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MED TECH OUTLOOK

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A FULL-SERVICE MEDICAL INJECTION MOLDER

RENYMED

MATERIAL MANUFACTURING EDITION

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Steve Raiken,
President

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MEDTECH OUTLOOK TOP 10
MEDTECH MATERIAL PROVIDERS - 2020

RENYMED

A FULL-SERVICE MEDICAL INJECTION MOLDER

By Alex D'souza

An artist sees a blank canvas as an opportunity to create something the world has never seen before. For Steve Raiken, the president of RenyMed, it was his educational background in fine arts that helped him design innovative solutions for customers in the medical device industry. RenyMed looks at each project with fresh eyes, without preconceived ideas about what the project requires. "This has allowed us to make the 'process specific to the requirements' instead of 'fitting the requirements into a known process,'" says Raiken. Having created a niche in design for manufacturing (DFM), RenyMed provides customers with creative solutions to bring their medical device's vision and innovation to life—all the way from design ideation on a blank canvas to the tangible, finished production process.

Raiken established RenyMed as a one-person tool shop in the mid-1980s using borrowed equipment in a rented garage. With a focus on the medical device market, RenyMed grew alongside the growing medical-device market in California, which necessitated the manufacturing of high-precision plastic components. Today, the company specializes in medical injection molding, utilizing engineering-driven speed to production solutions combining strong customer design support with modular tooling and scientific molding process development. RenyMed has developed technology and practices to manufacture plastic components for complex medical devices within an ISO 13485 quality system.

So, how did RenyMed leap beyond the constraints of a rented garage and evolve into a company that delivers molded medical parts for Fortune 100 medical device companies across the globe? According to Raiken, it's through innovation and listening to clients requirements. This process of DFM has allowed RenyMed to create validated manufacturing solutions that facilitate the development and production of devices in a timely and cost-effective manner.

Engineering Rather than Designing

As a full-service medical injection molder, RenyMed is vertically integrated with a state-of-the-art tool room and clean-room injection molding which provides customers with an engineered production solution to assist them in the full manufacturing cycle. The company has also developed a unique prototype to production program that enables a fast product development cycle while adhering to strict ISO 13485 quality standards. "Customers are often looking for an injection mold vendor that can deliver on both creativity and quality," says Raiken. They select RenyMed when they see its creative approach to solving difficult problems and are sold when they audit the manufacturing plant to the ISO 13485 standard. Over the years, RenyMed has successfully collaborated with numerous clients helping to develop a multitude of products across all healthcare specialties. "We make products that help sick people get healthy and products that help people live longer and more productive lives. This is something we are very proud of," says Raiken.

Unique. Compact. Modular.

RenyMed continually develops technologies for manufacturing complex plastic parts for medical devices. They use a modular mold build technology that reduces cost and time in the production process. "Our team has further innovated this system to bring out compliant products with the most demanding design requirements," says Raiken. The company has also developed 5-Axis machining and small

pin grinding to help meet the demands of the medical device industry. Being early adopters of Pro Engineer and CAD/CAM software has helped RenyMed in manufacturing molds to be compliant with the product design. "RenyMed has strategically invested in tooling know-how and equipment. We build 90 percent of our molds in house and deliver 100 percent of our maintenance and repair. We are exclusively a medical device manufacturing subcontractor. All of our components are manufactured in an ISO Class 8 clean-room molding environment to ISO 13485:2016 requirements," states Raiken.

To further ensure seamless production, RenyMed has a unique validation process to ensure production continuity. They use the Stasa software program which correlates the molding process to critical dimensions and attributes in our DOE. This software helps them to see the interplay between the molding process and dimensional conformance. "We differentiate ourselves by manufacturing products that can meet the quality and sustaining engineering requirements for on-going production. Our validation process assures product acceptance during production," says Raiken. RenyMed has received "best practice" during an audit from a large medical device customer for the use of the Stasa software to improve validation outcomes.

Case Study

In one project, RenyMed was courting a large medical device OEM. The client was very interested in RenyMed's technology, but they were restricted from adding the company to their approved supplier list. One year later, the OEM requested a quotation from RenyMed for a project that they wanted to complete in six weeks. "The product required a rigid urethane material and looked like an olive skewer with all the critical dimensions at the tip, the far end of the melt," Raiken recalls. Not only were the critical dimensions +/-.002, but the flash requirement was also .002. "We completed this project on time and met all of the drawing requirements right out of the box. A few weeks later, when I met with the project engineer I asked why they were able to use a non-approved vendor for this project. He told me that an established molder had built a hot runner mold that never produced a part, only foam oozed out of the gates. It appeared to me that the molder did not understand the requirements of molding rigid urethane," said Raiken. This project was undertaken six years ago, and to date, RenyMed has molded over four million parts for this customer with a very high acceptance rate. "We are now an approved supplier," Raiken adds.

Sustaining Engineering Requirements

Established in the pre-PC era, RenyMed has continually stayed ahead of its competition for the past 35 years through the early adoption of new technologies, including high-speed machining, electric molding, robotics, vision systems, and advanced manufacturing software. While most medical device manufacturers still reside in organized silos with separate R&D, Manufacturing, and Quality units, RenyMed believes in collaboration and synchronization involving all players in the process. As a result RenyMed's manufacturing solution continually meets the quality and sustaining engineering requirements for on-going production for its customers.

Another key differentiator of RenyMed, in addition to their unique processes and technology capabilities, is the work culture they nurture. "Many years ago, I heard a talk that focused on the idea that an equilateral triangle is balanced and no side has dominance over any other side. I used this triangle concept to create our company values with three equal sides—Care, Quality, and Creativity," says Raiken. "As a result, during audits, our customers have repeatedly commented that our staff is competent in what they do and are proud of the products we make. All of our employees are taught that our products interface with people who are sick and to stay mindful of the care they would want for their own families."

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Having carved a unique niche in the industry, RenyMed is continually looking to improve the reliability of its manufacturing with automation solutions. According to Raiken, 3D printing and rapid prototyping have eased the process of evaluating a design concept, and automation is becoming cost-effective for lower volume molding. Also, technologies such as in-line vision inspection have become affordable and more reliable. To this end, RenyMed has invested in laser marking and developed specialized technology for two-shot molding, over-molding plastic and nitinol. The company will continue to embed new technologies in the near future. "We see 2019 as the end of global outsourcing and 2020 will bring greater reliance on domestic manufacturing. We are one of the few remaining domestic injection molding companies that are exclusively a medical device subcontractor. We are well-positioned to attract more business from old and new customers looking to manufacture within the United States," concludes Raiken. MT

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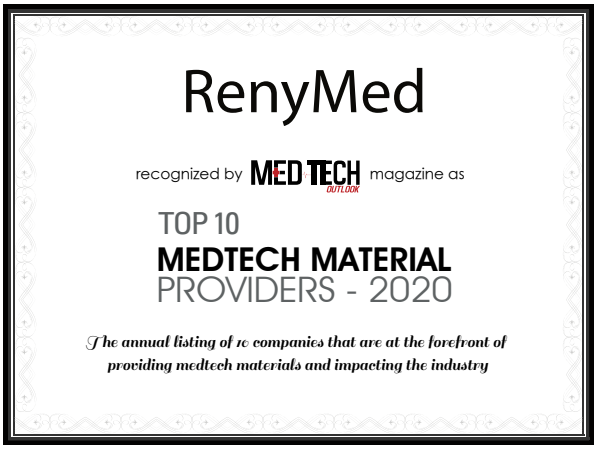

COMPANY:
RenyMed

WEBSITE:
renymed.com

KEY PERSON:
Steve Raiken,
President

DESCRIPTION:
RenyMed is a full-service Medical Injection Molder, from low to high volume production

TOP 10 MEDTECH MATERIAL PROVIDERS - 2020

From surgical gloves to imaging equipment, the medical device industry produces a wide range of products and plays a critical role in developing new medical technologies that can enhance the ability to diagnose and treat illnesses. To stay ahead of their competitors, medical device manufacturers around the world need to fast track their products to market, delivering high quality while minimizing the design and manufacturing costs. And this is why the selection of manufacturing material in the development of medical equipment is considered to be a critical step in the medical devices market.

Today, medical device design and manufacturing is benefiting from the ongoing advances in materials science. Furthermore, the development of new materials with improved properties is enabling medical devices to perform better and provide functionality that, until recently, was thought impossible. Besides, the requirements of medical device manufacturers are driving materials science to engineering new materials with improved chemical, mechanical, and electrical properties. Hence, medical device manufacturers need to collaborate with a healthcare material provider that makes strides in innovating new materials and follows the stringent regulatory standards.

To help medical device manufacturers produce high-quality products and simultaneously enable growth in the industry, MedTech Outlook has compiled a list of 'Top 10 Medtech Material Providers – 2020.' The companies listed here have the extensive business knowledge and exhibit competence in delivering cutting-edge solutions and services that meet customer needs. The magazine also comprises insights from thought leaders in the sector on the industry trends, best practices, recent innovations, and their advice for the aspiring CIOs.

We present to you MedTech Outlook's, "Top 10 Medtech Material Providers – 2020."