path for mutual success and resulted in constant growth for both companies."

In the end, says Powers, the payoffs of building a strong partnership between a device manufacturer and a contract manufacturing organization are well worth the effort. "Success breeds more success and that creates a virtuous cycle. Employees in both companies love to win as a team," he says.