



# Compliance with UDI Labeling Mandates: A Proven Methodology

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*A Cost-Effective Approach for Meeting the Healthcare Industry's Biggest Supply Chain Challenge*

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**LOFTWARE**

WHITE PAPER

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*There has never been a better or more urgent time  
for manufacturers of healthcare products to make a  
close examination of their product labeling systems.*”

**Why?** Because in most cases, existing solutions were developed over time, usually organically and often departmentally, individually and separately by each manufacturing entity to a labeling standard of their own choice. This approach has mostly worked, albeit at great expense, with much inefficiency, and at the tremendous risk of error, manufacturing interruptions, counterfeit labels and a host of other problems. But in addition to these well-known limitations, there is one additional major reason why now is a good time to explore labeling solution alternatives. New labeling mandates from the FDA – now expected to be imposed no later than September, 2013 – are going to require all healthcare products manufacturers in the United States to adhere to a uniform set of Unique Device Identification (UDI) labeling standards. This means that proprietary labels and any labels that are not part of a universally-accessible database for common use by all other manufacturers and at all checkpoints in any supply chain will, virtually overnight, be a thing of the past in the United States. In fact, it is likely the FDA initiative will further drive the global effort occurring at this time to effect this same kind of UDI solution worldwide.

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**Until now**, many healthcare product manufacturers have adhered to what they see as a sensible, cost-effective philosophy: if the current labeling system isn't broken, even if it may be Byzantine, hard to manage and unpredictable, why fix it? But as healthcare CIOs, IT directors, packaging engineers, quality engineers, corporate regulatory compliance officers and manufacturing professionals look to the near horizon of new FDA UDI (Unique Device Identification) mandates, many are questioning if the current patchwork of incompatible, siloed, redundant, remote or standalone labeling solutions can get them from here to there. This question is the essence of this White Paper. Specifically, can you get from here to there with existing solutions; what are the significant pain points you can anticipate in that process; and what is the best approach – the best methodology – to instead use this time to implement an enterprise-wide, wholly-compatible, and more permanent architecture to achieve a more streamlined, more secure, more automated, and more centralized and centrally-controlled solution that leverages and exploits core applications already in place that are both proven and well-known.

## **Step 1: Consolidation**

Medical products manufacturers with dispersed, departmental, standalone and multi-regional labeling systems face a daunting task of meeting UDI compliance enterprise-wide if the decision is made to sustain these systems. Reprogramming all of these separate solutions over many departments and across all labeling geographies is a time-intensive initiative that in the end, does nothing to fix the underlying problems of a decentralized labeling approach. A major Florida-based medical devices manufacturer that attempted this reported to Loftware that the project took them four years to complete. With the FDA's UDI implementation timetable now pointing to 2013, even if this salvage strategy could be invoked, it can't be finished in time.

Facing this reality but still not yet seeing the benefits of consolidation, some medical products manufacturers are contemplating a half-way solution that substitutes the current disarray with single-function stand-alone

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black box alternatives. If there is a benefit to this, it is that at least technology consistency can be achieved: all the silos everywhere will be of the same variety and vintage. But that's where the benefit, such as it is, ends. The boxes are empty of data; they must be populated with the data; everyone has to be retrained on these new systems; these solutions are not tied to any centralized system, control or authority; and, they don't leverage existing enterprise applications used to drive virtually every other aspect of every manufacturing operation.

But the most significant flaw of this approach is that once it has been implemented, the medical products manufacturing is still left with a dispersed array of department, plant, warehouse, and distribution center solutions, just to name a few. This approach, for example, leaves manufacturers with 10, 20... even fifty or more separate solutions. Instead, forward-thinking medical products manufacturers are telling us they want one way to solve the problem, once, that applies consistently across the enterprise, which will scale through inevitable future changes in labeling requirements, and which can be monitored and controlled from a central location and by all the appropriate label authorities. Of course, they still want the flexibility and efficiency of printing product labels anywhere, at any time, and to any volume. But with the right consolidated solution, this becomes a function of remote printers versus remote, standalone label systems ripe for error, tampering, and downtime.

## Step 2: Integration

Healthcare products manufacturers today know they need – and they have – systems for version control. They have solutions in place to manage the approval process for every label. These are not new requirements. This means manufacturers have systems in place for workflow; they have the right people already in place who are familiar with these systems. With this in mind, it isn't practical to buy new or redundant applications. Instead, it makes significantly greater sense to simply add the label data in these existing applications. Most notably, this refers to integration with Content Management Systems (CMS) and Product Lifecycle Management Systems (PLM) such as Filenet, Windchill, eMatrix and others.

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A reluctance to integrate in this way with known, proven, and familiar applications and to impose new applications with inescapable redundancies at some level, results in what we call a “swivel chair” solution. These require people to log in, on, and out of separate applications to handle a label requirement when these same requirements can be met within the existing infrastructure already well-known and understood. Moreover, swivel chair solutions like this – and an overall reluctance to integrate processes in general -- heighten the risk of human error. In healthcare products, a label error of course is more serious than in any other industry because the label is the product, or considered a part of the product. Bad label: bad outcome, since it can halt production, freeze shipments, and drive a recall.

### Step 3: Automation

In addition to application integration at the CMS level, the forward-looking solution in healthcare products labeling looks to all major enterprise applications to drive label printing. All of these major and widely-installed enterprise applications, from providers such as Oracle, SAP, and others, are considered ‘a single source of truth.’ As such, if they are leveraged to drive label printing and label data, then the practice of manual label data entry, which is super error-prone, is eliminated.

#### The Eventual UDI Standard is of Secondary Importance

Some medical products manufacturers are holding back on next generation labeling systems until the product marking standard that will ultimately be decided by the FDA by 2013 to meet its UDI mandate has been finalized. That’s a risky proposition on several fronts. For one thing, it stalls everything until 2013 at which time these manufacturers will be in serious catch-up mode against competitors who have been moving ahead. It is also an unnecessary proposition because ultimately, the UDI standard that is finally selected doesn’t matter. Whether it turns out to be GS1 or HIBCC and some other approach yet to emerge, it can be accommodated if you have a flexible, enterprise-wide and centrally managed labeling system in place. In other words, right now the investment in evaluating current systems and beginning a methodology like ours to contemplate your options transcends the importance of knowing who or what or which group will ultimately be favored by the FDA. At Loftware, we’re agnostic when it comes to which standard will emerge. Whatever it is, Loftware solutions will seamlessly integrate with the new approach.

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This approach is a super win for healthcare IT professionals for a variety of reasons. Automating enterprise wide on existing business applications is less costly. Instead of fifteen departments and fifteen different methodologies to support, there is one. IT is in a better position to both control the solution and to train everyone once and to one set of directions. In essence, intelligent automated systems simply minimize operator decision-making. This makes the labeling process faster, more reliable, more accurate, and significantly easier to manage, document and control.

At Loftware we have developed a portfolio of packaged, intelligent ‘Connector’ solutions configurable for virtually all of the ERP, SCM, PLM and ECM enterprise applications. In short, these software bridges integrate seamlessly to enterprise applications and with Loftware print servers for template development and label printing anywhere in the world. This gives IT professionals a centralized solution over which they have direct command and control of every label, and every label event can be captured.

### **Step 4: Validation**

This step is in every major software implementation methodology. However, what is often missing are the software services experts who can quickly and reliably perform the validation and have years of experience as well as thousands of validation events from which to draw upon. During this phase, manufacturers need Installation Quality, Operational Quality, and Product Quality (IQ,OQ,PQ) experts who are knowledgeable about how new software must be implemented in ways that accommodate existing systems versus the other way around.

Our validation process is quite direct. With old solutions still running in the background, our services professionals go through the equivalent of a pre-flight check list, including the writing and use of test scripts to

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validate the installation. In the next phase of production qualification, the labeling solution is tested under the pressures of the real world. Then, once completed validated and tested, new label templates and new data are put through the actual approval processes that drive the manufacturer's operation. This makes sure that new templates can be reliably routed for approval and electronic sign-off from marketing, regulatory, legal, engineering, and other departments.

## Ongoing Support

Loftware, like any reputable software company, offers 24x7 support worldwide. But that may not be perhaps the most or only reassuring aspect of our support methodology. First, our solutions have been developed, consistently versioned, and proven for 20+ years worldwide to perform reliably in virtually any setting and for any supply chain configuration. Also, since our labeling strategy is driven by a centralized software architecture approach, support is more readily and cost-effectively delivered to the one site that most often presents the easiest and fastest support fix.

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## *About the Authors*

**Christopher Piela** draws his unique perspective and knowledge of healthcare product labeling opportunities from more than 17 years experience in which he has worked in a wide variety of healthcare roles that span a cross section of the healthcare supply chain. His experience includes 9 years with a major life sciences manufacturing company where he specialized in validation systems. Later for approximately four years he was with a major provider of hospital operational services where he became immersed in the patient side of healthcare products and services. And, for more than four years, as Loftware's Director of Healthcare Solutions, he has established Loftware's presence and reputation worldwide in this highly specialized vertical with dozens of major, brand name healthcare products and services providers.

**Michael Rennell**, with over 30 years in Information Technology, brings a depth of understanding to the current evolution of convergences in infrastructure technologies and regulatory mandates. He has extensive experience in the deployment of major enterprise business solutions, coupled with significant expertise in compliance labeling technologies. In the last 5 years he has assisted organizations worldwide to prepare for the adoption of emerging technologies addressing requirements for IT centralization and consolidation as well as risk reduction tied to the increase in regulatory mandates.

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