Devising New Devices

Medical Device Industry Continues to Grow and Innovate

Jack McGuinn, Senior Editor

Trying to get one's mind around the staggering dollar figures generated by the U.S. medical device industry is a daunting task. And unlike the countless 24/7 television ads from Big Pharma promoting, for example, the latest blood thinner medication or antidepressant or pain reliever, we rarely see widespread advertising for medical devices. Perhaps it is because, unlike many medications, using any of these devices is typically not a matter of choice. Rather, it is very often a matter of life or death — as with pacemakers, defibrillators, surgical robots, etc. And these devices are used *everywhere* — from the biggest metropolitan hospital centers to the smallest private practitioners.

So it is little wonder that, according to Government reports, "The United States remains the largest medical device market in the world, with a market size of around $148 billion, and it is expected to reach $155 billion by 2017."

Other key numbers, according to the report (*www.selectusa.gov/medical-technology-industry-united-states*) — "The U.S. market value represented about 43 percent of the global medical device market in 2015. U.S. exports of medical devices in key product categories identified by the Department of Commerce (DOC) exceeded $44 billion in 2015. There are more than 6,500 medical device companies in the United States, mostly small and medium-sized enterprises (SMEs). More than 80 percent of medical device companies have fewer than 50 employees, and many (notably innovative start-up companies) have little or no sales revenue. Medical device companies are located throughout the country, but are mainly concentrated in regions known for other high-technology industries, such as microelectronics and biotechnology. The states with the highest number of medical device companies include California, Florida, New York, Pennsylvania, Michigan, Massachusetts, Illinois, Minnesota and Georgia."

The medical device universe, by application:

- ***Electro-medical equipment.*** Includes a variety of powered devices, such as pacemakers, patient-monitoring systems, MRI machines, diagnostic imaging equipment (including informatics equipment) and ultrasonic scanning devices.
- ***Irradiation apparatuses.*** Includes X-ray devices and other diagnostic imaging, as well as computed tomography equipment.
- ***Surgical and medical instruments.*** Includes anesthesia apparatuses, orthopedic instruments, optical diagnostic apparatuses, blood transfusion devices, syringes, hypodermic needles and catheters.
- ***Surgical appliances and supplies.*** Includes artificial joints and limbs, stents, orthopedic appliances, surgical dressings, disposable surgical drapes, hydrotherapy appliances, surgical kits, rubber medical and surgical gloves and wheelchairs.
- ***Dental equipment and supplies:*** Includes equipment, instruments, and supplies used by dentists, dental hygienists, and laboratories. Specific products include dental hand instruments, plaster, drills, amalgams, cements, sterilizers and dental chairs.

And don't forget the design-specific software that helps make all of the above possible. But that's another story for another day/issue.

Advocating and facilitating all of this activity is the Medical Device Manufacturing Association (MDMA). Formed in 1992, the MDMA's primary mission seems to be lobbying in D.C. for the industry's best interests. On its website (*medicaldevices.org*) we learn, "The medical device industry has seen significant regulatory changes in recent years, affecting legal and administrative issues, relationships with providers and more. Members benefit from MDMA's expertise on compliance issues through interacting with key government enforcement officials, legal experts and other member companies to discuss best practices."

Unlike say, the American Gear Manufacturers Association (AGMA), the MDMA is not a font of knowledge regarding engineering and manufacturing processes. But they will soon have available a "compliance toolkit" for members that includes "sample governance documents, training documents and auditing documents." Relatedly, MDMA's Compliance Working Group typically meets on the last Tuesday of each month (2:00 p.m. ET via teleconference).

The MDMA also informs: There are "numerous provisions of the Affordable Care Act (ACA) that continue to be implemented, impacting med tech innovators and all stakeholders in the health care delivery system." Also on the group's target

list: lead the effort to repeal the medical device tax; ensure that the regulatory environment is more predictable and reasonable; and that there is a fair and adequate reimbursement system in place for medical technology.

You may think the manufacture of these devices requires exceptional skill and attention to detail, and you'd be correct. That extra attention helps in making, for example, extremely precise FDA-certified injection-molded plastic parts and gears, or absurdly toleranced CNC-machined metal gears, as well as components like slewing drive controls with required zero backlash and many other parts.

(Before going further, it should be noted that the 3-D printing of gears and other medical device components is definitely a technology with momentum. And while the insanely fast, 3-D printing of pricey prototype parts is a huge benefit for product designers and production managers, other 3-D-print-generated wonders await. Or have already arrived; folks — we're talking *body parts.* Look to future issues for more 3-D-related content regarding 3-D technology's role in power transmission or medical device updates.)

We talked to two companies — one making metal gears for the medical machine/device industry, the other a supplier of plastic gearing — in order to get a better understanding of how this extremely complex, extremely niche industry works. Contributing are George Diaz, general manager, The Gleason Works-Gleason Plastic Gears; Brian Springer, Gleason senior plastic gear engineer; and Brian Dengel, general manager, KHK-USA.

PTE. Which plastics are typically being converted for medical device components?

Brian Springer: Gleason Plastic Gears has developed strategic relationships with all the resin suppliers in the world! Material (plastic resin) selection is highly dependent on the specific application(s). For gearboxes, the operating temperature and gear loadings (torque, speed and operational mode) will drive material selection. If the application involves human contact, plastic resin must be cleared for use per ISO 10993 and United States Pharmacopeia (USP) guidelines. It is important to note that material selection may also be impacted by the medical device's sterilization requirements.

Brian Dengel: We recommend food grade (FDA) nylon as it is suitable for washdown environments.

Which metals (titanium for example) are best-suited for metal medical device components?

Springer: Stainless steel has been the most commonly used metal in medical devices for quite some time due to low cost.

Dengel: We recommend 303 stainless steel for these applications.

Is strength the greatest attribute for metal gears in medical devices?

Springer: This is also highly dependent on the application, but I would say yes. Typically metal gears would only be used in medical applications if a plastic gear is not strong enough, or will not last long enough. Metal gears are typically a bit more expensive, heavier, and noisier. Plastic gears provide significant advantages in cost, weight and noise.

Dengel: Strength is the primary advantage. Nylon gears can be used but need to be sized accordingly. If the package size is the controlling variable, then metal gears are preferred. If size is not the controlling variable, then use of a nylon gear will eliminate the need for lubrication, will allow for quieter operation and will absorb some vibration in the system.

Please explain what a manufacturer must do to gain certification for the manufacture of medical components. Are both the ISO and the FDA involved in certification?

George Diaz: In order to manufacture and ship finished goods (medical devices), the FDA requires that the site be

photos courtesy KHK-USA.

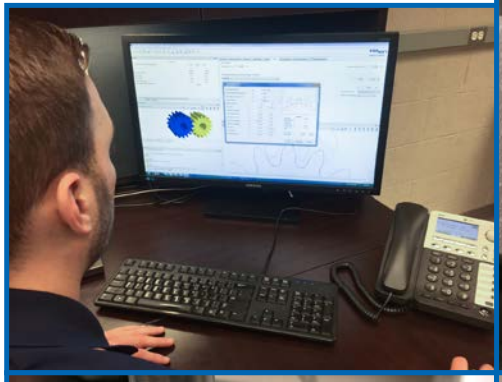
a FDA registered facility that complies with ISO 13485. Gleason Plastic Gears currently molds precision gears for medical and drug delivery devices. As a sub-tier supplier, Gleason is required to follow strict guidelines regarding the product and process validation for the supply of medical gears. In the product development arena, Gleason is typically involved in the design and development of the actual gear specifications and ultimately some of these specifications are included in the device's design history file (DHF). During the process validation, Gleason offers a variety of a la carte options for the execution of validation protocols and reports embracing the FDA's guidance related to installation qualification (IQ), operational qualification (OQ) and performance qualifications (PQ). In the end, these efforts ultimately define a process operating window that ensures the manufacturing process produces product that conforms to specifications!

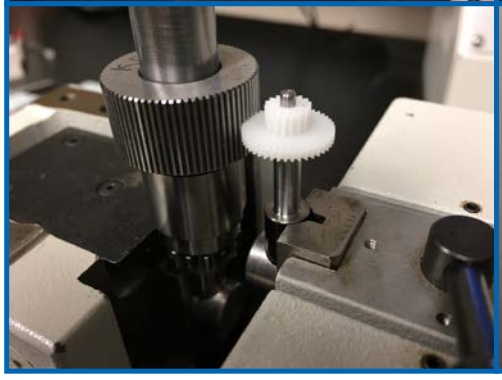
Dengel: The primary certification for medical devices is ISO 13485:2016. This is a much stricter standard than the ISO 9001:2016 certification that many gear companies have obtained. A big difference between the standards that is driven by the difference in scope is the primary focus of the results. The general nature of and the industries that use ISO 9001:2015 are driven by customer focus and making the correct risk-based decisions to minimize the risk of customer dissatisfaction. Meanwhile, the focus of ISO 13485:2016 is primarily driven by the need for regulators to ensure that the medical devices placed on the market by organizations are safe and effective.

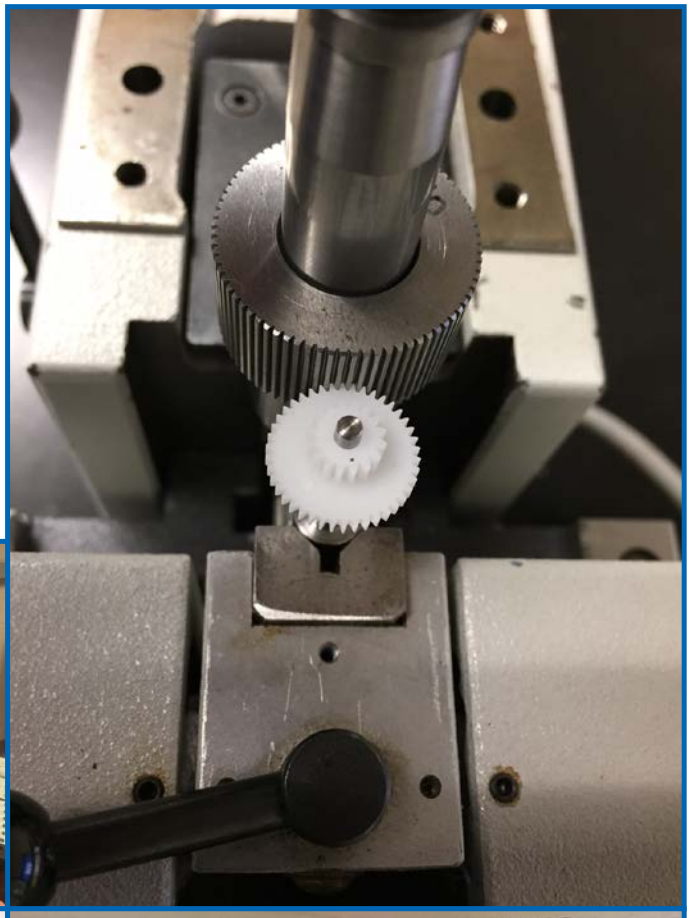
Given multi-discipline complexity in making these parts (e.g., design, material specification, sophisticated software, CNC machining, etc.), how "vertical" need a company be in order to compete in the medical device industry? For example, if a supplier is making gear motors for medical devices, does that motor supplier also make the gears or contract them?

Diaz: Gleason offers a variety of options to address the complex needs of the medical device industry. From a design perspective, the recent acquisition of *KISSsoft* gear software enables us to participate in the early stages of the gear / gear train development process. From a prototyping perspective, Gleason offers early prototype supply leveraging additive manufacturing technologies as well as CNC direct machined samples. Gleason can supply medical device customers with individual gears or modular gearbox subassemblies containing motors. Ultimately, Gleason's goal is to design and validate a gear manufacturing solution that leverages Gleason's world class metrology core competencies at the lowest possible cost.

Following up on the above—are single-source suppliers the biggest players?







photos courtesy Gleason Plastic Gears.

Diaz: The medical device industry is a very complex, highly regulated industry that demands 100 percent safety and efficacy in product performance. Given the complex idiosyncrasies of gear technology, Gleason's approach is to support all medical device customers in need of gears regardless of the company's size.

What types of gears are typically used in medical devices?

Springer: Typically gears are kept as simple as possible, especially if the device is for one-time use only. Most designs start with a combination of spur gears, racks/pinions, and crossed-axis helical. Reducing the complexity of the gears will help reduce the costs, especially if the gears are injection molded or powder metal. It is important that during the design stage, the performance versus cost/manufacture-ability is weighed carefully.

Leveraging Gleason's 152 year gear technology heritage, Gleason Plastic Gears offers gear design support for the cylindrical and bevel world! We can design spur and helical gear solutions for parallel and cross axis applications. We also can support cycloidal and epi cycloidal solutions.

Are bearings typically involved? Both plastic and metal?

Diaz: The *KISSsoft/KISSsys* software (recently acquired by Gleason Company) offers the capability to model bearings within the suite of product solutions. Gleason Plastic Gears can support the use of various bearing solutions based on specific operating conditions.

What hurdles are there in achieving the precision required for medical devices?

Diaz: Gleason Plastic Gears no weldline technology enables us to deliver the highest gear quality level within the injection molding industry! Keeping the gears round, especially when using highly engineering resins, is a difficult task. It is important that the manufacturing process is laid out correctly, the tools are accurate, and that the proper gear metrology is used to ensure gear precision. If making metal gears with heat treatment requirements, understanding how to account for and to correct gear distortion due to heat treatment is critical. This is something Gleason specializes in, in both the metal and plastic worlds.

Is the Food and Drug Association (FDA) the primary "watch dog" for component manufacture?

Diaz: The FDA is responsible to ensure that all medical devices are safe and effective. At minimum, all finish goods medical device manufactures must meet FDA requirements based on the ISO 13485 guidelines.

Is the International Standards Organization (ISO) the only regulatory body (e.g.—ISO 13485:2003), or is AGMA involved as well? Comparing metal gear standards with plastic gear standards is like comparing apples to oranges, correct?

Dengel: AGMA does not have a standard for medical device components. The standards are based on the type of gearing, i.e.—spur gears, bevel gears, worm gears. The standards are also independent of material selection. An AGMA 9 quality gear needs to meet the same dimensional specifications where it is made from aluminum, nylon or alloy steel.

Springer: The medical device guidelines are equally applicable to metal or plastic gears. Although the manufacturing processes are different between metal and plastic gears, the manufacturing process must be fully validated per the required medical specifications.

Where would you say the idea for a new medical device begins? With the surgeons/doctors? Design engineers? Elsewhere?

The requirement for a new medical device typically starts with the users and people most involved with its end use or need. When a need is recognized, it is trickled down to major players in the industry. If the desire for a new device is in high demand (and of course, if the dollars make sense), this triggers the medical device manufacturers to pursue a conceptual design phase in which product design and feasibility are kicked-off.

Are you coping with the scarcity of skilled personnel available for such quality-driven work? Or not a problem?

Diaz: Gleason's world-class heritage continuously attracts the best gearheads in the world. Our Gleason Plastic Gear Division (Rochester, NY) is always inundated with local skilled personnel interested in supporting our business needs. Our strong relationship with Rochester Institute of Technology's Kate Gleason School of Engineering enables us to recruit the best students within the school!

To what extent has the relatively recent "discovery" of mechatronics, along with the latest IIoT/industrial automation advances, affected the manufacture of medical device components?

Diaz: Medical Device manufactures are under significant pressures to produce defect-free products. The establishment of the Gleason Automation Systems Division has enabled our metal machining centers to become machining system solutions. Gleason can now offer highly integrated inline solutions involving the unique (marking) serialization of each part as well as the integration of a 100% online gear inspection system. These readily available machine options ensure that all critical gear dimensions meet the product specification. **PTE**

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