UDI Mistakes

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Q: *Regarding the implementation of UDI (unique device identification) across the medical device industry, what mistakes are being made?*

Some medical device manufacturers do not fully understand the requirements – including the need to design new systems that meet compliance requirements while maximizing the use of existing hardware, software, and personnel. While many have been through this process (first compliance deadline was September 2014), others have yet to address the regulation, as new deadlines for different classes of devices quickly approach. To adequately prepare, manufacturers should consider:

1. What hardware/software is currently used to manage device inventory and distribution?
2. What volume of devices does the company handle?
3. Does the device production volume allow someone to manually key in the information to the Global Unique Device Identification Database (GUDID), or will a software solution capable of automated transmission be needed?
4. Is there a staff member who understands the relationship between the manufacturer and the FDA, and is that person qualified to prepare data for the GUDID?

Additionally, some manufacturers are uncertain or have misperceptions about implementation time and cost, leading to delays. It is recommended to develop a detailed budget and project time frame for implementation, considering all necessary variables and allowing flexibility for unforeseen setbacks.

Manufacturers should also consider meeting with a supplier or systems integrator to help expedite the scope and implementation of a UDI-compliant system.