B BRAUN
SHARING EXPERTISE

allianz

Volume 4 ▪ 2019 | The Magazine for Partners of B. Braun's OEM Division

ASK THE EXPERTS

POLAND PLANT HIGHLIGHT

GOLDEN SNEAKER - VIA MARATHON

CONTENTS

CHECK OUT OUR MEDICAL WORD SCRAMBLE ON PAGE **35**!

B BRAUN
SHARING EXPERTISE

Volume 4 | 2019

Publisher: B. Braun Medical Inc.
Editor-in-Chief: Tom Black
Contributing Editor: Dave Williams
Co-Contributing Editor: Allison Longenhagen

Design & Production: Lehigh Mining & Navigation
Creative Director: Denis Aumiller
Design: Tom Doerfler
Project Manager: Cathy Wagner
Copywriter: Michael Drabenstott
Production Assistant: Donna Mugavero
Printing: Doug Earp

Photography: John Sterling Ruth Studio

YouTube B. Braun OEM USA – bboemchannel.com
LinkedIn linkedin.com/company/b--braun-medical

B. BRAUN MEDICAL INC.
861 Marcon Blvd.
Allentown, Pa. 18109
TF. 1.800.523.9676
P. 1.800.359.2439
us.bbraunoem.com


Tom Black

EDITOR'S NOTE

Now that 2018 has ended, all of us wonder what to expect in 2019. One thing is certain: The required documentation that supports the medical devices we manufacture will continue to expand.

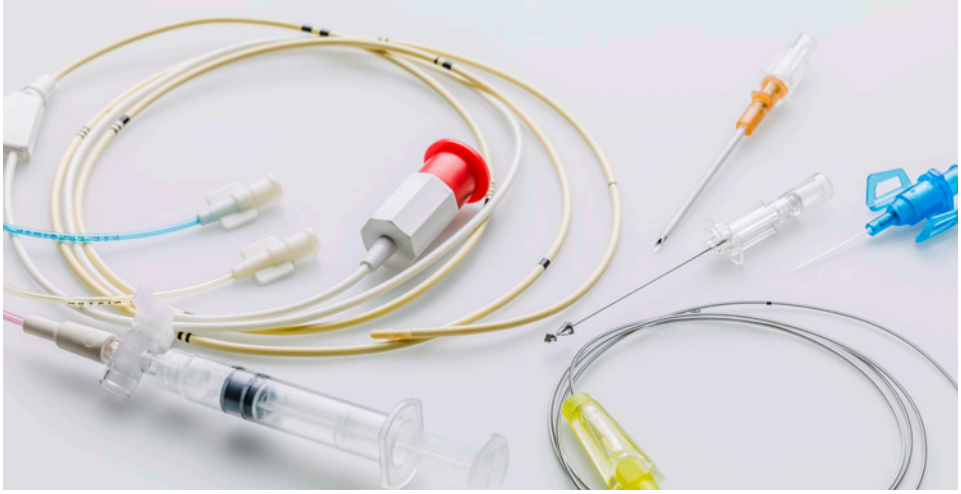
B. Braun has an advantage in outsourcing because our direct sales divisions interact daily on critical disciplines with our operations areas. Our contract manufacturing partners benefit from routine practices in development, quality, and regulatory affairs because of processes and regulations we follow to assure compliance at every level.

In this issue of *allianz*, we discuss how we support those requirements. Closely related topics in this issue include changes to this documentation, the new European Medical Device Regulation and highlights from the recent AdvaMed meeting down the road from us in Philadelphia. We highlight our manufacturing expansion here in the Lehigh Valley, and associates from the B. Braun facility in Poland share their expertise in manufacturing catheters and other devices in that market segment.

We also touch on the regional medical/pharma organizations throughout the U.S. that help promote your business and educate us all on industry trends affecting our daily lives. Finally, *allianz* would not be complete without news updates on the OEM team that supports your objectives and the "What I've Learned" segment with views from industry insiders who work to provide the best products and service to patients and healthcare practitioners.

I hope 2018 has been good to you and your colleagues. Certainly it's been another healthy year for B. Braun and our team. We cherish every customer as a partner and hope we can make your 2019 another successful year.

B. Braun has an advantage in outsourcing because our direct sales divisions interact daily on critical disciplines with our operations areas.



ASK THE EXPERTS:

BECKY STOLARICK AND NANCY SKOCYPEC

Becky Stolarick, Corporate Vice President, Regulatory

Nancy Skocypec, Associate Director, Regulatory

Ask any medical device manufacturer about the biggest challenges they face and the word "regulatory" will likely be among the first uttered. B. Braun's Becky Stolarick, Corporate Vice President, Regulatory, and Nancy Skocypec, Associate Director, Regulatory, offer their perspectives on the ever-changing regulatory environment.

Q: What are the biggest changes in the U.S. regulatory environment in the past couple of years?

We continue to see increasing requirements for testing and documentation, even for Class II devices. The FDA continues to raise the bar on functional performance testing to demonstrate the safety and effectiveness of devices, with the aim to protect public health. A 510(k) that was 50 pages 20 years ago might be 500 pages today.

Q: How do the FDA's guidance documents affect the regulatory process?

The FDA is trying to harmonize what companies need to submit to obtain approval on particular types of devices. Its guidance documents intend to create consistency and a level playing field among manufacturers by standardizing the requirements for approval. The guidance is not mandatory. However, if you decide not to follow it, you need to justify your rationale and provide an equivalent approach. Typically, it's easier just to follow the guidance.

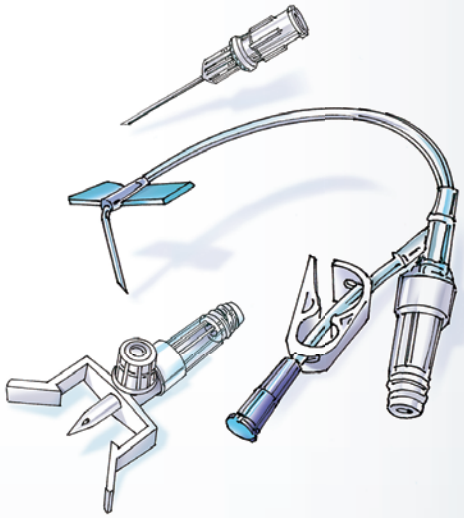
Q: How does B. Braun's regulatory expertise help OEM Division customers?

Most of our contract manufacturing customers take responsibility for their submissions to the FDA. We help by collecting the data and providing the requested documentation to support their submissions. We also work closely with our customers – as well as our engineering, manufacturing, packaging and other colleagues – to provide our perspective on how their designs or processes may be evaluated by the FDA. We then provide our expertise on potential regulatory strategies. As one of the largest medical device manufacturers in the world, we know the requirements in most countries where our customers want to market their products. We assist our OEM international customers by providing the documentation required by global affiliates to register our products in their countries.

B|BRAUN
SHARING EXPERTISE

These things make life convenient.

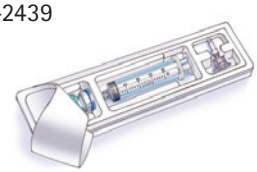
These things make your drug convenient.



Bundle your drug with devices to make administration convenient.

Caregivers have demanding jobs. What if you could help them work smarter by making your drug quick and easy to administer? B. Braun's OEM Division can create a customized bundle of all the devices needed to administer your drug. It'll make your drug convenient for caregivers and separate you from competitors. We offer an extensive selection of proven devices, plus design, regulatory, lab services, packaging and sterilization expertise. It's a full suite of capabilities designed for convenience.

B. Braun Medical | OEM Division | USA | us.bbraunoem.com | 1-800-359-2439



ALLENTOWN EXPANSION TO ADD CAPACITY, VERSATILITY

A substantial expansion is coming to the B. Braun manufacturing facilities in Allentown, Pa. – a change with the potential to bring on greater capacity and make us more versatile in the services we provide to contract manufacturing customers.

The new plant will occupy a 27-acre property next to our current facilities, connecting to an existing building. With a 310,000-square-foot plan, it's expected to support projected growth for the next five to 10 years.

A separate, 10,295-square-foot maintenance building also will be built to support the campus, along with a 326-space parking lot for new employees. We anticipate breaking ground in the spring with an expected completion date during the third quarter of 2021.

What accounts for the selection of this site? In anticipation of future growth, we acquired the property abutting our existing manufacturing facility 12 years ago. Also, our Lehigh Valley locations – what we call our Allentown Operations – are a Center of Excellence for B. Braun USA in injection molding, component assembly and extrusion.

"The core competencies are already here," says Joe Hammond, Component Manufacturing Business Unit Director. "It made sense to keep it in the Allentown facility and leverage that knowledge and expertise."

Besides anticipating growth in the next decade, this expansion also responds to demand for B. Braun products in the United States and internationally through recent years.

For B. Braun OEM Division contract manufacturing clients, important new advantages may emerge. New configurations and state-of-the art equipment can be expected to complement the deep capabilities and expertise already available at our existing location.

B. Braun first put down roots in the Allentown-Bethlehem-Easton metro area in 1979, developing the company's first U.S. location. The OEM Division grew out of our Special Products Manufacturing unit, which often did

specialized projects semi-manually. Today, our OEM Division offers in-house capabilities including injection molding, insert molding and over molding. Our 16,500-square-foot ISO Class 8 molding facility houses some of our 80 injection molding presses, which range from 55 to 330 tons.

An in-house tool and machine shop maintains production molds and works closely with in-house designers, process engineers and material experts to improve molding efficiency. It provides the flexibility to produce custom core pins and inserts to modify an existing mold to meet customer demands and accelerate development.

"We need to be ready to meet our customers' demands for the next decade. This expansion will allow us to do that," says Joe Hammond. "We have tremendous confidence in the talents and expertise of our Allentown Operations team. A new facility is only as good as the people who run it – and in that regard we know it will be successful."

HOW ADVAMED PROMOTES INNOVATION, PATIENT ACCESS AND SAFETY

Among trade associations in the medical manufacturing arena, AdvaMed is particularly important and singularly effective. Representing more than 400 member companies – B. Braun included – in Europe, Asia and the Americas, this D.C.-based organization has long served the medical device and diagnostics industry with distinction. AdvaMed's work with regulatory bodies in the United States and overseas fosters a business environment that promotes innovation and maximizes patient access and safety.

Recently, *allianz* had the opportunity to interview AdvaMed President and CEO Scott Whitaker, asking questions on a number of matters of real impact for contract manufacturers and their customers in the medical device space. His replies yield an informative picture of the efforts of a strong association to benefit us all.

What is AdvaMed's mission? What are the principal initiatives and methods by which it achieves that mission?

AdvaMed is the world's largest trade association for the medical device and diagnostics industry, and our mission – simply put – is to advocate on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation. We do this by working with our members, governments and other healthcare stakeholders around the world to drive consensus on health policy solutions that will support investment, innovation and patient access.

Explain how AdvaMed's advocacy and services can improve the operations and results of medical device vendors and end-users. How does your work also contribute to better patient outcomes?

AdvaMed supports the needs of member companies of all types and sizes – from start-ups to the largest multinationals – so that they can create more innovations that allow people to live longer, healthier and more productive lives. Beyond advocacy, AdvaMed provides professional development services – including educational conferences, workshops and webinars – that help medtech professionals anticipate and respond to constantly evolving regulatory, reimbursement, legal and compliance, and sales/marketing environments.

Describe the initiatives you pursue in cooperation with the Food and Drug Administration to enhance medical device quality. How does this work help medical device manufacturers reach beyond current quality regulations?

Patient safety is at the heart of what we do. Industry and regulatory bodies like FDA in the U.S. share one goal – to get patients the safe and effective products they need, when they need them. It only makes sense that industry and regulatory bodies work together to identify problems, create solutions and drive shared progress toward that shared goal. Industry is an important educational resource that possesses unique, often highly technical expertise to provide regulatory bodies with needed feedback and input.

As you consider the future of the medical device market, what trends do you predict to emerge, change or be sustained through the next five years? What challenges may be foreseen during that period?

The future holds boundless opportunities to continue to save and improve lives. We see aging populations worldwide, expanding middle classes in emerging economies increasingly seeking the best available care, and the continued need for solutions to the world's healthcare challenges. Innovation will continue to yield savings by replacing more invasive procedures, reducing hospital stays and getting people back home faster. The convergence of digital technology and big data, advances in artificial intelligence, and consumer-centric platforms, for example, hold great promise to continue to improve care. The public policy challenge we face is for regulatory, reimbursement and other systems to keep pace and be able to absorb all the innovation we will continue to see.

Beyond the support your work provides to all makers of medical devices, are there ways in which AdvaMed supports and acts on behalf of contract manufacturers?

AdvaMed represents the entire medical technology industry, including contract manufacturers that are required to comply with FDA regulations like establishment of registration and inspection requirements. AdvaMed works with regulators to help ensure that such requirements are efficient and predictable and that they provide information needed to appropriately evaluate compliance. Broadly speaking, AdvaMed advocates for policies – also including medical device tax relief, for example – that benefit the entire innovation ecosystem, including contract manufacturers.


B/BRAUN Omnifix®
latex-free

How is AdvaMed involved in maintaining and improving FDA's pre-market review processes as managed through 510(k)?

The 510(k) process has evolved in recent decades through continual process improvements – resulting from legislation and internal FDA evaluations – to meet the needs of patients and the diversity of medical technology. Throughout these changes, AdvaMed has sought to ensure that the 510(k) process remains a vital component of FDA's robust, risk-based regulatory framework.

Describe AdvaMed's contributions to the development of FDA's medical device user fee program, and other provisions of the 2017 FDA Reauthorization Act (FDARA).

AdvaMed and its member companies worked with FDA to reauthorize the user fee program and advance other pro-innovation reforms under FDARA. AdvaMed-supported provisions include more robust agency performance goals and process improvements to help speed product approvals, improvements to the FDA inspections process, streamlined device accessory classification and increased accountability. These provisions aim to help make FDA a partner rather than a barrier to innovators creating life-changing technologies.

How has AdvaMed's commitment to research benefited its member firms – and ultimately, the medical community and patients? What have been your most important research initiatives?

AdvaMed's commitment to research supports our policy agenda and serves in part to highlight the strong value of medical technology to patients, healthcare systems and our economy. For example, to address stakeholder concerns about healthcare costs, an AdvaMed-supported study demonstrated that medical device prices in the U.S. over recent decades have actually risen at an average annual rate that is less than one-third that of prices in the overall economy and that spending on medical technology has remained virtually constant for decades as a percentage of national health expenditures, at about 5 to 6 percent.

In addition to the issues we've already addressed with these questions, what other matters has AdvaMed been focused on recently?

AdvaMed's post-election policy priorities remain the same, including the following bipartisan issues: The need to: secure permanent repeal of the medical device tax; encourage CMS to be more transparent and predictable in evidence requirements; minimize the impact of tariffs on our industry; support anti-kickback statute reform to allow better company participation in value-based arrangements; encourage diagnostics regulatory reforms to spur innovation; and ensure full implementation by FDA of important provisions of the 2017 FDA Reauthorization Act, the new device user fee agreement (MDUFA IV), and the 21st Century Cures Act of 2016.

Scott Whitaker, President and CEO, AdvaMed

REGIONAL ORGS SUPPORT NATIONAL EFFORTS

National organizations such as AdvaMed aren't alone in advancing the essential tasks of advocacy and development for the medical device industry. State and regional associations also make important contributions on many fronts. Here are several such groups B. Braun supports.

Colorado BioScience Association – Representing more than 350 member organizations, Colorado BioScience is a standard-bearer for the state's thriving bioscience sector. The association promotes the interests of 600-plus bioscience companies; it also focuses on education, economic development and member resources.

Florida Medical Manufacturers Consortium – Medical technology firms in the Sunshine State benefit from the efforts of the consortium, which identifies its strategic priorities as networking, industry knowledge/expertise and advocacy.

Life Sciences Pennsylvania – Formerly known as Pennsylvania Bio, the LSPA was founded in 1989 by two Penn State researchers. Today it provides public policy clout and strategic connections benefiting the state's powerhouse life sciences establishment.

Medical Alley Association – Minnesota's Medical Alley is a hot zone for health technology innovation. The association supports and advances the interests of the healthcare industry there. MAA, its website explains, "delivers the collective influence, intelligence and interactions that support Medical Alley."

Medical Device Manufacturers Association – A national rather than a state group, the trade association MDMA is another leading provider of "educational and advocacy assistance to innovative and entrepreneurial medical technology companies." Founded in 1992, the association is a strong voice for smaller companies, helping shape policies that impact medical device innovators.

See you in

St. Petersburg

FLORIDA MEDICAL DEVICE SYMPOSIUM

MAY 13–14, 2019 • HILTON CARILLON PARK • ST. PETERSBURG, FL

Join your medical device industry peers in St. Petersburg, Florida for the annual Florida Medical Device Symposium—Florida's premier event for medical technology firms—featuring nationally recognized speakers, expert panels on regulatory issues and industry trends, company exhibits and quality networking opportunities.

FMMC
Florida Medical Manufacturers Consortium

WWW.FLORIDAMEDTECH.COM/SYMPOSIUM

MEET THE TEAM

Sondra Hines

As an Account Support Associate in the OEM Division, Sondra acts as a liaison between the account managers and the various departments in B. Braun's manufacturing operation. (See the article on page 28.) She sources answers to the myriad questions that customers ask. That includes information required for their documentation, questionnaires and regulatory needs.

She combines a background in customer service with undergraduate work in the sciences, making her as efficient and expedient as possible while serving both internal and external customers. "I am able to understand technical and engineering requests more than someone with just a business background. You also need attention to detail and good time management."

Sondra has been in her current role for more than a year and with B. Braun for nearly two. "It's a great company to work for. They really do put their customers first," she says. "My role is evidence of the company's desire to better service customers. We work as a team in the OEM Division to help our customers. We're a big family here."

In her time away from the office, Sondra enjoys the outdoors, especially hiking and camping.

Stephen Watt

The job title of Product Development Engineer only describes a portion of Stephen's role at the OEM Division.

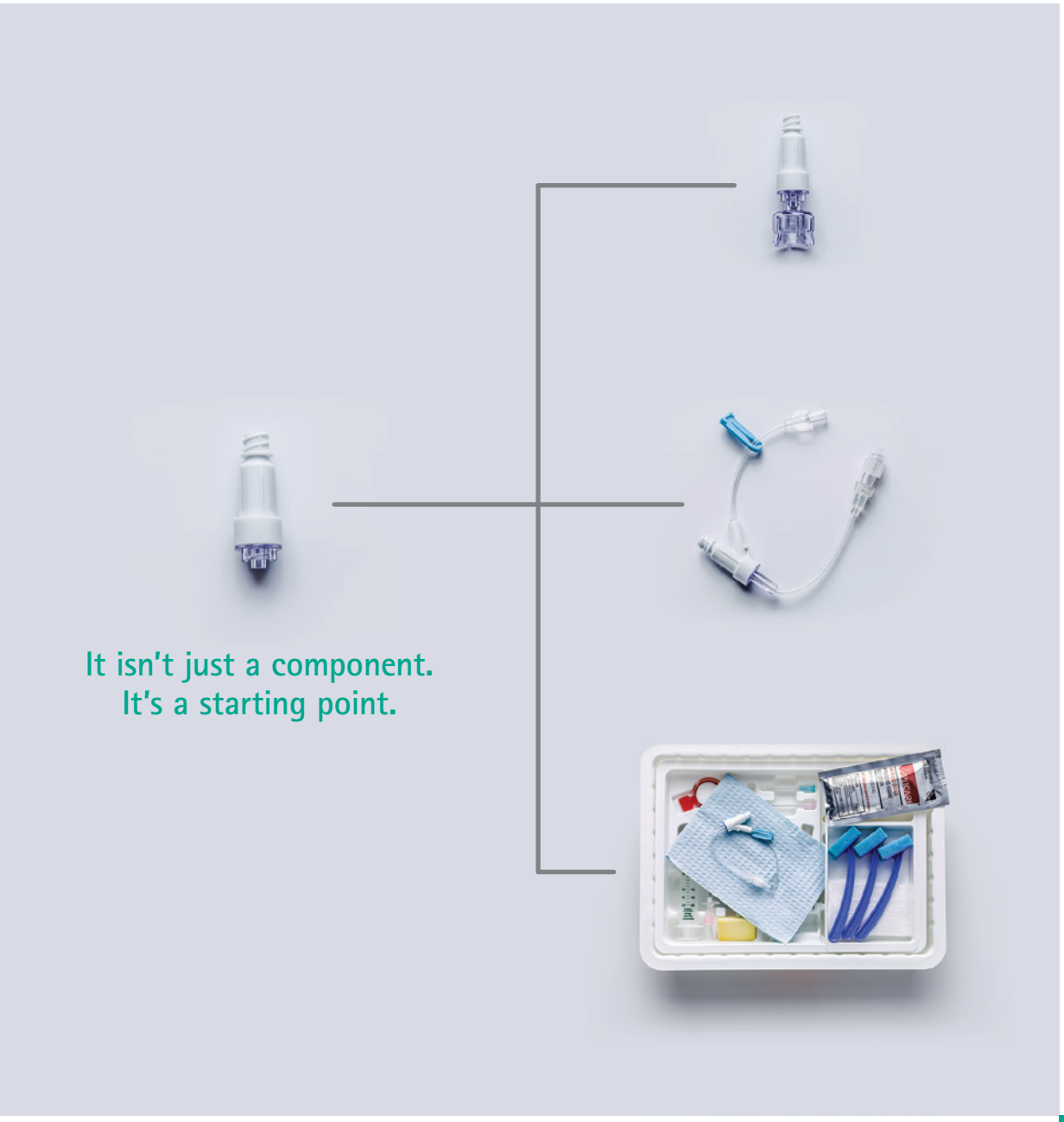
Yes, he works with customers to design products that facilitate drug delivery, such as IV sets and custom devices and components. But he spends a good deal of time seeking out process inefficiencies – both internal and external – and developing steps to streamline operations and create added value for customers.

"It's a constant feedback loop," Stephen says. "I coordinate with our internal team to make sure they understand the customer's vision and then help obtain information and develop solutions. We listen to customers to learn how we can meet their needs even better and input that feedback into the system."

Before joining B. Braun in 2018, Stephen earned a master's degree in biomedical engineering. He previously worked at pharmaceutical and orthopedic device companies. The experience gained there and his desire to continue learning allow him to look at things objectively and find solutions – a process he finds invigorating.

"Everyone uses the word 'work.' If you enjoy what you do, it's not work," says the Lean Six Sigma Green Belt. "I'm always trying to get better and push the ceiling of my capabilities. You need to have challenges and set the bar high to be successful."

B BRAUN
SHARING EXPERTISE



It isn't just a component. It's a starting point.

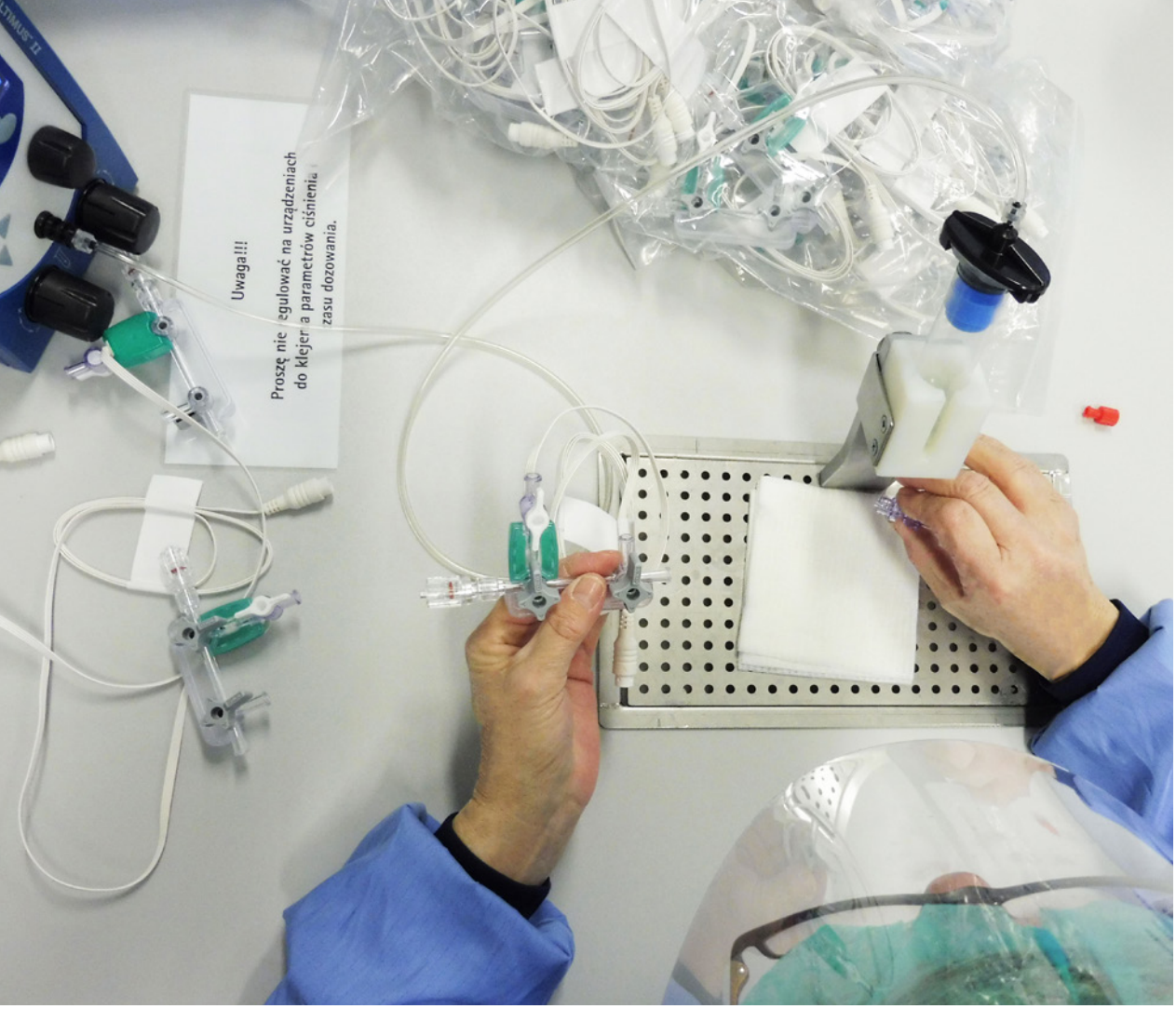
Start with B. Braun OEM's deep product catalog. Add in some serious design and engineering chops. It means we can create a device, set or kit tailored to your exact specifications. Once we've finished designing, we'll handle everything from project management and manufacturing to packaging, sterilization and regulatory approval. With endless products and a full suite of capabilities, we're the ideal choice to speed your project to market. B. Braun OEM. The only outsourcing partner you'll ever need.

B. Braun Medical | OEM Division | USA | us.bbraunoem.com | 1-800-359-2439

POLAND FACILITY PROVIDES CATHETER EXPERTISE, ADDED CAPACITY:

MANUFACTURING SKILL & PRODUCTION OPPORTUNITY

An important consideration in choosing a contract manufacturing partner is the breadth of specialized capabilities and resources that may be available across the organization – and perhaps across an ocean. A perfect example for B. Braun customers is our facilities in Radzyń Podlaski and Nowy Tomyśl, Poland, part of our integrated international network for engineering, manufacturing and packaging medical devices.



For example, the 2,000-employee Polish operation produces B. Braun heart catheters, a capability that many North American contract customers have been seeking. End-products include right heart catheters, balloon catheters, and left heart and coronary sinus catheters as well as kitting for big cardiovascular packages.

"We use Poland as a resource for B. Braun USA to complement our capabilities, knowledge and space," said Lynn Wirth, Senior Manager, OEM National Accounts and New Business Development at B. Braun Medical. "We're aligning projects that we manufacture here with what they're doing there. When it makes sense for our customers, we can use our Poland team's skills and expertise to complement ours."

On a project originating in the United States and utilizing the Polish facilities, Lynn explained, both the North American and European teams make essential contributions. "We in the U.S. would handle all of the communication and design," she said, "then work with our team in Poland to get the manufacturing set up. Then the products would ship back to the U.S."

The Polish manufacturing facility is registered with the U.S. Food and Drug Administration, enabling distribution to customers in this country. With TÜV and ISO certifications, the factory in Poland can also manufacture for distribution to many other countries in Europe and beyond. It boasts 3000 m2 of ISO Class 7 and 8 production floor clean rooms.

An onsite EtO sterilization facility now under construction is scheduled for completion in 2019. It will provide added efficiency, Lynn said, as well as vertical integration and improved control.

"The company in Poland is growing year by year," said Adam Nowaczkiewicz, Manager, Marketing and Communications Section. "We have built and recently extended a new factory in eastern Poland. We continue to manufacture more and more medical instruments. In the near future, we will start with the assembly of angioplasty catheters, vascular grafts and patches."

"Since the moment we became part of the B. Braun family, we have adopted the company's technical culture and competence," he said. "We cooperate in various programs, which aim at making B. Braun's offerings more competitive around the world."

> Since the moment we became part of the B. Braun family, we have adopted the company's technical culture and competence.
>
> — Adam Nowaczkiewicz, Manager, Marketing and Communications Section

B. BRAUN ON THE RUN FOR PA. CHARITY

When Jason Curtis, a project manager for Braun Interventional Systems in Pennsylvania, talks about the company's involvement with the Via Marathon, there is no disguising his pride and enthusiasm. "There's real excitement in getting people to take part in this charitable event," said Jason, who serves as B. Braun's point person for the annual race.

The Lehigh Valley Health Network Via Marathon is a weekend of events encompassing a marathon, half marathon, relay marathon, kids' race and 5K. Proceeds from this event support Via of the Lehigh Valley, a non-profit organization that has provided vital services to children and adults with disabilities since its inception in 1952. Via helps children overcome developmental delays, helps adults find meaningful and sustainable employment, and works with individuals of all ages to gain life skills, develop friendships and learn how to take advantage of all the community has to offer. Since 2007, B. Braun and Aesculap have been a major sponsor of the Via Marathon, and hundreds of employees have taken part in a wide variety of ways – running on relay teams, serving as course marshals, staffing water stations, handing out medals and even providing entertainment at the finish line.

"Our participants do not have to be elite runners – probably 85 percent of them train only for this specific event," says Jason. "Volunteers are also a crucial part in the success of the event." This year alone, B. Braun, Aesculap and CAPS will provide over 200 runners, race marshals and others needed to assist in making this event a success.

About 20 major sponsors back the event, which is held the weekend after the Labor Day holiday each year. Marathon runners and relay teams depart just west of Allentown on a scenic course that winds its way through Bethlehem and concludes 26.2 miles away in Easton. The half marathon starts from historic downtown Bethlehem, and the 5K and Kids Race take place on the Southside of Bethlehem.

According to Jason, the value of B. Braun's sponsorship in the running events has totaled more than $75,000 across recent years and serves multiple purposes: team building, corporate and community wellness, civic engagement, economic development – and supporting people with disabilities. "Run, jog or volunteer, this event offers something for everyone, and we're proud to be an integral part of it," he said.

"There's real excitement in getting people to take part in this charitable event," said Jason, who serves as B. Braun's point person for the annual race.

ROLE OF ACCOUNT SUPPORT ASSOCIATES

No one will dispute that there is a deepening and unrelenting demand for data and information in the medical device field. Whether it's compiling information to supply to the FDA, documenting quality procedures, performing supplier audits or tracking numerous other functions, the need for information seemingly picks up speed on a daily basis.

Thankfully, the OEM Division at B. Braun Medical has two individuals charged with collecting and preparing data and information for customers. Their nondescript job title, Account Support Associates, understates their important value to the project team.

"Over the years, customers have been requesting more information as regulations get tighter – and the requests keep getting more detailed and more frequent," says Account Support Associate Sondra Hines.

"I act as a liaison between the account managers and the manufacturing operations. Our customers send requests, and I source the answers."

The role involves more than simply forwarding customer emails to B. Braun colleagues and waiting for replies. It involves delving into the context of the request to expedite the gathering of information. "It's important for us to gain a complete understanding of why customers are asking for information. When we learn the reason, we can make sure to get what they need in the right format from the right people on our end," says Account Support Associate Kristy Spairana.

Obtaining the right information from a variety of sources requires a unique blend of aptitudes: technical knowledge, communication ability, organizational skills, a customer-service mindset, persistence and a willingness to learn, to name a few. As a bridge between the customer and B. Braun's manufacturing operations, they play the critical role of information broker.

"They need to be flexible and personable because they need to build relationships with our manufacturing teams, but at the same time be forceful because they're representing the customer's voice," says Donna Luckenbach, Associate Director, Sales Services.

Most of the ASA work is done diligently behind the scenes, leaving B. Braun's territory representatives as the voice and the face of the OEM Division to customers. But make no mistake: They are a core part of the team that works to meet customers' needs.

"Customers should be comforted to know there's someone on the back end who knows about the data and capabilities," says Spairana. "There's more than the product: There's information behind the product. That's what we help deliver."

"I act as a liaison between the account managers and the manufacturing operations. Our customers send requests and I source the answers."

—Sondra Hines, Account Support Associate

ARE YOU READY FOR MDR IN EUROPE?

The landmark Medical Device Regulation (MDR) in Europe is changing the way manufacturers must do business if they compete on the Continent. The regulation went into force in May 2017, heralding the start of the three-year transition period for compliance. Half of that period has elapsed.

If the status of any device that is sold (or is expected to be sold) in Europe hasn't already been carefully examined, the time to do so is now.

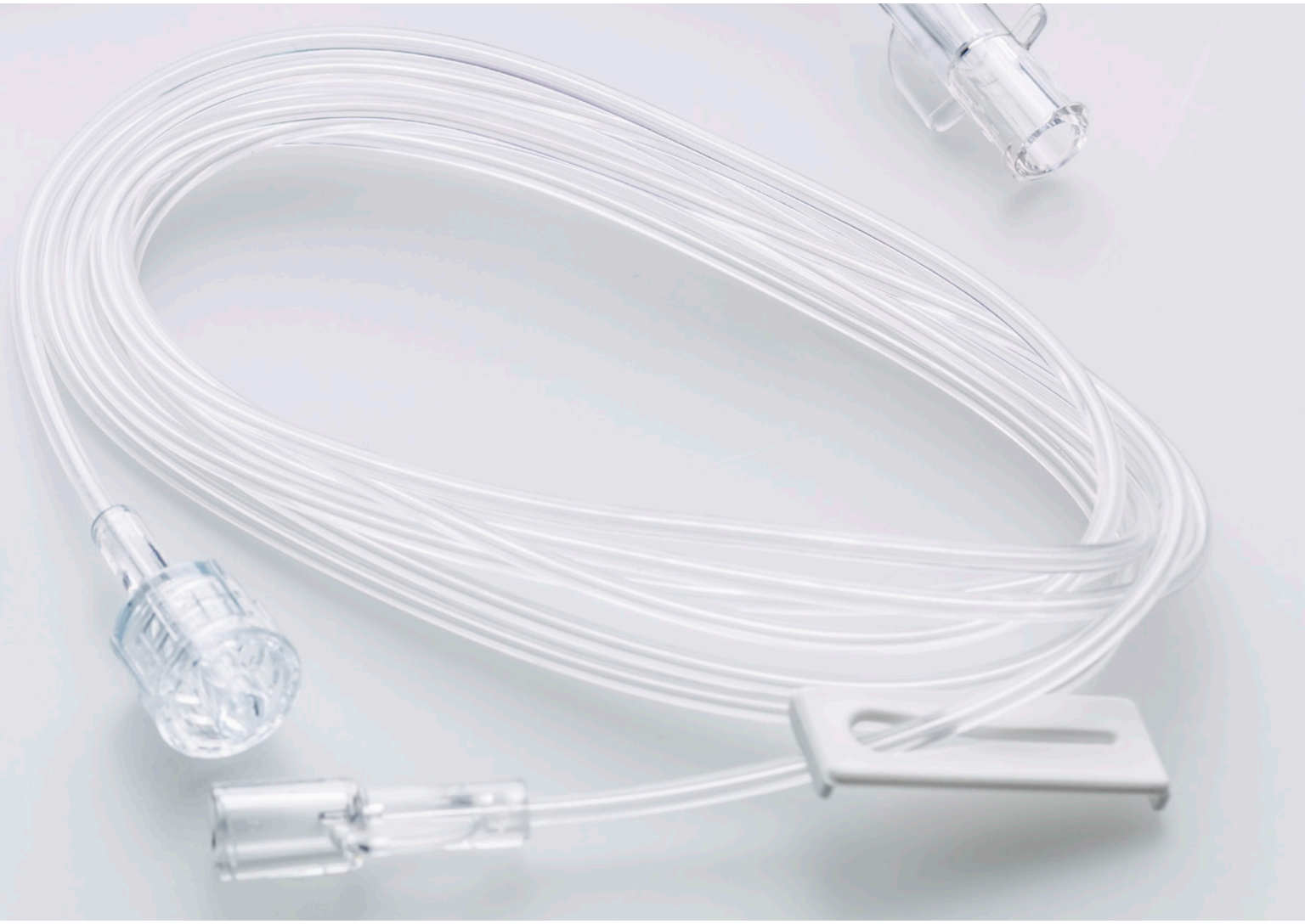
About 90 percent of all medical devices will retain their current classifications, according to *Regulatory Focus*, an online publication of the Regulatory Affairs Professional Society (RAPS). Even if the classification of a legacy device is unchanged, the publication warns, manufacturers can't assume "that the steps to ensure it remains compliant will be quick or easy."

A whitepaper from EV- a part of Ernst & Young Global Limited – cautions that medtech companies may have to:

- Provide substantially more clinical evidence to get products to market, or even to keep some products on the market.
- Conduct deep portfolio audits to determine the new rules' impact on margins.
- Relabel products and make data ready to be made publicly available.

ECN® (*Electronic Component News*) flags three critical implications of the new regs. First, there's no grandfathering of old rules. All devices must be reviewed; though grace periods may apply, everything must be brought up to new standards. Second, new rules mean that equivalence claims to existing devices must be supported with significant documentation, making that process "onerous." Third, medtech firms must devote substantial time and staff to engage the new requirements they face. They should be prepared to beef up EU compliance budgets.

Fleshing out its recommendations, *Regulatory Focus* says manufacturers must thoroughly review the safety and performance of every product to make sure they meet all MDR requirements. They must address reclassification if



necessary. They should create an action plan for conformity to the new rules; starting with a pilot program for one or two products can be a way to avoid feeling swamped by the process overall.

The *Regulatory Focus* article, published last year, suggested starting early; with more than a year already gone, anyone who hasn't, should start immediately. Like *ECN*, *Regulatory Focus* said firms must expect to invest substantially in the process.

As manufacturers wrestle to comply with Europe's MDR, a contract manufacturing relationship with B. Braun remains extremely valuable. B. Braun is already engaged in both the broad regulatory issues and the many details that must be dealt with, product by product.

"B. Braun has dedicated resources that are already implementing systems to meet the demands," says Becky Stolarick, Corporate Vice President, Regulatory Affairs. "We have a very large team in Europe, and they have been providing us guidance on how to interpret and meet the regulation. Smaller companies may not have the same resources.

"This new level of oversight is a step up on what we're already doing there, but we know our team is up to the task."

"Always remember that patients benefit from our products. Seeing the B. Braun products that supported our 19-year-old son during his 13-hour spinal fusion surgery provided an extra level of comfort to my wife and me while we were waiting for updates from the surgeons."

– Ed White, Manager,
OEM & International Sales Operations

It's all about the people in the end. Sometimes it's easy to lose sight amid the stress and struggles we face. But in the end, it's the people we are able to impact and the relationships we cultivate along the way that will have a lasting impact on our lives and theirs.

– Philip Milia
Account Manager, Northeast Territory

"Approach every client opportunity with the thought of helping them solve their current problem or achieve their immediate expectations, not with the thought of only selling our products and services. This will help to strengthen and develop long-term partnerships for the future."

– Mike Saylor, Account Manager,
Southeast Territory

"Stay a step ahead or fall behind. While the requirements for the medical device market are continuously changing, we at B. Braun are committed to new quality and regulatory requirements that promote the safest and most effective products."

– Michael Chacko,
Account Manager, Mountain Territory

"I am serious. And, don't call me Shirley!"

-Dr. Rumack on the wrong Airplane

Customer Service is a key ingredient to being a successful contract manufacturer. Treat your customers how you would treat your own family. Listen to their needs, be respectful, and most importantly be honest.

– Chad Zaengle
Account Manager, Midwest Territory

"Successful account managers navigate the internal workings of their client's company just as well as their own. I have heard 'You know more people here than I do' more than once while hosting a meeting at a client site. I've come to fully appreciate B. Braun's commitment to individualized customer representation as part of our full-service OEM capabilities."

– Jonathan Andrews,
Territory Manager, Europe, Middle East & Africa

"Whether it be Engineering, Regulatory, Quality, Marketing, or any of the other fields that play a part, it really makes your job a lot more enjoyable when you have great people around you"

– David Holland,
Territory Manager, Asia Pacific

MPO SUMMIT 2019

OCTOBER 3-4 • SILICON VALLEY

Learn and Discuss—Grow and Succeed

MEDTECH OUTSOURCING'S

PREMIER CONFERENCE EVENT

*Helping **you** do business better*

For more information, contact: Howard Revitch · 201-880-2243 · hrevitch@rodmanmedia.com · mposummit.com

B. BRAUN MEDICAL WORD SCRAMBLE

Words related to I.V. treatment. Enjoy!

1. TSFESIEA _____

2. OKTSCOPC _____

3. SIUNIFON _____

4. LIPAUERD _____

5. RSECHETAT _____

6. SNHTAEAIES _____

7. EEAOICCSRSS _____

8. INSTSOULO _____

9. TVOSEIRNAUN _____

10. NSELEED _____

11. IGSERYSN _____

12. EELLODITNHA _____

13. AYPILARCL _____

14. TARSINSFOUN _____

15. HOLBOGINME _____

WORD BANK

ANESTHESIA	INFUSION	INTRAVENOUS
CAPILLARY	HEMOGLOBIN	STOPCOCK
SYRINGES	EPIDURAL	SOLUTIONS
TRANSFUSION	ACCESSORIES	NEEDLES
CATHETERS	ENDOTHELIAL	SAFESITE

B|BRAUN
SHARING EXPERTISE

You can try to juggle many vendors.

Or just call us.

Don't waste time & money dealing with multiple vendors when all you really need is one partner.

B. Braun OEM has all the capabilities to get your product from drawing board to market. Project management, design and prototyping, engineering, quality systems, sterilization and regulatory guidance, to name a few. The best part of having all these capabilities under one roof is that they come with decades of expertise we can't wait to share. Choose B. Braun OEM—your true outsourcing partner.

B. Braun Medical | OEM Division | USA | us.bbraunoem.com | 1-800-359-2439