Medical Device Data Systems

An expanded FDA ruling may affect your organization. Learn how and what you can do now to prepare.

Today’s Environment
At a time when healthcare providers are already overwhelmed with regulatory-driven initiatives, another compliance deadline is fast approaching—and it’s very possible that organizations are unaware of it, or assume they’re unaffected.

Under the FDA’s recent Medical Device Data System (MDDS) regulation 21 CFR 880.6310, some hospitals, healthcare facilities and IT companies will now qualify as “MDDS manufacturers.” Those who fall under this reclassification must demonstrate compliance with the new federal regulations by April 18, 2012—just as mainstream manufacturers will.

This new rule is the first time that the FDA has potentially imposed manufacturer regulations on hospitals. It extends the definition of an “MDDS manufacturer” to hospitals, healthcare facilities and IT companies that design, develop, modify, install or market Medical Device Data Systems. In the simplest terms, MDDS are conduits for medical device data—hardware or software that connects to a medical data device to capture, transfer, store, convert or display medical device data. Examples of MDDS are as common as products that transfer lab results to a nursing station, collect and store patient CO2 levels or blood pressure, convert pulse oximeter digital data into a printable format, and display a patient’s electrocardiogram.

The FDA’s new ruling affects many organizations that have never considered themselves to be “manufacturers.” Does your organization fall under this reclassification? If so, what must you do to demonstrate compliance?

Point B’s Perspective
In our work with healthcare providers across the country, we are identifying potential risks and gaps that organizations face in complying with the new MDDS rule. At a minimum, hospitals, healthcare facilities and IT companies need to devote the time and resources it takes to interpret the ruling, determine whether they’re affected by it, and assess MDDS solutions accordingly.

The new rule’s most significant impact will be on hospitals and healthcare facilities that are not in the business of “manufacturing”—and are not accustomed to interpreting these FDA regulations or demonstrating compliance. Hospitals and healthcare facilities that find they qualify as MDDS manufacturers under the new rule will most likely have work to do in implementing MDDS evaluation and management systems compliant with FDA design controls (21 CFR 820). The amount of effort required will depend on the magnitude of an organization’s MDDS scope and the maturity of its existing quality systems.

How to proceed? You’ll want to develop a compliance readiness roadmap that includes assessment of existing quality processes and reporting capabilities, followed by alignment efforts to address any compliance gaps. If you have design control-compliant processes in place and MDDS have been validated through an existing quality lifecycle, you are well positioned to demonstrate compliance. If not, you’ll need to roll out improved quality processes and put existing and future MDDS through the lifecycle.

You’ll also want to be prepared for a potential FDA audit. Take time now to define an FDA audit readiness strategy—and to identify the roles, responsibilities and documentation required to prove due diligence and compliance.

For hospitals that fall under the purview of this new ruling, compliance efforts could take several months or more. Project and change management will be essential to facilitating the
change needed and ensuring adoption. We recommend that the ultimate goal should be to operationalize the process to become part of the day-to-day system development lifecycle (SDLC). You may want to consider establishing controls that mitigate additional “manufacturing” of MDDS products to minimize the burden of compliance. You’ll also want to evaluate your MDDS manufacturers to validate that they are compliant with this ruling.

Finally, in addressing this new regulation, we encourage organizations to take advantage of the opportunity for device manufacturers and hospitals to work together. Hospitals can benefit from a manufacturer’s knowledge of FDA device rulings—how to interpret the ruling, the best practices for implementing design controls and quality systems, and what it takes to demonstrate compliance. Also, there may be strength in numbers: When manufacturers and healthcare facilities unite around a shared interpretation of the new rule, they demonstrate a united, good faith effort to comply.

For MDDS manufacturers that are not currently regulated, this rule is a clear message that the FDA intends to regulate these products. The magnitude of your work to achieve compliance will depend on the maturity of your product development lifecycle, quality system and reporting capabilities.

Begin by analyzing each product’s intended purpose and determine whether it qualifies as an MDDS. If it does, you’ll want to develop a compliance readiness roadmap and execute it. This should include designing and implementing design control compliant processes and adverse event reporting capabilities, the redesign of product development processes to integrate quality and compliance readiness, and the education and training that your organization will need to operationalize the change.

Savvy manufacturers should also look to this new ruling as an opportunity to revisit their go-to-market and sales strategies as consumers seek out manufacturers that are recognized for their compliance.

MDDS manufacturers that are currently regulated by device classification requirements will find good news in this ruling. The original intent to classify MDDS as Class III devices was reconsidered as part of the rule drafting process. In result, MDDS are considered Class I devices. For manufacturers accustomed to demonstrating compliance with device regulations, the impact of this new rule should be minimal. In theory, this rule should enable them to get products to market faster and more cost effectively.

Still, it represents a change that must be assessed to realize the benefits of reclassification, minimize the risks of an adverse event, and maintain product quality. Adapting to this change calls for understanding what products meet the definition of an MDDS, educating the organization accordingly, adjusting product development and quality processes as needed to ensure compliance, and actively managing the change to ensure that businesses operations and customer service are not negatively affected.

The Bottom Line
The FDA’s new MDDS ruling is uncharted territory for many of the organizations that are affected by it. Even if your organization deems that it does not “manufacture” an MDDS, it should at least conduct a risk assessment to prove that it has done its due diligence and validation in the event of an FDA inspection. In its final ruling, the FDA indicates that a risk analysis should be completed, making it in your best interests to take this step.

About Point B
Point B is a national management consulting firm. We help our clients solve their toughest business challenges by combining strategic insights with hands-on practicality. We serve organizations from visionary start-ups to Fortune 100 companies across a variety of different industries and functional areas. Point B is regularly honored by many publications as an exceptional place to work, including the Wall Street Journal and Consulting Magazine.