



Subscribe FREE!
Magazine
eNewsletter



- Magazine
- News
- Opinions
- Top 30
- Research
- Events
- Outsourcing Directory
- Knowledge Center
- Resources
- Microsites

Home / May 2015 / Features

- Email
- Print
- RSS Feed

Full-Service Outsourcing: Change is Constant

Medical device companies pursuing a full-service outsourcing offering must (or learn how to) be nimble to deal with constantly changing customer demands, technological challenges and swirling market forces.

By Christopher Delporte , Editorial Director

Published May 6, 2015

Related Searches: [product outsourcing](#) • [Materials](#) • [Design Services](#) • [Molding](#) •

- Email
- Share
- Tweet
- Share
- Like 4



Progress is impossible without change, and those who cannot change their minds cannot change anything.

— George Bernard Shaw

Each year, Medical Product Outsourcing takes the pulse of the full-service outsourcing market, soliciting feedback from a variety of contract manufacturers who fall along different points of the medical device manufacturing value chain. This year, as in years past, there was plenty to discuss. Also, as has been evident in prior full-service outsourcing Q&As, there are many issues of overlap among industry experts in addition to a range of unique perspectives, which keeps this topic so interesting.

As far as the outsourcing sector as a whole, a recent study would seem to indicate a rosy picture—at least in the very near term.

According to San Francisco, Calif.-based Grand View Research, increased pricing pressure on medical device OEMs means good things for medtech outsourcing. And, if more firms are going public, that also bodes well for contract manufacturers and service suppliers because it means more companies are looking to produce without large investments in brick-and-mortar footprints.

Analysts with Grand View predict that spending cutbacks by major healthcare establishments are the primary reasons for the rise in pricing pressure. In addition, with a more complicated reimbursement framework, and with payers and patients focusing on the value of money, medical device manufacturers are expected to adopt outsourcing as a viable sustainability tool, analysts noted.

"Implementation of stringent government initiatives such as the imposition of an additional excise duty of 2.3 percent on medical devices is also expected to drive market growth by encouraging manufacturers to curb costs through outsourcing," analysts wrote. "The global medical device outsourcing market was valued at \$23.6 billion [in 2013] and is expected to grow at a CAGR (compound annual growth rate) of 11.5 percent during the forecast period." The forecast period is until the year 2020.

The changing dynamics of the healthcare industry have heightened the importance of practitioners and patients in buying decisions. The oligopolistic nature of most medical device markets, coupled with increasing buyer awareness levels has forced manufacturers to adhere to business strategies involving constant research and development investments and new product innovations, according to the report. Such endeavors significantly increase expenditures and medical device OEMs are, therefore, rapidly adhering to outsourcing as an effective cost-curbing tool, Grand View analysts wrote. Statistics suggest that medical device outsourcing helps OEMs reduce the cost of production by roughly 15 percent.

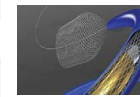
Regulatory consulting, product design and development, testing, implementation, as well as upgrade-and-

Features



[Device Insecurity](#)

[Design Complications](#)



[Extrusion Solutions](#)



[Doubling Up](#)

[Speeding Toward a Cure: Regulation in the 21st Century](#)

Top 30 Medical Device Companies

[Johnson & Johnson](#)

[Baxter International](#)

[Olympus](#)

[Essilor](#)

[The Medical Device Top 30](#)



[View Current Issue »](#)

FREE MPO The SOURCE eNewsletter

Sign up now to receive the weekly newsletter, and more!

Enter your email address:

[Sign Up Now!](#)

Industry events

[May 27 - 29, 2015](#)

16th EFORT Congress
Prague, Czech Republic

[May 28 - 29, 2015](#)

iHealth 2015 Conference

maintenance services are the major service segments analyzed in the study. Product design and development was the largest segment in 2013 and is the most capital-intensive manufacturing phase and, therefore, claims the highest rates of medical device outsourcing. Product implementation emerged as the fastest-growing services segment and is expected to grow at a CAGR of more than 13 percent through 2020. Growing adoption of processes overlapping as a profitable option and the simultaneous execution of product design and implementation processes are some factors accounting for its rapid growth, according to analysts.

Class II medical devices (moderate risk) were the leading application segment of the outsourcing market in 2013. Class II devices encompass relatively simpler technologies (as compared to Class III medical devices) and therefore, are the most outsourced ones. Class III medical devices were the second most revenue-generating segment in 2013. A growing number of initiatives aimed at minimizing product recall instances and the need for external expertise is expected to positively reinforce the growth of the Class III medical device outsourcing market. North America was the largest medtech outsourcing market in 2013 (no shock there), while Asia-Pacific is the fastest-growing region of the medical device outsourcing sector (also no surprise), according to the report. Yet another recent market review examined the effect of all of the company consolidation on the contract manufacturing marketplace of late.

“The highly fragmented medical contract manufacturing/outsourcing market is undergoing significant transformation, driven by the consolidation among OEM clients as well as sound macroeconomic conditions,” according to a research report released in February by P&M Corporate Finance LLC (PMCF). “Medical OEMs are increasingly aware of CMOs’ (contract manufacturing organizations) capabilities as true providers of lower-cost, time-sensitive and high-quality solutions. This versatility enables OEMs to improve their operational performance, and meet shorter product life cycles while maintaining focus on their core business. As a result, the outsourcing of manufacturing functions has increased, a trend that is expected to continue as OEMs seek one-stop solutions to accommodate their growing needs in terms of increased volume, product differentiation and compliance with a more stringent regulatory environment.”

According to PMCF analysts, the move toward outsourcing “likely will prompt further consolidation, particularly in the therapeutic, diagnostics and cardiovascular segments. Large CMOs are expected to lead this industry consolidation by acquiring smaller specialized companies with complementary services from engineering and precision machining to quality assurance. As their multi-faceted cost-saving capabilities broaden, large CMOs are better positioned to become the preferred supplier among OEMs and ultimately benefit from additional partnerships.”

To get some on-the-ground perspective, MPO turned to a group of manufacturers for their thoughts on the state of full-service outsourcing. To try and sum up one central theme—as if there were just one—companies need to be nimble and constantly prepared to change and adapt. Looks like they’ve been reading their Shaw.

Contributing to this year’s article are:

Tom Black, vice president, OEM and international sales and marketing for B. Braun Medical Inc. B. Braun’s Bethlehem, Pa.-based OEM division provides a broad range of standard products and contract manufacturing services for medical devices and pharmaceuticals.

Valerie Chittester, marketing manager for Cabot, Pa.-based Penn United Technologies Inc., which provides manufacturing solutions for companies in a variety of industries, including medical.

Shem Fischer, manager, contract manufacturing-medical, for OraTech LLC, a Riverton, Utah-based contract manufacturing and packaging firm.

Kim Goodwin, director of quality for Charlton, Mass.-based MTD Micro Molding, which provides micro molding of advanced medical products.

Gary Hulecki, operations manager for MTD Micro Molding.

Calvin Kuo, general manager of Peter’s Technology (Suzhou) Co., Ltd., a Taiwan-headquartered maker of medical components, cable and wire harness assemblies, and medical device subassemblies and final assemblies.

Lindsay Mann, project manager for MTD Micro Molding.

Brian Matachun, director of sales for MTD Micro Molding.

Mark McCourtney, director of sales and marketing for JunoPacific, a medical device design, development and manufacturing firm offering full-product life-cycle services from prototype to high-volume manufacturing. The company has facilities in Minnesota and California.

Jim Schoepfle, new business development manager for Youngsville, N.C.-based Robling Medical Inc., a provider of manufacturing, regulatory and engineering services to medical device firms.

1. MPO: There are all sorts of outsourcing/contract manufacturing relationships in medtech. How do you define full-service outsourcing?

Shem Fischer: As a full-service supplier, you are entrusted by your client to provide a unique service. Full-service outsourcing takes the guesswork out of the project for the customer. The supplier will see the product through completion using their own experience and resources. By providing them with only one primary contact to work with rather than multiple, the project becomes not only more cost efficient, but time efficient. Ideally, the partnership will evolve over time as markets change and technology progresses. It’s important for both parties to continue to be innovative and knowledgeable about the industries they serve.

Mark McCourtney: Full-service means providing a complete turnkey solution for a customer’s device. That may include all or portions of part and product design, models, prototypes, verification and validation, short-run or “bridge” tooling and production, high-volume tooling and production.

Boston, Mass.

June 5 - 8, 2015

AAMI 2015 Conference & Expo
Denver, Colo.

June 7 - 11, 2015

10th Biennial ISAKOS Congress
Lyon, France.

June 16, 2015

IMPLANTS 2015 Conference
Paris, France

[More Industry Events »](#)

Most Popular

- [Device Insecurity](#)
- [Extrusion Solutions](#)
- [Doubling Up](#)
- [Speeding Toward a Cure: Regulation in the 21st Century](#)
- [Making the Transition from Healthcare Products to Healthcare Solutions](#)

Follow Medical Product Outsourcing



Lindsay Mann: We define full-service outsourcing as a partnership. Looking back at our most successful projects, they are all marked by excellent communication, trust and teamwork from the get-go, and a comprehensive understanding of both parties' expectations.

Tom Black: "Full service" requires the supplier to be able to provide design and development support, testing and human factors support, along with a widget in a variety of styles, within a variety of specifications, from plastic pellets to sterile-packaged finished goods, along with the support of well structured documentation supporting engineering design, quality systems, and regulatory. Full service provides all of that with a team of people who will guide the customer through the process, provide as much value as needed, and allow the OEM to be able to focus on its strengths.

Brian Matachun: Because MTD is a molder, we would define being a full-service molder by providing our clients assistance in the six main areas, which are: design for manufacturability; design for molding; material selection; mold design and manufacturing; pilot production; statistically capable metrology; and, ultimately, validation and full production with custom packaging. Being a full-service provider starts by knowing exactly what the core capabilities of your company are and excelling at them. Knowing what you are not good at is just as important as knowing what you are good at.

Calvin Kuo: Full-service outsourcing is providing customers with a one-stop solution, customers provide their needs and we provide the solution.

Valerie Chittester: Full-service means supplying our customers with solutions that simplify their supply chain. We work with our customers to offer vertically integrated manufacturing solutions from the inception of an idea through manufacture and assembly of their components.

Jim Schoeplein: When Robling uses the term "full-service" contract manufacturer, we mean that we are prepared and experienced in providing our customers with any and all of the following services related to their medical device—design and development support, U.S. and foreign government regulatory clearances, manufacturing process development and validation, full scale manufacturing, packaging, sterilization management, distribution and postmarket surveillance.

2. MPO: How has the outsourcing of medical devices changed in the last five years? Why do you think it has changed?

Fischer: The changes seen in the past five years are a continuation of what started over 10 years ago. Large life-science companies continue outsourcing their manufacturing needs to independent contractors. As a result, many medical device contract manufacturers are stepping up their game to meet this growing need. China's middle-income earners have created greater demand for medical devices made in the United States with FDA (U.S. Food and Drug Administration) approvals. The FDA is changing their relationship stance with U.S.-based innovators. As such, the FDA has pledged to act as a partner with new medical startup firms in an effort to keep this revenue in the United States.

Mann: Through experience, our customers are seeing the value of "doing it right the first time" and spending the time sourcing vendors that will meet their needs, with the priority being on quality—not only cost. Experience shows customers that the vendor with the lowest bid isn't always the best choice for their critical component projects.

McCourtney: OEMs have become more willing to outsource design and manufacturing needs to contract manufacturers, realizing that their resources are better employed in R&D and conceptualizing new products, sales and distribution. Manufacturing requires investment in facilities, equipment and labor that can tie up capital unnecessarily. We are also seeing a lot more pressure to reduce costs year on year—similar to what the automotive industry did 10 years ago. As a contract manufacturer, we need the ability to add value to what we provide as a means to hold margins. Automation has also become increasingly important to minimize labor content/cost and compete on a more global basis.

Gary Hulecki: In past years, it was customary to have the purchasing people drive the decision-making process. Now, purchasing normally has an engineer present to guide them through the process. This seems to be commonplace now, where it wasn't before. When engineering groups are involved in the decision making process, it results in a smoother process.

Kuo: We feel there is increased opportunity in the outsourcing of medical devices. Many companies see outsourcing as a strategic way to save cost and time.

Black: The new requirements and expectations from the FDA have changed the way outsourcing is managed. OEMs now expect and demand more information, better design and quality systems in place. They expect their partners to have experience in a variety of disciplines that will allow them to add as much value to their products as they can and at the same time be able to sleep at night—while being able to acquire an outsourced product on time and at a competitive price.

Chittester: Device companies are simplifying their supply chain and utilizing fewer suppliers in their manufacturing processes. We are constantly looking for ways to offer our customers the best quality, services, development and advice from the inception of an idea through manufacture of their product. We are a contract manufacturer focused on product development, R&D and innovation. The manufacturing industry has changed dramatically since the economic crisis of 2008. We had to take a deep look at our strengths and weaknesses as a company,

then learn and grow from there. We knew to stay strong in the markets we are in that we would have to differentiate ourselves from the competition.

3. MPO: What kinds of services are your customers asking for most? Why are these services so important? Have you had to add services recently that you previously didn't offer?

McCourtney: We have been aggressively adding capabilities to the front end of the product development cycle. Speed to market is critical to our customers, and our organization has added quick-turn tooling, prototyping—additive manufacturing—and short-run molding/assembly capabilities. In many cases, our medical device customers stay with short-run manufacturing for the life of lower-volume products, as it is more cost effective in terms of up-front tooling expenditures. We feel the more services and flexibility we can offer, the easier it is to differentiate ourselves and the more value we provide our customers.

Black: Customers are asking for more and more regulatory support, along with design and quality systems/documentation, which provides them with the confidence they are looking for to commercialize a product. The last thing an OEM wants to have to deal with is the lack of support documentation if and when there is either an issue with their product in the field, or when a regulatory agency comes to inspect their business practices. They need to rely on their outsourcing partners and trust that an inexpensive device will add the value they need without compromising the supply chain practices required to distribute products in the healthcare industry.

Fischer: First and foremost, it's important to identify the kind of services your company will provide. Then, become the best in your field of work. In our case, our primary focus is in oral healthcare. Medical device 1-2 compounding, molding, assembly, and packaging are emerging as a second core competency. This is achieved via internal and external networking efforts. Medical contract manufacturers are the key to executing the critical development path needed to bring a product to market. It is necessary to add services to meet customers' needs. As we move forward in a changing world, contract manufacturers will be required to make sound business decisions that meet their customers' needs while keeping their business healthy.

Schoeplein: Recently, we have had several customers looking for ISO Class 7 clean rooms. We have upgraded two of our four clean rooms from Class 8 to Class 7 in response to the need. It is imperative that we provide our customers with whatever the services they require in order to meet the needs of the markets they serve.

Kuo: Though we have not yet added it, our customers have been asking about design services that we previously didn't offer. We're looking into it now as an added service.

Chittester: The services we offer our customers are customized to their component. Our customers' specialized components give them a competitive advantage in their industry. This is the reason we maintain close, confidential relationships with all of them. We are constantly looking for opportunities to simplify supply chain logistics for our customers and increase their ROI (return on investment).

Matachun: Customers are asking us to stretch the limits of insert molding small components to reduce assembly steps and at the same time mitigate risk of utilizing adhesives. We are happy to help and have had great success with these types of applications. Ultra-precision thin-wall-molded devices versus heat formed components that may present high degrees of variation in tolerances inherent to the forming process.

Hulecki: Rapid prototyping is a service we do offer for special projects with specific geometries and materials. This allows us to produce homogeneous parts in the material the customer wants. We can help our customers prove their concept by enabling them to perform functional testing on representative parts. The only way to find out if your part is a candidate for rapid prototyping is to talk to us and show us your design.

4. MPO: How do you manage cost pressures—on your end as well as the margin demands from customers?

Schoeplein: By providing our customers with design-for-manufacturability expertise, we are able to design lower-cost manufacturing alternatives into the product. As the production volumes scale, we continuously design, qualify and implement semi-automated assembly fixtures and production lines. In addition, our combined contract manufacturing volumes, allow us to offer cost-effective sterilization options.

Matachun: When it comes to our value proposition to our clients, we strongly believe in our process, which is: First, solve the problem; make one good part; scale it up to make several high-quality parts; and then work with our clients to remove non-value added cost.

Fischer: Communication is key. It is important to discuss the process of price changes up front to avoid any conflict in the future. There is no way around it; costs increase and manufacturers need to remain profitable but competitive. We make an effort to be as transparent as possible with our customers when it comes to raw-material costs. Our customers really appreciate and value this kind of relationship. This also allows the customer to recommend vendors or suppliers to consider what would be a better fit to keep the price point they desire.

Kuo: We are constantly working with our customers to improve production methods and processes for better efficiency. We are also trying to improve our supply chain by developing cost- and quality-competitive suppliers.

Chittester: Our focus is creating high-quality, consistent products. We may not always be the best price, but the quality of our products is never sacrificed do to cost issues. When possible, we work with our customers at the

idea/design phase of the product life cycle. We can then evaluate the best processes to use in the manufacture of their components and create the best cost savings at this point.

5. MPO: Many medical device firms still won't discuss how they outsource or with whom. Are there medical device sectors or types of companies that are better, more open or more accepting of outsourcing than others? How has that evolved?

Fischer: Continued global networking is reshaping the way we conduct business as a whole. Transparency is key to building the trust needed to forge a long-term, positive business relationships. Companies that recognize and implement these practices succeed. This concept will evolve by cementing trusted relationships—one at a time.

McCourtney: For the most part, we see companies of all sizes and market segments becoming more interested in outsourcing for the reasons we've discussed here. There are a few companies, a large one in particular, that are going the other way and are becoming more vertically integrated. This is surprising given the recent trend. However, they might be doing this as a result of moving assembly operations outside the U.S., thereby freeing up facilities and people for other types of manufacturing. Smaller companies and startups are aggressively outsourcing as a means of conserving cash. Unless a company has a process that gives them a competitive advantage in their market, it makes sense to push the capital burden to a company with the required resources and quality-management system in place.

Hulecki: We find that medical device companies are more accepting of outsourcing when they believe we can help push their product to the market. When it is not feasible to get a product validated at their facility in a short amount of time, companies hire us to get them to the next step quicker than they would be able to.

Schoeplein: It is our experience that medical device companies are very interested in engaging us as their outsourcing option because of our experience and comprehensive understanding of the entire product life cycle and our ability to provide robust, creative, timely solutions that comply with specifications and regulations.

6. MPO: How do you stay technologically innovative? Where do you attract the best talent?

Hulecki: Ten percent of our annual sales go to internal R&D projects. If you stay stagnant in this industry, someone will blow right by you. As far as retaining the best talent, we believe in the benefits of promoting from within. The key is to have the passion, drive and self-motivation to succeed. Floor sweeper to process technician, no experience to lead metrology specialist, machine cleaner to head of production. These are real stories about real people that apply to a good portion of our workforce.

McCourtney: A key factor in staying innovative is simply listening to our customers' needs. They are looking for ways to innovate and lead in their markets so we strive to give them what they need in terms of capabilities to manufacture what others cannot. This may mean taking on projects on a "time and material" basis to see what we can do to achieve our customers' goals. Sometimes, we are even able to help those companies achieve patentable novelty.

Schoeplein: Our team participates in biotechnology exchanges and opportunities readily available in the Research Triangle Park [area of North Carolina]. We are located in an area rich with talent from local universities and medical device, medical technology and pharma[ceutical] firms from where we have attracted our team.

Fischer: Thinking outside of the box and exploring new technologies from around the globe is the best way to stay technologically innovative. Innovative companies tend to attract the best talent. Cocooning yourself against all outside interaction yields the opposite effect. Low innovation and talent seem to gravitate to companies that share these attributes.

Chittester: We keep in touch with our customers and their needs; we research our industry and track our competition. Our skilled engineers, machinists, tool makers and quality personnel are constantly looking for ways to keep us ahead.

7. MPO: Are there any market trends that cause you worry? Optimism?

Schoeplein: We view change as a constant and an opportunity to lead the way in navigating new paths and providing prompt solutions. We are very optimistic about the trends we are seeing in the market.

McCourtney: The trend to require annual cost-downs is worrisome. We strive to achieve highly manufacturable products/processes early in the development process through design-for-manufacturability studies. This allows us to produce highly repeatable products at least cost. This makes it challenging to further reduce cost every year. This trend most likely causes some contract manufacturers to increase the cost up front so they can give back in subsequent years. Of course, this only artificially drives the cost of devices up at introduction.

Mann: We are optimistic that the 3-D printing technology required to enable true rapid micro prototyping will emerge in the coming years. This will help our customers get their new products to market faster. MTD is learning that current available technology allows this as an option only for limited, simpler geometries. There is technology for achieving micro detail, however. This technology shows that ultra-precise 3-D printing can be done on a micro scale, so our expectation is it will eventually grow to a larger platform to allow us to use the technology for our mold inserts. The idea is to scale up the existing technology and add more options for materials to be useful for prototyping. This will make this technology even more useful to the world, specifically the medical device world.

8. MPO: What qualities—on both sides of the relationship—make for a solid outsourcing partnership?

Fischer: A solid partnership is truly dependent on trust and communication from both sides. Communication is so important in any business relationship. It is vital for the customer to express their questions or concerns as often as possible and equally important for the supplier to really listen and take action quickly and efficiently. I believe that as conflicts are resolved, the relationship becomes stronger over time.

Schoeplein: Open and prompt communication. We have formed long standing relationships with both customers and suppliers by openly and honestly communicating needs, goals and our plans for obtaining those objectives. This is all followed by continuous communication regarding execution of the plan.

Mann: It's important to have trust, flexibility, a problem-solving mentality, and be open to out-of-the-box thinking to meet/exceed goals.

McCourtney: Willingness to share information and expectations is important to ensure success. Also, given the time sensitive nature of most programs, frequent schedule updates and quick response to key questions is critical.

Hulecki: Managing expectations, internally and externally, is critical to creating a solid relationship.

9. MPO: Is the word “partnership” overused or do medical device firms truly view their outsourcing providers as partners? What has been your experience?

Black: A true partnership requires that both partners have the same objectives. While OEMs are asking for more and more transparency from their suppliers, they also need to be open and want to work together in the best interest of the project's requirements in order for it to be a success. Suppliers need to make sure they thoroughly understand what the OEM needs, and the OEM needs to be flexible enough to work within the partner's systems and processes if they truly expect the project to succeed. It is a business, so both sides need to make a competitive profit, while at the same time, the supplier needs to be able to provide product and process value to their OEM—process value in the way of an acceptable and thorough design system, a quality system that they feel comfortable with, and regulatory support and experience that assists the OEM with either their submission or commercialization.

Fischer: The word “partnership” really captures the relationship between medical device firms and suppliers. At OraTech, we make our customers' goals and expectations ours. By sticking to this frame of mind, the customer has the peace of mind that we have a plan of action that aligns with their specific needs. A partnership relies on trust. We gain that trust by meeting our customers' expectations and delivering quality products.

McCourtney: The word partnership is a bit overused and can imply many things. Obviously, it doesn't mean the supplier shares in the profits. More often, it implies the supplier shares more of the cost. Having said that, we have in fact “invested” certain resources in our customer's business and have been rewarded with a share in ownership.

Schoeplein: At Robling Medical, partnership is a way of life. We work together within our organization as partners to achieve the customer expectations and that partnership extends to our customers and our suppliers. We believe all parties involved in a partnership must be healthy and satisfied in order for the partnership to be a success.

Matachun: I don't think the word partnership is overused, but I do believe everybody's definition is different. A true partnership is definitely built over time and what strengthens that partnership is working with each other and successfully completing projects. This does not mean that every project has gone smoothly and there have not been any challenges but what it means is that challenges were faced but collectively overcome with the knowledge, experience, and understanding of both parties. I believe that a strong partnership exists when two parties fully understand each other's expectations and deliverables, which requires a very good understanding of each other's systems, whether they be engineering, quality or sourcing.

10. MPO: What role do emerging markets play in a full-service outsourcing model?

McCourtney: Several of our customers are trying to figure out a strategy for utilizing emerging markets as a source of supply for more generic and cost sensitive and/or commodity-type products. That can create many challenges for them in terms of logistical issues and intellectual property concerns. As a contract manufacturer, we have sources in Central America and Asia for tooling, molding and assembly. These resources are used typically for higher volume opportunities where there is a certain amount of labor required and no cost-effective means for automating the assembly process.

Fischer: Emerging markets help to provide cost savings and additional support. Developing and maintaining relationships offshore is beneficial when material costs increase. By using these alternatives, you are able to pass the savings on to the customer.

Kuo: Emerging markets provide competitive cost and capacity.

11. MPO: How do you maintain quality in a full-service outsourcing setting? How do you tie your quality systems with your clients' systems?

Kim Goodwin: We established our quality system based on the customary quality-system requirements of the medical device industry, with the ultimate goal of exceeding customer expectations, not just their requirements. We try to look beyond their requirements and anticipate the customer's next request. Each customer's specifications are unique to the customer and their products. As we begin to develop relationships with customers, we integrate the customer's specifications as our specifications. Our goal is to duplicate the customers expected internal performance with our external performance. As customer requirements may change over time, our goal is to adjust our systems to satisfy their evolving requirements.

McCourtney: We have a robust quality management system based upon ISO 13485 and are FDA-registered. We don't really tie to our customer quality systems as much as we all tend to conform to the same standards and processes/procedures. We are audited by many of our customers on a regular basis and have many individual companies in our facilities each month.

Fischer: We take the time to learn as much as we can about the product before development even begins. It is imperative to determine the customer's needs and expectations from the very beginning and make sure that all expectations are clear.

Schoepflein: We maintain quality in a full-service outsourcing setting by careful training of all team members in the unique requirements of the customer and the products. We also maintain a very flexible system, one that allows us to incorporate customer-specific needs and requirements into our system, whether it be unique specifications, numbering schemes, documentation change control or customer communication forms. In many cases, our customers have elected to utilize and leverage our quality system to support their own.

Kuo: Quality is essential, no matter if we are providing full-service outsourcing or not, maintaining good quality is the foundation. We have our own quality system, but also tailor to every customer's quality requirement.

12. MPO: Are there any instances/cases when outsourcing doesn't make sense? Please explain.

Fischer: Outsourcing should not be pursued if the scope of work falls well within your core competency and you have plenty of capacity to do it yourself. Added costs are associated with outsourcing. For example, freight, handling and overhead.

Mann: If a company has been producing product at their own facility and the specifications for the process have been "set in stone" with the FDA, it can be perceived to be daunting to validate the process at an outsourced vendor with different tools and methods and redo all the testing that comes along with that. But it is not impossible. In our experience, it is worth the added work to get there in the end for the customer, as it can result in a substantial cost savings and a vast improvement in part quality.

Hulecki: The only time it doesn't make sense to outsource is if, a) no one else can do it, or b) you can do it cheaper.

13. MPO: What do you predict the medical device industry will look like in the next five to 10 years? What shape will the outsourcing market take?

Mann: The race to market for new medical devices will become even fiercer. The trend of components and devices getting smaller and smaller will continue. We are hopeful that the 3-D printing technology required to enable true rapid micro prototyping will emerge in the coming years. This will help our customers get their new products to market faster. MTD is learning that current available technology allows this as an option only for limited, simpler geometries. There is technology for achieving micro detail, however. This technology shows that ultra-precise 3-D printing can be done on a micro scale, so our expectation is it will eventually grow to a larger platform to allow us to use the technology for our mold inserts. The idea is to scale up the existing technology and add more options for materials to be useful for prototyping. This will make this technology even more useful to the world, specifically the medical device world. Strategic partnerships with outsourcing providers, like molders, will become even more crucial to guarantee successful and smooth development and production ramp-up phases.

McCourtney: We are starting to see more consolidation of medical device companies leading to fewer large OEMs. Startup medical device companies may become the R&D source for many large OEMs as their resources are put more into managing the supply chain and dealing with clinical care providers. Contract manufacturers are also consolidating and/or looking for ways to provide more services to ensure relevancy to the mega medical device OEMs. Hospital buying groups may even start developing their own products and/or devices and enlisting the help of contract manufacturers to supply them.

Matachun: My prediction on where the medical device landscape will be in 10 years is that you'll actually see it get smaller. In order to qualify this, we must acknowledge that today we see more and more large OEMs growing through acquisition of technologies from smaller startup companies. In 10 years, I believe that novel and innovative young companies will still emerge to the forefront. These companies may be acquired by larger OEMs, while at the same time, larger OEMs may merge with or acquire other large OEMs, thereby reducing the actual number of OEMs. This phenomenon is already prevalent in the industry today, seen by recent large acquisitions in the past six months. By leveraging each other's market share, market presence, technology, or location, they can take this strategic step to enhance their global footprint. As a possible outsourcing partner to these OEMs, I see it as a tremendous advantage to leverage our experience and market share at particular OEMs that may now open the doors to opportunities that we may have never been considered for before.

Fischer: The next five to 10 years will yield a number of strong medical device hybrids capable of serving the demands of healthcare on a global scale. This will encourage more large life-science companies to increase their outsourcing efforts. Companies that do this will become stronger as they continue focusing on their scope of work.

(Editor's note: An interesting fact that has absolutely nothing to do with outsourcing: Though George Bernard Shaw is most widely known for his literary work, he also was a co-founder of the London School of Economics.)

Related Breaking News

- [Samsung Introduces Ultrasound System Featuring 5-D Applications](#)
- [Biotronik Completes Patient Enrollment in BIOFLOW-IV Study](#)
- [3D Systems Names New Chief Financial Officer](#)

Related Technical Features

- [EtO Gas Mixtures for Ethylene Oxide Sterilization](#)
- [Multi-Layer Extrusion Processes Tackle Tubing Challenges](#)
- [New Coating Technology Could Prevent Premature Orthopedic Implant Failure](#)

News from our Sister Sites



Two Executives Leave IMRIS Without Comment



Janssen, Achillion in HCV Development Pact



Study Finds Statins Inhibit Vitamin K2 and Harden Arteries



Micro Powders Appoints Superior Materials

Health Canada Approves First Implant of St. Jude Medical's Prodigy Chronic Pain System

Hospira, Theradiag Enter Assay Kit Supply Pact

SourceOne Partners with Gee Lawson

The Best Summer Ever?

Coty To Launch Miu Miu

Please visit our sister sites:

Nutraceuticals World

Beauty Packaging

Label & Narrow Web

Printed Electronics Now

Coatings World

Happi

Nonwovens Industry

Contract Pharma

Ink World

Orthopedic Design & Technology



Subscribe to a Magazine:

Subscribe to eNewsletter:

Copyright © 2010 Rodman Media. All Rights Reserved. All rights reserved. Use of this constitutes acceptance of our [Privacy Policy](#)
The material on this site may not be reproduced, distributed, transmitted, or otherwise used, except with the prior written permission of Rodman Media.