Perspectives on the FDA UDI Rule, Part I

The FDA's upcoming UDI rule will impact all medical device manufacturers. To what degree, however, will vary from company to company, based on what systems and technologies are already in place. For this month's Perspectives, industry leaders gave their opinions on how they thought the rule would affect the industry.

What impact will the FDA's UDI Rule have on the medical device industry next year and into the future?

Rene Inzana
Product Manager, SYSPRO

FDA's UDI rule should have little impact on the medical device industry. Most medical device manufacturers currently employ sophisticated software that enables them to trace parts and lots back to their source. SYSPRO ERP software, for example, even allows one-to-one tracking between component serials/lots and parent item serials/lots, which gives manufacturers the ability to track a component to a specific parent. The introduction of an identification standard can, however, have tremendous benefits for users and technicians by providing a simple means of determining the exact function of a device that may be similar in appearance to another device.

Nick Lukianov
Technical Director, Avnet EMA - Vertical Segments

When involved in the medical device product lifecycle, it is critical to remain cognizant of the developments and implementation of an industry wide UID standard. What type of UID technology will be mandated? What will be the compliance and certification requirements? What will be the ability to withstand a variety of sterilization methods? How receptive will the supply chain be to the adoption of a UID system and the obvious cost issues involved? What are the enterprise level integration issues? Who's going to pay for it? What are the privacy issues?

Technologies being considered for the implementation of the FDA UID mandate are bar codes, RFID, OCR, and DPM (direct part mark). RFID is considered to be "intelligent" based on its one-time and multiple programming capability. A serial number is embedded during the manufacturing process along with a number of security and data management features that address cloning, multiple use, shelf life, patient/device data, and device parameters. Device manufacturing methodologies exist that withstand sterilization techniques. Custom inlays with extensive adhesive and label conversion services accommodate a variety of solutions to provide a true "smart tag" RFID solution.

Laura Weisensell
Senior Medical Consultant, IQS

The FDA is aggressively pursuing the development of unique identifiers (UDI) for medical devices, in collaboration with industry and healthcare providers, in order to easily identify specific medical devices for the purpose of patient safety, delivery of clinical care, and tracking of clinical outcome, as well as improving product, supply, and material management processes. Challenges associated with developing an automated UDI track and trace process include designing and/or buying and implementing the proper technology systems–bar code identification systems or RFID–and the basic system components, and understanding the implications of industry standards associated with each of these technologies. Another potential challenge for UDI is the enormous diversity of medical devices available on the market, and the cost-to-benefit justification of technologies as one system may not work for every type of device.

Unique identification is key in helping track and trace surgical instruments and other supplies through the decontamination and sterilization process, and most importantly, in tracking recalls of medical devices. With the appropriate inventory management system in place, companies can instantly validate that an action has occurred or that a particular item is no longer available to be shipped. The opportunities to reduce risk through validating an action by bar code or RFID scan could help reduce errors and waste while providing device identification and documentation to assist management in establishing service or replacement directives.

Eric Ostini
Product Manager, GF AgieCharmilles

The FDA's UDI Rule will present some new challenges to manufacturers of implant devices. For many such devices, surface finish is vital to the human body accepting a component in a healthy manner. Breakthroughs in EDM and other machining technologies have made great strides in achieving these surface finishes in a cost effective manner. When the UDI Rule goes into effect, many companies will have to rethink aspects of part design and manufacture, as even the smallest of variations in surface finish can affect a part's effectiveness.

Take, for instance, a standard hip replacement, which requires four unique components. For the piece implanted into the femur, there are several spots where a small marking would have little effect. On the other hand, the cup portion that actually holds the joint is far less forgiving. The main surface of this component needs to be completely free of any variation or else it can create great discomfort for the recipient. Placement of a UDI marking will require special consideration during design of this type of component.

Additionally, many manufacturers now produce parts in one or two setups, minimizing machining time and costs. For most implants, UDI markings will require either laser etching or acid burning, adding an additional step to the manufacturing process.

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