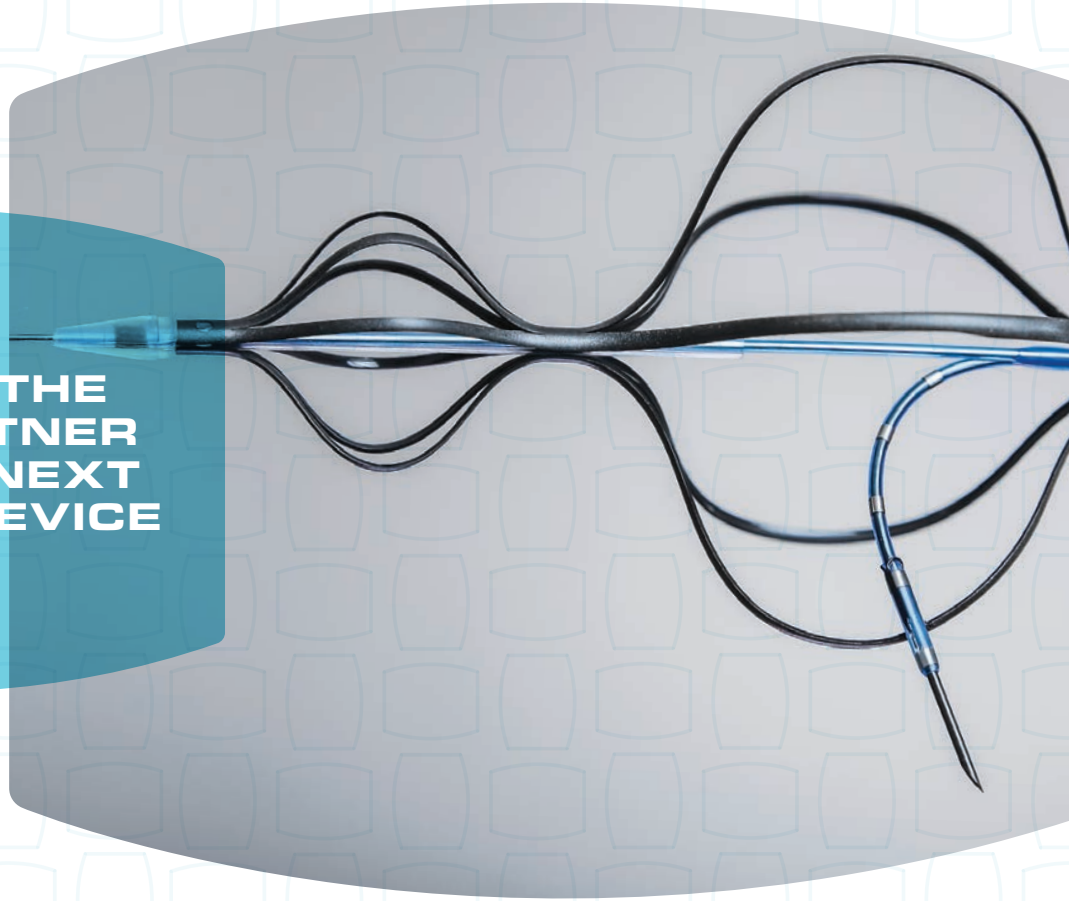
CHOOSING THE RIGHT PARTNER FOR YOUR NEXT MEDICAL DEVICE



HEALTH

The medical device industry creates products that enable people to live longer, healthier and more productive lives. As the market continues to drive demand for innovative products, medtech companies are committed to developing new devices that are safe, effective and of the highest quality, while also striving to bring these products from concept to commercialization as quickly and efficiently as possible. To meet all these objectives, device makers often contract with design & development companies, contract manufacturers and other partners. Lubrizol Life Science Health created this e-book to provide an overview of the fast-changing medtech contract development and manufacturing landscape to help you find the right partner to translate your idea or technology into a commercially viable product.

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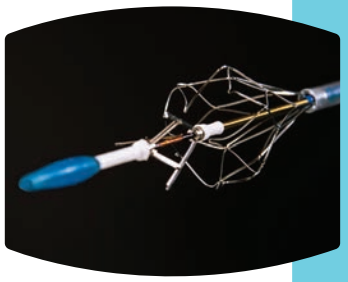
THE CHANGING MEDTECH INDUSTRY

Before the financial crisis of 2007-2008, large medical device companies tended to be integrated across the product life cycle from new product development to manufacturing, whereas companies that outsourced device design and manufacturing tended to be smaller in size. Following the financial crisis, these large, integrated OEMs came under pressure from investors and other stakeholders to reduce fixed costs. Most restructured to shed manufacturing assets and free resources to focus on their core competencies of research & development, clinical development, and sales & marketing.

With capital infusion from private equity firms, contract manufacturers acquired many of these manufacturing assets. As the industry continued to evolve, CMOs began to acquire device design & development companies to expand their offering, creating a new medtech industry category: the full-service, or single-source, contract development and manufacturing organization. Concurrently, OEMs were becoming more willing to outsource higher-value phases of the product value chain. Meanwhile, demand for contract design and manufacturing services further increased from the medtech startup sector.

Of course, not all device design & development companies and smaller CMOs have been acquired. Many of these independents have also flourished in the rapidly growing industry as reliable partners with specialized resources and niche expertise.

As this transformation continues, medical device OEMs have expanded their vision beyond simply outsourcing to encompass supply chain simplification, risk reduction, accountability, and accelerated speed to market. Outsourcing decisions are increasingly based on strategic long-term partnerships focused on enabling technologies and specific manufacturing know-how that would be difficult for OEMs to develop internally. Pandemic-related supply disruptions have further intensified reevaluation of global supply chains, with a focus on partner/supplier proximities and supply chain redundancies.



QUESTIONS TO ASK YOURSELF

- Should you develop your next device internally, or is an outside partner or partners better suited to bring it to market faster and at less cost?
- Do you have a device design firm or an integrated development and manufacturing organization on your approved vendor list that is well qualified to develop this device?
- Is this a good time to look into a potential new partner?

DEVICE DESIGN & DEVELOPMENT

Medical device OEMs and startups alike are increasingly seeing the advantages of working with an integrated organization that can provide a single-source solution. Lubrizol Life Science Health is now such a partner.

Lubrizol's July 2019 acquisition of Bavaria Medizin Technologie GmbH (BMT) exemplifies the trend of medtech CMOs adding device design & development capability to create a true end-to-end partner. The acquisition is now integrated into Lubrizol Life Science Health's Contract Manufacturing business.

The combination above enhances Lubrizol's product design, development and manufacturing expertise and provides access to proprietary catheter, balloon and delivery device technologies. These align well with Lubrizol's pharmaceutical CDMO business to position Lubrizol as the ideal partner for developing combination devices such as drug-coated balloon catheters.

Based near Munich with a manufacturing facility in Romania, BMT was originally founded by a group of scientists and cardiologists in 1992. It built its reputation on working with scientists, physicians and entrepreneurs on early-stage device concepts and became a pioneer in catheter-based technologies. It developed into a designer and manufacturer of intravascular and similar minimally invasive devices with 100 employees and a worldwide customer base.

The Munich facility is mirrored by Lubrizol's new U.S. Device Design Center located at the Vesta thermoplastic precision extrusion plant in Corona, California. The center is strategically situated in the heart of Southern California's medical device industry. Both the Munich and Corona facilities are well equipped with tool and process design capabilities, as well as test laboratories for benchmarking and material testing, prototyping development, various functional models, and clean rooms for high volume serial production. The core capabilities of precision extrusion and catheter assembly in the Corona facility further facilitate a rapid device design process.

CONCEPT DEVELOPMENT

- Generating new ideas and technical solutions
- Converting your idea into a real product

INNOVATION

- Optimization of existing designs, new features and expanded indications
- Realize an innovative and efficient solution

ROBUST SCALABLE DESIGN

- Navigation through device design phase – feasibility, design reviews, design freeze, design verification and design validation
- Approved and ready for sale product

QUALITY – Ensuring quality throughout the design and development process

PROJECT MANAGEMENT – Shorten time and reduce expense

The integrated Device Design Team consists of highly experienced project managers, design engineers and specialized technicians who work together to rapidly bring concepts to commercialization. Our 35+ engineers and technicians have generated more than 85 patents and boast more than 425 total years of experience.

Our comprehensive design & development services include:

- Proof of concept, early prototyping
- Feasibility studies
- Predicate device evaluation
- Benchmarking of products and materials in different models
- 3D-CAD Design for devices and packaging
- Pilot products, performance and mechanical tests
- Full balloon development, including drug coating
- Entire product development including design verification, process verification and process validation
- Generation of detailed design history files
- Production transfer including process validations
- Regulatory support – FDA, CE and other regional agencies
- Accelerated aging tests, biocompatibility tests, packaging and transportation simulation, etc.
- Support for both in vitro and in vivo testing
- Customer access to design & development facilities and labs

Unlike contract design and manufacturing organizations with a broad scope, Lubrizol Life Science Health focuses specifically on a range of interventional vascular therapies and similar minimally invasive technologies. We use our deep knowledge of these fields, combined with our polymer expertise, to help our clients advance their technology with new, improved and breakthrough devices.

The device design team has generated more than 85 patents and boasts more than 425 total years of experience.

QUESTIONS TO ASK YOURSELF

- Do you have a device design partner that is a true expert in your type of device?
- Do you have a partner who is conveniently located for in-person meetings and site visits?
- Do you have a partner with both design and manufacturing capabilities on multiple continents as well as multi-disciplinary capabilities and experience?
- Is this a good time to qualify a new design firm with a trial project?

THE POLYMER FACTOR

Lubrizol's long experience as a leading polymer innovator and contract manufacturer of complex polymer-based components, assemblies and devices represents a distinctive strength that few if any contract organizations can match.

Our expertise in polymer synthesis and production together with our custom contract manufacturing services have made us a valued partner to the medical device industry since the 1970s. We have served more than 750 customers in 40+ countries, from small, venture-backed startups to 25 of the top 30 medical OEMs.

Lubrizol is one of the world's largest formulators and manufacturers of medical-grade thermoplastic polyurethane (TPU) polymers. In fact, TPU was invented in 1959 while the operation was part of BF Goodrich Specialty Chemicals. Lubrizol acquired the Specialty Chemicals business in 2004, creating Lubrizol Engineered Polymers.

All our medical-grade TPU polymers are manufactured in ISO-9001 certified facilities and formulated for superior biostability, biocompatibility and processing versatility. Our comprehensive array of TPU solutions includes Pellethane®, Isoplast®, Tecoflex™, Tecothane™, Carbothane™ and Pathway™ polymers. We also specialize in formulating customized polymers to improve product design and performance.

Our medical-grade TPUs are ideal for use in interventional vascular, neurovascular, pacing and neurostimulation, electrophysiology and other long- and short-term applications. Product areas of focus include minimally invasive devices, catheters and delivery systems.

One current area of R&D interest in the industry is polymers for drug-device combination products, which provide for localized therapy as an alternative to oral medications. Another focus area is ever-smaller minimally invasive devices to navigate to more distal regions of the body. These devices will require softer yet stronger materials that will not harm the tiny vessels.

The selection of component materials is often crucial in the development and sustainability of a medical device. The choice may be based on many considerations:

BIOLOGICAL PERFORMANCE

- Biocompatibility, biostability, hemocompatibility, infection risk

APPLICATION PERFORMANCE

- Strength, flexibility, fatigue resistance, heat and/or electrical resistance

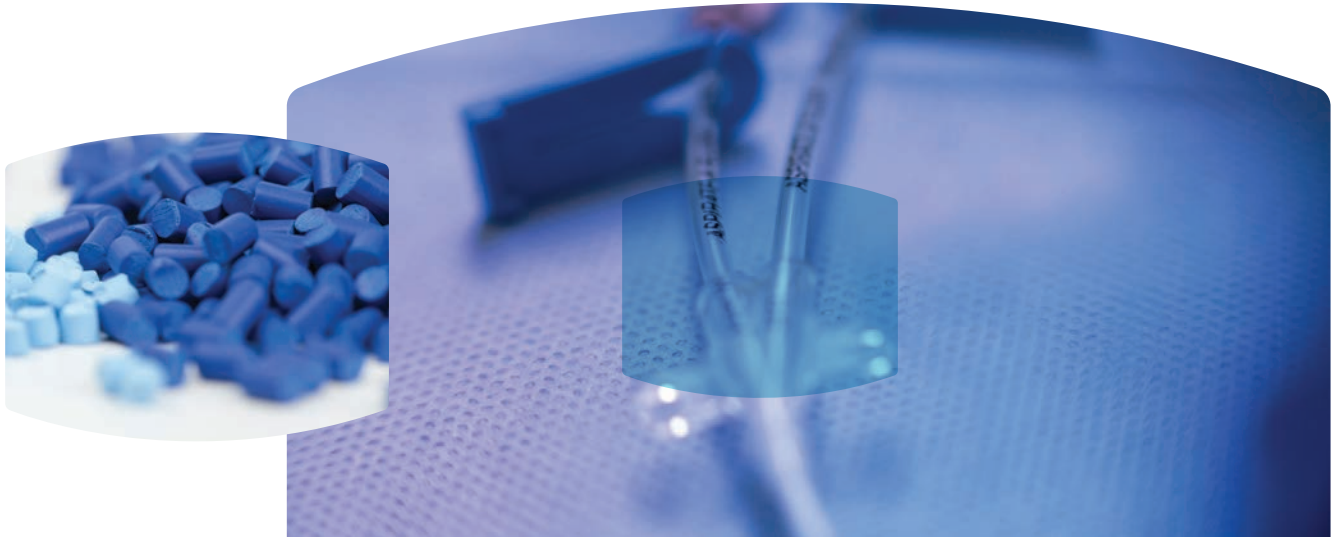
CHEMICAL RESISTANCE

- Cleaning-product resistance, drug resistance, sterilization stability

PROCESSABILITY

- Thermal methods (extrusion, molding, forming)
- Solvent (casting, dipping, spinning)
- Secondary assembly (reflow, bonding)
- Compatibility with other materials within the device

We currently serve more than 750 customers in 40+ countries.



PRICING AND TERMS

- Volume-specific pricing, annual access, licensing and/or royalty fees

REGULATORY AND COMPLIANCE REQUIREMENTS

- Does the material contain REACH, RoHS or other substances of concern?
- Has the material been used in devices cleared by regulatory agencies?
- Are non-medical-grade polymers an option?

Consideration also needs to be given to other factors such as the robustness of the supplier's manufacturing processes, quality systems, and regulatory and compliance support.

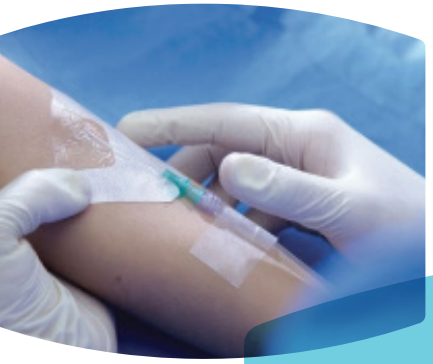
Medical polymer customers can count on Lubrizol to provide comprehensive materials-related support to help ensure compliance with the regulations specific to the markets in which they plan to sell their medical device. Our support begins with polymer selection and extends through the customer's application for market approval – and on an ongoing basis thereafter.

In the device development/polymer selection phase, we offer customers access to our technical, regulatory and compliance experts. Where needed, we supplement this guidance with detailed, regularly updated Material Information Packages on each of our families of medical-grade TPU polymers.

As part of an FDA premarket notification or premarket approval submission, OEMs are required to provide detailed information about the materials the device is made from, including product formulations and manufacturing processes. Material providers often regard some of this as proprietary information that they are not willing to disclose to the OEM. This can be problematic if the FDA analysts have questions.

To help preserve the trade secrets and facilitate the approval process, the FDA established the Device Master File (MAF) system. The OEM can request a Letter of Access from the supplier in order to reference the supplier's MAF in the application. This reduces the possibility of the material being the cause of any delay.

Materials suppliers are not required to provide MAFs to the FDA, but OEMs should expect their suppliers to be able to do so. Lubrizol maintains MAFs with the FDA on all our widely used medical grade TPUs.



QUESTIONS TO ASK YOURSELF

- How important is the polymer material to the success of your device?
- How knowledgeable is your company and/or your device designer about polymers and other types of materials under consideration?
- Are you confident in the level of regulatory and compliance support your partner will provide?

Medical polymer customers can count on Lubrizol to provide comprehensive materials-related support.

CONTRACT MANUFACTURING

There are many types of medical device contract manufacturers. They come in all sizes, with ranges of experience, capabilities, sophistication and areas of expertise. Typical OEM requirements include engineering support, a proven quality management process, continuous improvement for manufacturing efficiency, and the ability to handle low- to high-volume production.

OEM outsourcing decisions are increasingly based on long-term strategic partnerships focused on specific manufacturing know-how that would be difficult for the OEM to develop internally. Most OEMs prefer contract manufacturers that work exclusively within the life sciences industry and specialize in manufacturing the type of device in question. They look for the best overall fit, taking into consideration capabilities, quality, experience, innovation, speed and cost effectiveness.

Lubrizol Life Science Health has provided contract manufacturing exclusively for the global life sciences industry for nearly 50 years. All our manufacturing facilities are ISO 13485:2016 certified and solely dedicated to medical device manufacturing services. We produce more than 85 million medical device components, assemblies and devices per year across more than 4,000 different SKUs. Our rigorous processes and quality systems ensure we deliver a consistent product to meet customer specifications, time and again.

WIth expertise in both thermoplastics and silicone, our specialties include precision extrusion, molding, dipping, sheeting, braid and coil-reinforced catheter shafts, balloons, drug coating of components and devices, subassemblies and finished medical device assembly. Our manufacturing expertise is aligned with products that utilize minimally invasive catheters and delivery systems as well as a broad array of thermoplastic and silicone-based medical devices.

As a leading precision extrusion supplier, we produce thermoplastic medical extrusions that meet the most precise specifications. In close collaboration with our customers, we have delivered extrusions used in a range of advanced medical procedures – including cardiovascular, structural heart, neurostimulation, pacing, neurovascular and electrophysiology applications. We can handle challenging levels of product complexity in virtually any type of thermoplastic while always optimizing production for cost effectiveness.

Engineering and production resources are available to support quick design changes, short lead times for custom designed products, and development runs with the same quality, in-house equipment used for full-scale production.

Our contract manufacturing team works with clients throughout the product development process beginning with assistance for defining and specifying the extrusion and support in materials selection. We design and manufacture most of our pin-and-die sets in-house and provide rapid response prototyping to verify manufacturability. Our process expertise, strong supplier relationships, and equipment availability keep lead times short and help ensure a successful result.

Quality means a lot of things. In medical device manufacturing, it always means strict regulatory compliance. We work with customers to ensure their designs meet their intended safety, ease of use and performance of the medical device.

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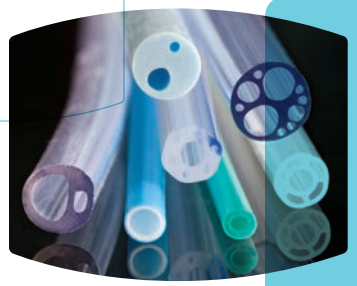


QUESTIONS TO ASK YOURSELF

- Do you need a contract manufacturing partner specializing in precision medical extrusion?
- Do you need one specializing in minimally invasive catheters and delivery systems?
- Do you want one that also provides device design & development services?

GUIDEWIRE CASE STUDY

GUIDEWIRE JACKET SOLUTION UTILIZING CUSTOM POLYMER FORMULATION AND PRECISION EXTRUSION

Market: Interventional Cardiology
Product: Interventional Guidewire
Application: Coronary and Peripheral Interventions
Company: Top 10 Medical OEM
Device Class: II
Material Platform: Thermoplastic Polyurethane (TPU) with radiopacifier

CUSTOMER NEED

A leading medical device original equipment manufacturer was facing concerns with their existing interventional guidewire manufacturing process. The OEM's initiative was to improve the manufacturing consistency with the guidewire tip polymer jacketing process, which utilized a variety of thin-wall extruded radiopaque polyurethane extrusions. Inefficiency and quality issues with the existing component were leading to increased scrap and cost. In addition, we supported the OEMs efforts to confirm that the design of their polymer jacket would perform as expected during the manufacturing of their portfolio of guidewire products.

LUBRIZOL LIFE SCIENCE HEALTH (LLS Health) SOLUTION

The LLS Health team first addressed the material composition of the guidewire tip.

The team worked closely with the OEM to understand their material requirements. They customized a range of materials using Lubrizol's portfolio of TPUs specifically designed for the OEM's guidewire tip manufacturing process. The next step included precision extrusion to meet the OEM's product requirement. With several years of supplying precision extruded components across the global market and expertise in wire jacketing technology, the team was able to exceed the OEM's expectations for product component quality.

By offering both polymer customization and high-precision extrusion capabilities, the LLS Health team provided a consolidated solution to help to address the OEM's manufacturing consistency requirements.

Interventional Guidewire Polymer Jacket Formulation and Extrusion

FINAL OUTCOME

The problem-solving attitude and technical expertise of the LLS Health team helped the OEM continue to manufacture their products with reliable quality and reduced manufacturing scrap. By taking a wholistic approach to address the OEM's challenge, the team demonstrated reliability as a trusted supplier for a critical project.

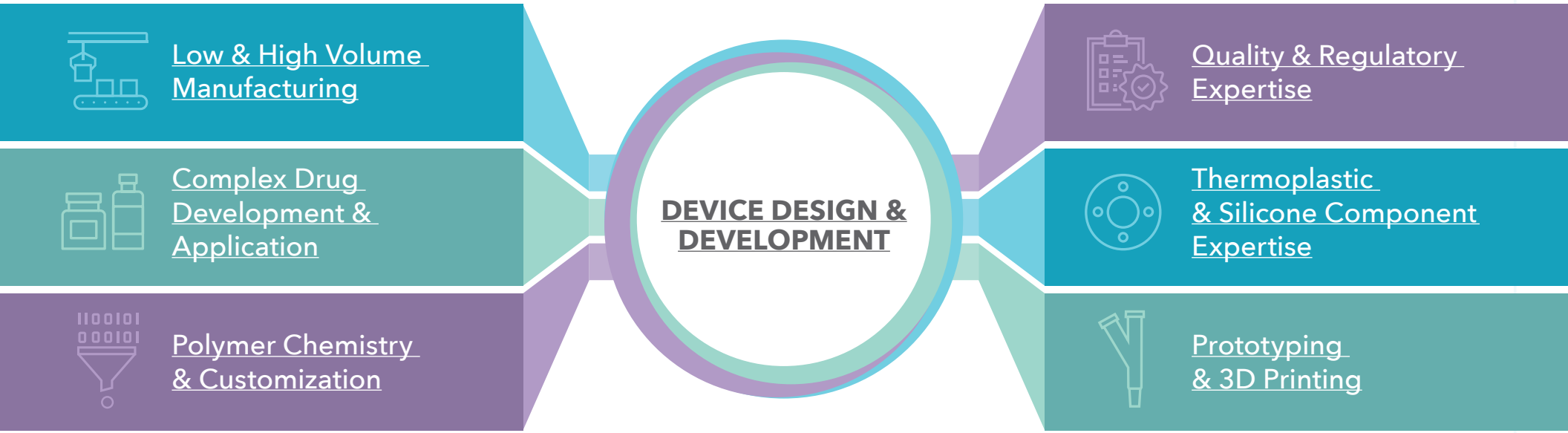
SINGLE-SOURCE SOLUTION PROVIDER

According to a recent industry report, quality standards and the ability to serve the full product lifecycle are perceived by medical device contract service providers as the two leading factors of competitive advantage today.*

At Lubrizol Life Science Health, we have the ability to serve the full product lifecycle. And we do it from a unique vantage point that other full-service providers can't match: our polymer expertise. As for quality, our rigorous standards throughout the development lifecycle help ensure prompt regulatory approvals, ease of manufacturing and, ultimately, consistent product performance at the point of care. Our many customers can attest to our commitment to quality, and we are happy to put you in touch with them.

As a device design provider, we bring a practical perspective to even the earliest stages of product development. Our five-phase Product Development and Manufacturing Transfer Process starts with the end in mind to ensure that we create a scalable, robust, volume-manufacturing process for the device we design.

Considering both immediate and long-term production, we evaluate a design to see if it can be simplified or enhanced in any way to smooth the transition into manufacturing, improve the speed and flow of production, minimize product variation, and make assembly faster and easier. Our concurrent engineering methodology allows for consideration of the device design and the production process simultaneously.



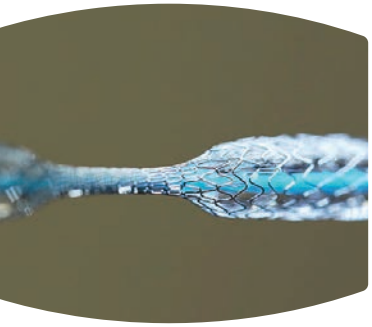
* Medical DeviceContract Development and Manufacturing: Global Trends & Opportunities, Mass MEDIC, June 2020

Our diligence doesn't end when the design is perfected and the production line is ready to roll. When you partner with Lubrizol, you will see the care we put into maintaining a lean and robust supply chain. Our close relationships with an approved list of best-in-class suppliers ensure an inside track to the highest quality inventory available.

Finally, in the post-market stage, we support our customers in their efforts to identify product improvement opportunities for potential next-generation devices.

Lubrizol Life Science Health continues to provide discrete component design and contract manufacturing services. However, we encourage existing customers and potential new customers to fully leverage our integrated end-to-end capabilities for your next appropriate medical device project.

To discuss a specific inquiry or project need, please contact us to get in touch with one of our medical device experts.



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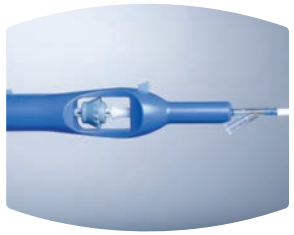
QUESTIONS TO ASK YOUR PROSPECTIVE PARTNERS

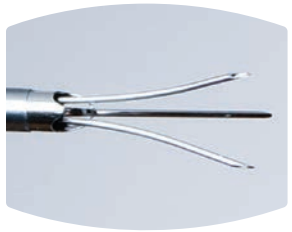
- What types of products, technologies and clinical areas are your strengths?
- What is your experience designing, developing and manufacturing my type of product?
- What are your areas of materials expertise?
- How does your quality management system work?
- Do you have a certified quality management system that includes the product development process?
- How robust is your design team if things get busy?
- Can you handle low- and high-volume manufacturing?
- Do you provide supply chain management service?
- What kind of testing services do you provide?
- Can you manage our inventory and distribution?
- Can we tour your design center and manufacturing facility?
- How do you handle communication and information sharing?
- Will we be an important client for you?

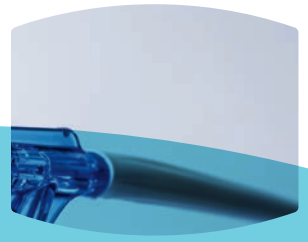
ABOUT LUBRIZOL LIFE SCIENCE HEALTH AND THE LUBRIZOL CORPORATION

The Health business of Lubrizol Life Science partners with customers to speed innovative medical devices and differentiated pharmaceutical products to market. Our dedicated team provides best-in-class polymers and excipients, along with state-of-the-art product design, development and manufacturing services, with the ultimate goal of creating solutions that improve patient outcomes.

Lubrizol Life Science Health is a unit of The Lubrizol Corporation. Lubrizol was founded in Cleveland, Ohio, in 1928 by a small group of local entrepreneurs with backgrounds in chemistry. The company's early success in the automotive industry foreshadowed its long-term ability to identify meaningful market opportunities and advance science for good.







WHY LUBRIZOL?

If your focus is on interventional vascular therapies and other minimally invasive technologies, Lubrizol Life Science Health should be on your preferred provider list. We offer full finished medical device design, development and manufacturing – plus engineering, quality management, and regulatory and compliance support. But what truly makes us unique is our polymer chemistry and customization expertise. This total package of integrated technologies and capabilities is designed to provide truly differentiated solutions and optimal clinical outcomes for medical device makers like you.

To discuss your next project, contact a Lubrizol device design expert.

LUBRIZOL LIFE SCIENCE

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