Perspectives on Manufacturing Technologies, Part IV

The capabilities of manufacturers are growing to enable the fabrication of components that are extremely tiny, very complex, and incredibly intricate. These advances are leading to medical devices that could not have been developed just a few years ago. With this in mind, this months Perspectives asked about how these capabilities would impact future devices.

How will new(er) manufacturing technologies impact the design and/or capabilities of upcoming medical devices?

Jennifer Petrosky
Life Sciences Industry Market Development Leader, ENOVIA, Dassault Systèmes

Success in medical device manufacturing requires continual innovation to deliver improvements in the quality of patient care that will, in turn, drive revenue and profits. However, as one of the most heavily regulated industries in the world, the process of developing and documenting new innovations creates a number of barriers for medical device companies. This situation is also made more challenging by the fact that too often product development and regulatory compliance functions are siloed, creating multiple information systems and manual processes that extend the design cycle, increase costs, and ultimately, impact product quality.

Solutions like product lifecycle management (PLM) can have a critical role in creating a standardized approach to managing key business processes (including regulations, compliance, and IP management). By creating a collaborative environment, different functions within the organization can work together more

efficiently to design, manufacture, and distribute new products in a timely and cost effective manner. Having a technology that can span the entire product development process and the majority of the quality systems processes within a single environment is beneficial to manufacturers as it makes it easy for contributors within the different groups of product development and quality systems to access the information they need regardless of who created or owns it. Workflows can be developed that cross boundaries within and between product development and regulatory compliance, enabling the automation of many processes that are currently handled manually.

Successful medical device companies are supporting the FDA's Total Product Lifecycle (TPLC) methodology with supporting technologies such as Product Lifecycle Management (PLM). Together, TPLC and PLM enable medical device manufacturers to deliver innovative, compliant-ready products that meet revenue targets and are consumer price-friendly. Compliance is a necessity throughout the product lifecycle, mandated by increasingly vigilant government agencies. In successful companies, compliance is the outcome of an effective, proactive business strategy that uses a PLM end-to-end system for providing complete product lifecycle traceability while facilitating manufacturing efficiency and productivity. In addition, these companies can achieve strategic, competitive growth measures, such as increased quality, more innovative products, and faster time-to-market.

Adrian Possumato
Global Director, Healthcare Packaging, Multisorb

Medical device development has become very complex in recent years. Device manufacturers are looking to create products that are not only more functional, but also aesthetically evolved as compared to products previously available on the market.

One critical aspect of preserving device performance without compromising its design appeal is the regulation of moisture and oxygen levels within the product's primary packaging. Sorbents (also known as "active packaging components") are a proven method for preventing device malfunction from moisture, oxygen, and/or volatile hydrocarbon to maintain product stability and shelf life.

Traditionally, sorbents were simply dropped into the product packaging to effectively manage the environment within the device. Today, this approach has given way to new sorbent technologies that offer greater value by assuming the role of design enablers.

Next-generation sorbent technologies are custom manufactured to a particular shape and size to fit into the device itself, creating an "onboard" solution. Sorbent properties are now built into the structural components of the device, adding multifunctional capabilities to an existing device part. The design flexibility offered by such sorbents enables customized moisture and/or management to preserve reagent efficacy and, in turn, brand integrity.

Faina Zaslavsky
Group Director, Microelectronics Solutions, Crane Aerospace and Electronics

Smaller footprints and added device functionality are trends and desires nearly every electronic manufacturer has experienced in recent years. The methods with which these goals are achieved have varied by product application and manufacturing capabilities. However, medical device manufacturers face the additional challenge of balancing a limited design workspace with long term reliability requirements.

Medical packaging can only miniaturize as quickly as new materials and process capabilities allow without impacting reliability. As widely accepted commercial methods, such as thermosonic stud bump flip chip and multi-chip stacking, become

more proven, the medical industry will adopt them. Material manufacturers are also influential during this transition as low stress encapsulants are developed, for example. Shrinking package dimensions also alters material properties and device behavior which drives this continuous demand for novel materials.

Process capability becomes increasingly crucial as package sizes shrink while component densities increase. Therefore, in addition to material development, the enhancements of semiconductor possessing equipment are just as important. New features, such as real-time wire bond deformation sensors and integrated barcode reading capabilities, help improve product yields and device traceability. These improvements are just as vital to maintaining the level of product reliability demanded by medical device manufacturers.

Richard Parenteau
Director of Applications Development and Nakamura-Tome Product Manager, Methods Machine Tools Inc.

Increasingly intricate design features, high accuracies, and a competitive industry dictate a manufacturing process for medical devices that will produce quality parts and yield optimal productivity and profitability. Each time an additional operation needs to be performed and a new set-up is required, costs are higher and productivity is decreased.

To address today's more complex design features and manufacturing efficiencies, advancements in multitasking lathe technology can offer significant benefits. Machine tools builders now offer turning systems with a twin spindle (20 to 30 HP) and three turrets with all turrets Y-axis capable. The three turrets provide 36 to 72 tool stations–capable of 10 HP milling at 40 Nm torque on all stations.

This technology allows production of medical parts with intricate features. Three tools simulations can occur in the cut for dramatic cycle time reductions. And since

the bar stock actually becomes the fixture, no additional fixtures are necessary to produce complex shapes with tight geometric tolerances.

Both short and long production runs can be made with great efficiency because no setup time is required. The three turrets with multiple tools resident means no tool changes are needed–the operators can change the bar size or workholding, call up a new program, and start making the part.

Multitasking offers several advantages to medical device manufacturers–most significantly, reduced process time/cycle time to produce a complete part.

Jacques Hoffmann
President, InterTech Development Co.

The industry is trending toward 100% inspection and testing of every device (and every component) to come off the assembly line and to incorporate in-process testing whenever possible. In the coming years, we expect this trend to continue and for it to drive attention toward ways to cut testing costs during medical device assembly.

In-process testing, as opposed to end-of-line testing, will be especially important for medical devices that require high amounts of labor to assemble or that incorporate higher-priced materials in later stages of production and assembly. Already, we see that the more competitive medical device manufacturers make intelligent use of in-process testing to avoid finishing otherwise defective parts.

More rigorous leak testing, for example, with custom-built sensors that yield a higher gauge R&R, as well as cut testing cycle times, will continue to gain in popularity because the return-on-investment of such leak test instruments compared to off-the-shelf generic testing technology is significant in nearly every medical device and medical product application.

A variety of integrated test centric systems will be used, from dials for high volume applications to lean cells for manual operations in areas where labor costs are lower to power and freed up for more flexible capabilities.

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