Zero Defect Product Labeling

A White Paper Presentation

For World-Class Manufacturing
and
Life Sciences

171 Forbes Blvd.
Mansfield, MA 02048
www.isdweb.com

Toll Free: 800.600.2242
Fax: 508.339.2257
info@isdweb.com

Table of Contents

Towards zero defect labeling

Identify the product properly, place it in the right package and ship it to the right customer – this sounds like an everyday occurrence in every good manufacturing or distribution business, right? Wrong.

Achieving zero defects in product identification, packaging and shipping is not so easy. Industry data shows that errors are not only much higher than analysts initially believed, but the resulting financial losses are greater as well.

In particular, errors caused by mislabeling, such as sending the wrong product to a customer, may have especially grave consequences in the Life Sciences industry, where loss of life or medical emergency may result. Besides the irreversible tragedy of human suffering, litigation costs can cause substantial economic hardship.

In addition, Life Science companies have to comply with increasingly stringent labeling regulations and standards set by both the government and private sectors. Noncompliance to these standards also affects the bottom line through fines, merchandise returns or loss of trading partnerships. Competition within the supply chain adds extra pressure for each company to achieve zero-defect labeling.

Many Life Science companies have identified zero defect labeling as an achievable goal that can save them millions of dollars annually. Creative solutions such as vendor compliance programs reduce the costs associated with errors and increase profitability. Implementing a labeling solution that has been designed for compliance and that can integrate seamlessly with current systems guarantees success. Expert help in implementing a solution will reduce the overall cost.

Planning is key! Life Science businesses simply cannot afford identification, packaging and shipment errors. Zero defect achievement is vital. And yes, with proper planning, execution and process validation you too can achieve it!

171 Forbes Blvd.
Mansfield, MA 02048
www.isdweb.com

Toll Free: 800.600.2242
Fax: 508.339.2257
info@isdweb.com

Labeling compliance and today's business environment

Today the FDA, OSHA, DOT and other government agencies enforce strict requirements and regulations governing product identification, labeling and shipping. As a result, most world-class manufacturers and Life Science companies appropriate significant resources to comply and minimize errors. However, merely appropriating a large amount of money does not guarantee efficient results.

In a recent visit to a client site, I noticed that the labeling department was as large as the product development department. Their answer to compliance had been to increase personnel, implement re-evaluation procedures and require additional documentation each time their program was reviewed. However, even after allocating all of this labor and procedures, they were still seeking to implement yet another process layer (in this case, a vision system) to further QA and verify their process.

The implementation of procedures and documentation without a long term plan resulted in a complex system. Operational redundancies, repetition of tasks, and duplication of effort caused costs to skyrocket. Moreover, the system was still inefficient, counterproductive and error prone.

This company could save time and money by planning and implementing a formal compliance program instead of developing a piecemeal solution. The total cost of ownership of a well-planned program is actually much lower than a patch worked, multi-tiered and semi-manual process. Long-term maintenance costs are also much lower.

The lesson that this company learned…

Plan a formal compliance program and do it right the first time.

How to choose the best solution

There is a range of possible solutions for building a program to achieve zero defect product identification, packaging and shipping, whether it is the first implementation of such a system or it will replace existing systems. These solutions range from building a system "in-house", to buying several components for integration, or to using a hybrid partially manual and partially electronic system. Another alternative is to implement an existing solution and configure it to meet your specific needs.

Industry best practices for successful implementation of a zero defect product identification and labeling compliance system show that the best solution is a turnkey system specifically designed for this application. Such a system must be compliant with FDA and other regulatory requirements and specifications. This approach results in a reliable and guaranteed overall solution. Once again, there are no short cuts to achieving zero defect labeling.

The following are requirements, features and other issues that are important to review when evaluating a system to meet industry best practices.

Labeling life cycle and areas of vulnerability

Before moving forward with the evaluation of alternative methodologies for zero defect labeling, it is important to understand the labeling life cycle.

Although the sequence of events may vary from business to business, a typical label control process includes similar steps. Table 1 outlines a typical labeling life cycle including areas of vulnerability and issues that are of common concern to businesses.

171 Forbes Blvd.
Mansfield, MA 02048
www.isdweb.com

Toll Free: 800.600.2242
Fax: 508.339.2257
info@isdweb.com

Table 1: Typical Label Design and Production Life Cycle

Description	Audit trail req.	Vulnerability		
		High	Med.	Low
1. Establish new label requirements	✓			✓
2. Research content and design criteria	✓			✓
3. Choose a pre-approved template/format or create a new one	✓			✓
4. Create and/or modify format	✓	✓		
5. Merge or map variable data (ex., product specific data, lot number, MFG date, etc.) to complete product label	✓	✓		
6. Send to internal & external authorities for approval	✓		✓	
7. Map and resolve ties to business system or ERP for production printing	✓	✓		
8. Approve final label and submit to document control	✓	✓		
9. Purge old label from production	✓	✓		
10. Enter new label for production	✓	✓		
11. (Operator) Request/trigger a label	✓	✓		
12. Enter other variable data (ex., lot #, expiration, best used by date, etc.), and how many labels to print	✓	✓		
13. Print labels in batch, on-demand or in-line mode	✓		✓	
14. Match label to products and apply manually or automatically	✓	✓		
15. Verify labeling quality and accuracy	✓	✓		

Are these steps a depiction of best practices for zero defect labeling? Yes and No. Yes, because in most cases all of these steps must be practiced in an enterprise labeling implementation. No, because additional modifications, enhancements and processes (discussed later in this paper) transform these steps into the best practices blueprint for a zero defect labeling system that can be used in any world-class manufacturing or life science business.

Label compliance and the Life Sciences

Achieving zero defect labeling is crucial for Life Science companies. Not only can defective product labeling be damaging financially, but it can also cause injury and trauma to clients.

Regulatory agencies (i.e., FDA, OSHA, DOT, etc.) involved with manufacturers and distributors of dangerous goods, drugs, medical devices and medical electronics, have prescribed guidelines for quality assurance and strict controls for product identification, packaging and shipment. These guidelines are enforced through inspections and audits, which verify that companies have set up internal processes and procedures to track and record evidence of adherence. Companies must be able to provide a traceable history of their compliance activities when called upon to do so. As a result of these requirements, many companies have set up procedures that are manual and exhaustive, with a large number of employees performing duplicate tasks and creating seemingly endless paperwork.

FDA and other regulatory agencies have also realized that information technology and high tech solutions assist businesses in developing programs that adhere to regulatory standards. Therefore, they have set information technology guidelines to assure that systems used for automation of compliance requirements adhere to regulatory standards for system, software and technology development, maintenance and certification. For example, Title 21 CFR Part 11 for electronic records and electronics signatures sets guidelines for the architecture of closed-loop, fail-safe and secured systems.

The ultimate goal in the design and development of a world-class labeling and product identification system is to guarantee zero defect labeling in identification, packaging and shipping of products to the right customers, and ultimately, to the end user.

171 Forbes Blvd.
Mansfield, MA 02048
www.isdweb.com

Toll Free: 800.600.2242
Fax: 508.339.2257
info@isdweb.com

However, other areas can have a significant impact on businesses by causing ill-health, safety problems, patient death and financial setbacks. Table 2 describes the consequences and ramifications of defective product labeling in the Life Sciences.

Table 2: Safety and Business Impact

Area	Consequences and Ramifications
End user	Public safety; errors may cause significant harm or loss of life
Litigation	Case studies show significant business losses that have, in some cases, resulted in bankruptcy
Clients	Loss of market share to other competitors by clients and distributors losing faith
FDA audits	Delays in approvals ultimately result in late shipments
Quality	Significant public image setbacks
Shareholder value	All of the above contribute to heavy losses in market capitalization and shareholder value

Steps must be taken to assure the design and implementation of solid processes and procedures that address the safety and business issues detailed above. These must be supported by appropriate technological tools to guarantee zero defect packaging, labeling and shipping of products.

The same levels of care that are used in research, development and manufacturing must be used in packaging, labeling and shipping. Packaging, labeling and shipping are an integral part of product manufacturing and delivery and should be subject to the same level of quality.

The following sections review implementation criteria for a world-class labeling system.

Enterprise labeling – process or event?

Sadly enough, many companies treat labeling, a mission critical business process, as an event. It is considered important, but not mission critical or vital to a business until they are cited for non-conformance by regulatory agencies or by clients.

In manufacturing of consumer products, product and shipping labels need to conform to regulatory (CS and UL) and customer (retail, automotive) requirements. Major retailers have built elaborate receiving systems to accept shipments into their inventory by simply scanning bar codes on the incoming labels that correspond to their purchase order and the product code received. The scanned bar codes are then matched with the order and with the specific line items corresponding to the product in the order. This process saves millions of dollars annually for businesses by reducing keyboard entry and eliminating data entry errors in receiving.

Retailers have gone to great lengths to put compliance standards in place and train their suppliers to conform to these standards. The consequences of non-conformance in these scenarios are all business in nature. Offenders receive fines, or in the event of repeated non-conformance, retailers simply take their business elsewhere.

Life Science companies, on the other hand, face life-threatening consequences that ultimately affect their business. However, life science companies seem to be somewhat behind retailers in meeting compliance criteria and in acquiring the technology necessary to insure identification of the products they receive.

Life science companies commonly deploy labor to assure that they meet corporate quality standards and satisfy regulators. This exacerbates the problem. Adding labor increases errors and compromises the reliability of the system as the vulnerability of existing processes increases. When companies take time to analyze the effect of labor versus process and technology, they quickly realize that labor-based or labor-intensive systems are inefficient and ineffective. The reality is that the labor force will not be able to meet future demands for increased speed and productivity, making this approach doomed.

So, where does the answer lie for achieving zero defect product identification, labeling and shipping? The components of such a system are simple:

- Create and print the right label with the correct content
- Put the right label on the right product

171 Forbes Blvd.
Mansfield, MA 02048
www.isdweb.com

Toll Free: 800.600.2242
Fax: 508.339.2257
info@isdweb.com

- Pack the product in the right box
- Ship the right product to the right customer
- Keep detailed audit trails and records

Building a comprehensive system requires a healthy combination of labor and technology. The most advantageous enterprise-wide zero defect labeling application has proper processes and procedures along with critical, but controlled human intervention at defined stages.

Only a true enterprise labeling software platform offers a comprehensive solution to labeling applications subject to rapidly changing regulatory and customer requirements. An enterprise system not only offers technology, but also processes, and in-process verification mechanisms to guarantee that products are properly identified, correctly packaged and shipped to the right customers and end users.

There are low cost solutions, such as using one of the many label design software packages on the market. However, these software packages only offer a piece of the solution. They do not offer work and process flow or the proper set of integrated modules to assure full compliance and zero defect labeling.

There are also short cuts, such as using a combination of disparate systems tied together. To be successful, this approach must provide connectivity between components capable of interfacing with packaging, shipping and product tracking to fully close the zero defect compliance loop. In practice, this level of continuity can rarely be achieved, so this approach often compromises quality, safety and does not result in zero defect labeling.

A world-class enterprise level label compliance system must be certified to offer a complete work and process flow for the design, electronic approval, QA, archival and electronic deployment of labels, signs and forms for a global enterprise. Table 3 outlines the minimum components necessary for a world-class system.

Table 3: Minimum Components of a Zero Defect Enterprise Labeling System

Component	Description
Design	A comprehensive label design module with built in ERES and audits
Workflow	Label life cycle workflow integrated with the design module compliant with regulatory specifications
ERES certification	Electronic Records and Electronic Signatures (ERES) Compliance integrated with components
Security	System security & authentication per closed system specs – One security for all
Approval	Label approval module offering a tightly integrated process with the design module
Electronic messaging	Automatic email notification & messaging integrated with the overall process
QA	Label review & quality assurance process tightly integrated with design and approval
Production printing	Plant visible front ends with error free label requisition and operator interaction
History and reports	Audit trails and full reporting capabilities integrated in the closed-loop system
User classification	Managing users, authentication and authorization levels with built in utilities that offer closed-loop system compliance
Approval authentication	Managing approval groups and routings integrated with design, approval and QA
Verification	Base line setting and management for QA and archives to insure system integrity
Connectivity	Modules to interface ERP and other business systems to ensure data integrity. Secure compliant Web enabled access
Trace ability	Lot number, mfg. date code, and best use date mgmt. for maximum reliability
International	Technological compliance for multilingual applications and markets
Synchronization	Multilevel synchronization to assure continuous processing
Quality & Validation	IQ, PQ & OQ plan, script & documentation for system validation & proof of performance

171 Forbes Blvd.
Mansfield, MA 02048
www.isdweb.com

Toll Free: 800.600.2242
Fax: 508.339.2257
info@isdweb.com

Zero defect labeling – process or event?

Implementing a zero defect labeling system to ensure compliance is a process, not an event, and must be treated as such. System components must be configured for adherence to compliance and not just be an afterthought.

Companies must be wary of solutions that are lacking a sufficient level of detail. Low level systems, bargain software and solutions that are quickly developed or pieced together do not offer the required features or seamless closed loop process that is necessary for a world-class labeling system.

Existing systems often lack the proper infrastructure, security and workflow, so they cannot be retrofitted with add-on compliance capabilities. These systems also do not offer the closed-loop requirements that a reliable system needs. Such systems are vulnerable to intruders, hackers and are subject to failure. Their validity will not withstand litigation and proof of performance for reliability and security.

There are no short cuts to achieving zero defect labeling.

Validation, verification and certification

Regulatory requirements, specifically FDA compliance procedures, require that a process certification be conducted on a regular basis. The minimum recommendation is for annual certification and verification of processes.

An enterprise level system must incorporate a built-in structure for continual in-line verification of software, input, output and in-between processes. In-line verification occurs as the label output is checked randomly or on a pre-defined schedule with a base-line electronic image that has been archived for the same label. This process is repeated at different stages of the system. If any variations occur, the system responds in a predetermined manner (such as halting operation) until the system is checked, fixed and certified as stable and reliable before continuing operation.

In some labeling applications, formal processes for system validation are required while they are optional in others. Best practices demonstrate that a validation plan is best outlined early in the design of the new system. A detailed plan should be developed towards the completion of the project or just before the initial steps of implementation.

An adequate validation plan contains various qualifications for installation, processes, performance and operations to be evaluated by discrete and continuous tests. Validations tend to be highly customized to the situation. Using experts to write the plan and the scripts is highly recommended. The execution of the validation plan may be accomplished by collaboration between in-house and outside experts to assure execution of objectives and detailed analysis and testing of real life operational situation.

Implementation today and tomorrow

Although most companies have a labeling process, companies that have a fully functioning enterprise wide label compliance process are in the minority.

Table 4 shows the most common types of processes and systems in use today. After reviewing this table it becomes apparent that it is impossible to create a world-class compliance labeling system that offers zero defect labeling and conforms to best practices unless such a system is designed specifically for this purpose.

It is projected that the practice of implementing a world-class compliance labeling system, which currently amounts to 5% of total market, will reach double digits in 2003 and 40% by 2006. This is a very dynamic growth rate which is further accelerated in regulated industries.

In the future, visionary companies will either build world-class compliance labeling systems from start to finish or invest in such systems built by third parties that specialize in these types of systems. With the current trend of increasingly tighter regulation and

171 Forbes Blvd.
Mansfield, MA 02048
www.isdweb.com
Toll Free: 800.600.2242
Fax: 508.339.2257
info@isdweb.com

compliance standards, building anything but a world-class system is a waste of resources and will be obsolete quickly.

Table 4: Common Labeling Practices

Practices	Percentage				
		Compliant with			
	In use	Best practices	ERES	Part 11	Zero defect
Built "in-house" w/manual tracking & labor intensive processes	45%	35%	N/A	N/A	70%
Retrofitted "in-house" w/semi automated tracking tools based on engineering change mgmt systems	20%	55%	30%	50%	60%
Combo purchased label design tools w/engineering change mgmt systems retrofitted	20%	55%	30%	50%	60%
Combo purchased label design, document mgmt & lab or database mgmt tools retrofitted	10%	35%	20%	50%	60%
World-class system specifically designed for enterprise wide labeling compliance & workflow	5%	100%	100%	100%	99.9%

The following two sections further describe some of the practices mentioned in Table 4 and their shortcomings in delivering a world-class, zero defect labeling system. We also ask the question:

Can multiple system integration or "in-house" development be considered as an alternative to procurement of a world-class system?

Integrating multiple components

Integration of multiple components, such as label design software, engineering document management systems or third party databases is common practice in today's organizations. Integration may also include workflow software or laboratory information systems to create a controlled environment for labeling.

This practice is primarily executed for several reasons.

- The need for the "real thing" is not recognized in the company.
- It gives the perception of being low cost
- It gives the perception of being quick to implement
- It takes advantage of other technologies that are available in-house
- IT department insists they know their company best
- Management does not support world-class enterprise level system implementations
- There is no money

None of the above rationalizes the execution of a substandard system where compliance labeling is a mission critical priority.

Regulatory requirements for software validation, which are published by FDA, DOT and OSHA, are very specific and require labeling and other software for mission critical applications in regulated industries to be designed with approved/recognized methodologies.

A hybrid approach where a stand alone labeling package is integrated with a document control, a laboratory system or a work flow product does not pass the basic Electronic Record/Electronic Signature (ERES) and other FDA requirements for a closed-loop environment. For example, ERES requires that pertinent information be present in the primary file structure. This is impossible in hybrid systems where information is maintained, at a minimum, in two and possibly more locations with links that are not secure.

Hybrid systems offer separate internal architecture and use varying security services. They also fail to use proper encryption, and are subject to tampering with exposures and points of system vulnerability. In short, hybrid systems are not designed for compliance and fail the closed-loop concept. They do not have tamper proof architecture. Nor do they have a detailed audit trail for trace and track that is

171 Forbes Blvd.
Mansfield, MA 02048
www.isdweb.com

Toll Free: 800.600.2242
Fax: 508.339.2257
info@isdweb.com

required to assure secure recording of critical process data for future reference and possibly in a litigation.

To create a system that offers zero defect labeling, the documentation and process validation amounts to volumes of information. All of this information must be tracked and maintained throughout the design and the life cycle of the product. This is not a task to be thought of after the fact or built-in once the product is completed, and added as another bolt-on feature to existing disparate systems. This initiative must be incorporated in the development and design of the new system from the initial stages. The infrastructure must be built into the system. A hybrid system, which integrates multiple packages, fails this test.

Industry best practices show that neither low-end label design packages nor building a world-class look-a-like system with in-house tools and resources comply with approved methodologies and therefore do not comply with regulatory standards. A world-class regulatory system for zero defect labeling must be in full compliance with software development best practices, design methodologies recognized by regulatory agencies and incorporate the grass root requirements for ERES and Part 11 as well other regulatory requirements.

Further, standards set forth by the FDA and other agencies subscribing to similar standards, require the use of specific data structures for the representation of information that is uniquely designed in compliance with regulatory requirements. For example, audit information and digital signatures must be encrypted and stored with the primary document in one single electronic representation. In the case of labels, the primary document is the secured electronic file or record that contains the proprietary label information.

Low-end software packages and systems do not offer this. Nor can the integrated systems technically offer this. A world-class system for labeling compliance and zero –defect labeling has been designed with this requirement in mind and, therefore, all relevant information is maintained in a secured single file or record, which is encrypted and follows proper regulatory guidelines. Only world-class software specifically designed for regulatory compliance and zero defect labeling fulfills this requirement. Modifying or building such software from scratch is not feasible nor a wise business decision.

In addition to specific data structure, the audit trail and archived information must follow certain documented standards. This information must be tightly integrated with the label file. This requirement precludes the use of other document management or workflow software programs or "in-house" developed systems unless heavy customization and changes are made to these systems. The time and labor involved in making these changes is prohibitive. Because of all of these hurdles, many companies end up back at "square one" after having invested resources and time trying to take the short cut.

Build or purchase?

Why build your own vehicle from parts when you can buy it at any dealership for the fraction of the cost?

According to industry's best practices, the knowledge required to build a fully compliant system, the regulatory constraints and the design and development make it an extremely costly undertaking. It requires a long-term commitment to software development and the creation of a responsive maintenance organization.

Unless compliance software development and marketing is the core business of an organization, there are no compelling reasons to build a compliance system. Companies in this business enjoy profits and ROI by selling many systems to similar industries. To enter the market to build just one implementation is not a good investment of time or money. It is similar to entering the automotive business only to produce one vehicle.

Therefore, unless your company wants to seriously entertain entering a new business venture – building compliance systems, or your company has a huge IT staff, it is recommended to leave the work to the experts and focus on your core business.

171 Forbes Blvd.
Mansfield, MA 02048
www.isdweb.com

Toll Free: 800.600.2242
Fax: 508.339.2257
info@isdweb.com

Additional system components

The next sections highlight several other components which are necessary in the implementation of a world-class labeling system. These components are:

- Integration with ERP or other business systems currently being used in-house
- Access control
- Application security
- Electronic signatures
- Audit trails

Integration with manufacturing execution system or ERP

There are several major components to an enterprise labeling system. The first group of components offers the design, management, workflow, validation and all the regulatory and compliance requirements. A world-class compliance system for zero defect labeling offers the design of labels, tracking of changes, archiving and adherence to regulatory and corporate requirements.

The next major group of components includes interfaces, which also contain the plant visible front-end as a component that is visible by the print operator and is deployed in the facilities that offer production printing. Plant visible front ends must comply and be integrated with the overall system architecture, security, authentication and ERES requirements.

The plant visible front-ends offer access to label designs that have gone through the approval process in a world-class labeling system and have also interfaced with another component, which is responsible for connectivity to the MES, ERP or LIMS for the retrieval of dynamic data or reporting of labeling results.

Dynamic data such as product information, lot and batch numbers, best use dates, and manufacturing dates are among the data that may be shared from the ERP or MES systems to the labeling system. This sharing of data assures data integrity, reduces redundancy and errors that may result by manual transcription of data.

Further, information obtained at the labeling system level may be shared back to the ERP or the business systems to report activity, production, labeling usage and other control information that may be required for shipping, billing, inventory or enterprise-wide audits.

Access control

A world-class zero defect labeling implementation, at minimum, must require user ID and password to log into the application. All login attempts must be recorded in the Security Log. The log must display the user ID, user name, date, time, if the login attempt was successful or not, and where the user logged from (web or LAN client).

Other configurable security options of a world-class labeling system are password change frequency, password minimum length, and maximum number of login attempts; all three configurable by the customer. Whenever the maximum number of login attempts is reached, the system inactivates the account and immediately notifies up to several authorities of breach of security.

Application security

Another requirement is additional options to ensure that access to labels is restricted to the appropriate individuals.

- User Access Levels – this is the basic control mechanism in a labeling implementation where user access privileges can be set to View Only, Data Entry or Administrator.
- User access can be further restricted to specific departments, menu options, label directories, and modules.
- The user can be prevented from performing certain activities like creating new revisions or changing existing labels.

The flexibility of a world-class enterprise labeling system must also allow your company to distribute the workload among areas or departments. For example, a master administrator can set up user accounts that are restricted to specific areas (ex., safety), specific departments (ex., packaging), and even restrict access to the system configuration area.

171 Forbes Blvd.
Mansfield, MA 02048
www.isdweb.com

Toll Free: 800.600.2242
Fax: 508.339.2257
info@isdweb.com

"Data Entry" and "View Only" users are also configured this way, allowing more options when deciding to centralize or to delegate system maintenance to specific departments.

Electronic signatures

A typical world-class labeling compliance system supports electronic signatures using four different methods:

- User ID / Password combination – the basic method utilized by most software. No additional hardware or configuration is necessary.
- I-button – an electronic button that the user places in a cradle when the signature is executed. The button contains a unique ID and has additional memory that can be used to store user information.
- Signature pad – a pressure sensitive pad on which the user inscribes his handwritten signature and it is compared to one stored in a database. This provides more security than bitmapped signatures.
- Finger scan (biometrics) – scans the fingerprint of the user and compares it with one stored in a database. The most secure method supported.

A configurable system must allow the customer to decide which actions require execution of the electronic signature and which signature methodology or combinations thereof is appropriate for the business.

Audit trail

Audit trail and tracking have been mentioned several times in this paper as a key component for compliance. The labeling component must feature an audit trail that works automatically in the background and cannot be disabled by the users or even the system administrator.

- The audit trail may be configured to capture all fields of the modified label, and highlights the specific field(s) that was modified. The audit trail includes the user name, user ID and the date and time that the transaction occurred.
- A world-class system utilizes the database server date and time to stamp all transactions. This feature guarantees the integrity of records, and avoids confusion if the workstation date and time is changed. The customer is responsible for providing the appropriate measures to ensure that the security features implemented in the system are not bypassed.

Audit trail, electronic signatures and proper access control mechanisms assure proper security and tracking that are critical in the implementation of a zero defect labeling system.

Conclusion

Only a world-class system that is compliant to regulatory requirements and which is specifically designed and developed for such implementations offers zero defects for enterprise-wide labeling that guarantees that the right products are properly labeled for shipment to the right customer at the right time.

"Off-the-shelf" but configurable systems that have been designed with compliance and zero defects in mind are recommended over integration of multi-vendor components or development of an "in-house" system. The overall cost of ownership is lower for a purchased system and adherence to standards is guaranteed.

Expert help in such implementations is highly necessary and recommended and it will reduce the overall real cost of implementation and system maintenance.

Do it right the first time. There are no short cuts in compliance and achieving zero defect labeling. Your investment in this necessary process will bring the greatest short term and long term ROI.

171 Forbes Blvd.
Mansfield, MA 02048
www.isdweb.com

Toll Free: 800.600.2242
Fax: 508.339.2257
info@isdweb.com