



# Innovatum

## Case Study - FDA Mandates Prompting Changes

Change for the sake of change does not make sense. However, when change is mandated by the FDA it can be a good impetus to do more than just comply, it can be a driver to make the most of an opportunity to improve as a company. One such example is the way that a medical device company called Key Surgical, located in Eden Prairie, Minnesota took advantage of FDA compliance mandates in a number of innovative ways. In the process they revamped their product labeling, realized new levels of efficiency and return on investment (ROI) as well as improved their relationships with their customers. Understanding Key Surgical as a company helps us to better understand their proclivity for change.

### About Key Surgical

Key Surgical is a leading manufacturer of medical device products that are used for central sterile and sterile processing areas of a hospital. Key Surgical manufactures for themselves and produces OEM products for other companies. Their core focus is disposables that are used for cleaning, tracking, marking, and identification of instruments after they have been used. The disposables are designed for getting the instruments ready for the next use. Key Surgical also has a growing line of sterile operating room products for use during surgeries. What makes Key Surgical different is their branding and personality, being out there as a fun, colorful, vibrant and innovative company in a field that is (as they describe it) generally considered to be pretty boring. They have a focus upon fun but most importantly, an emphasis on quality and great customer service. Key Surgical prides itself on getting to know its customers and delivering products that make their customer's jobs easier. But their product labeling process was making these aims difficult.



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### Finding a Labeling Solution

Prior to finding their present labeling solution from Innovatum, Seagull Scientific, and QuickLabel Systems, the Key Surgical labeling operation was very tedious. In the beginning of the evolution of Key Surgical labeling operations, if label producers needed to make a change, several databases needed to be updated while figuring out where to go to find information. Labeling not only took a long time, the labels for all of the various product lines had the same template and feel. The people who were responsible for creating the labels were going in and setting up the labels and entering the part number and all of the required information manually. A database for the labels was not in use. Consequently, there were a lot of opportunities for errors. Labeling was very time consuming and inefficient and controls could have been stronger.

Eventually, a new found International market for their products created a corresponding need for Key Surgical to deliver language translations on labels. This made the desire for the improvements that can only be brought about by a database driven labeling system even more paramount. Initially Key Surgical worked with a different company to build a database driven product labeling solution using Microsoft Access. As a result of this initial effort, Key Surgical was able to know which label they were going to use and did not need to worry about content because it was coming from a database. However, this system was soon outgrown. Key Surgical was not able to maintain as many changes as they liked and the solution lacked many important FDA controls such as having a record of when changes were made to a label. Most importantly, when label management personnel were not available, label operations were held up. According to Lena Cordie, Director, Operations, “We needed to grow our labeling process to match the efforts that our company was going through and that brought us to making some important changes.” Product labeling needed improvement in order to be able to deliver maximum benefit to customers regardless of whether they were product users or OEM customers.

### FDA Announces New Plans

The urgency for an improved medical device label management and printing solution grew exponentially when the FDA announced their plans to institute a mandate for UDI (Unique Device Identification). Since adopting a solution set from Innovatum, Inc. known as ROBAR which embeds BarTender® from Seagull Scientific, along with the Kiaro! printer from QuickLabel Systems, Jana Hydukovich, Key Surgical Manager, Quality & Regulatory says, “We have been able to brand our labels in a way that defines them in a format that matches our marketing formats and also come up with a formal label management program for creating, reviewing, revising, and releasing labels, approving translations, more or less just streamline the entire process.” Hydukovich goes on to say, “We now have multiple people review the approving of labels rather than having to just wait for one central person to manage that process. It just really helped improve our entire operation.” Regulatory label compliance is mandatory but it is nice to wrap it in with ROI.

Commenting further on the ROBAR software that ties their solution together, Cordie says, “I think that it has brought confidence- it has helped us to take out opportunities for error and to automate. We used to manually inspect our labels, but taking a few steps out of this process has helped us to gain much more productivity.”

Both Hydukovich and Cordie strongly agree that Key Surgical is benefitting greatly from the partnership between QuickLabel and Innovatum. Using the Kiaro! printer, they are able to match color coding in their catalogue to correspond with label template colors. This greatly simplifies the order and replenishment process and makes their customer’s jobs easier. But sometimes, finding the right path can involve a close call.

Prior to finding Innovatum and QuickLabel, Key Surgical was knee deep into going down another path with a different labeling solution. But according to Cordie, she was attending a device labeling conference and as she puts it, “I saw the labeling software and I saw the printer and my mind started to explode. I remember texting Jana with the message- don’t do anything.” Lena scheduled a ROBAR labeling demo a day or two after she got back. As she put it, “literally it was like slamming on the brakes and going in the opposite direction. Once we sold it to management and I got the team on board, from the time we said go ahead to the time that we implemented it, was about a month.”, “Previously it had taken about six to nine months planning out how we were going to do this upgrade and decide on a solution.” But a label design and management solution can only be as good as its underlying design engine.

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Hydukovich says about ROBAR's integration of BarTender from Seagull Scientific, "It has a lot of flexibility, creation of the templates is easier, we can add many more images. We have been able to add barcodes, just kind of enhance our labels and make them look a little more mature than they used to." And regarding the combination of ROBAR and Kiaro! Cordie says, "The flexibility of the software for creating and designing allows us the opportunity to do private labeling for our customers. If they (OEM customers) want us to put their label on a product we can easily do that. For one reason, we are now using blank stock. Using the Kiaro!, we are able to use colors and we are able to use images. The technology is allowing us to do things that we were not able to do before. There is more functionality available to us." The UDI rule from the FDA creates some challenges for medical device product labeling but the challenges extend beyond mere label design and printing.

Regarding the exclusive ROBAR solution that encompasses both label management and printing as well as UDI (attribute) information upload management, Key Surgical says, "We like to use the ROBAR database as our central repository for regulatory information so if we are already able to store a lot of those UDI product attributes in that database and more efficiently upload to the GUDID, it will save a lot of time." Being able to use a database that reaches out into other databases to pull together UDI related information in a 21 CFR Part 11 compliant way and then upload to the FDA GUDID, GS1 GDSN or other similar databases sets the ROBAR solution apart.

Regarding ROI from the ROBAR, BarTender and Quicklabel solution, Cordie says, "It is smart software, it is smart technology. When you have a company that is always thinking ahead, that is already thinking about UDI implementation, we thought hey, lets jump on this and grow together." She went on to say, "It was off the shelf but works as if it is custom. It was the best tool for us."



Innovatum builds enterprise software systems for the compliance challenges of highly-regulated industries. Our personnel have years of experience implementing ERP and enterprise labeling systems and integrating the two in validated Part 11 compliant environments. Combining this with our executive leadership role in the AIM North America UDI Committee and our technology, including the GS1 certified label design and print engine, makes Innovatum an exceptional partner in addressing all labeling challenges.

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Key Surgical is a leading provider of sterile processing, operating room and instrument care supplies. Committed to manufacturing and distributing the highest quality products, Key Surgical maintains the highest level of applicable ISO and FDA requirements. Continual dedication to personalized customer service and an extensive product line allow Key Surgical to serve the needs of hospitals, surgical centers and more throughout the U.S. and internationally.

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