

Best Practices for Medical Device Label Management Compliance

Insights on FDA and EU MDR Regulations and Effective Label Management Solutions and Tools



In an increasingly stringent regulatory landscape, the importance of accurate and compliant medical device labelling cannot be underestimated. Detailing specific product data in accordance with local and global requirements is the cornerstone of ensuring safety and efficacy.

This eBook takes a deeper dive into EU and FDA regulations, and provides best practice guidance for updating and maintaining compliant medical device labels.

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Introduction

Regulation and Patient Safety: The Importance of Label Management in the Medical Device Industry

As a member of the Life Sciences community, you know that patient safety is the number one priority. Providing accurate and error-free safety information about your medical device products is paramount. **Accuracy is crucial.**

Just as your medical devices play a crucial role in diagnosing, treating, and monitoring patients and their medical conditions, label management is equally vital to ensuring regulatory compliance, enabling patient safety, and maintaining product quality.

You can't afford to publish or post documents with errors in any business sector, especially in a regulated environment like the **medical device industry**.

Adequately managed medical device labelling helps meet strict regulatory standards, provides clear instructions for device use, and facilitates traceability throughout the product lifecycle. Failure in label management can lead to regulatory penalties, patient harm, and damage to your company's reputation and bottom line.

Why Adherence to Medical Device Labelling Standards is Essential



Regulatory Compliance is crucial, as incorrect or misleading labelling can compromise patient safety and lead to costly recalls.



Legal responsibilities pertain to compliance with regulatory standards, accurately represent the device's specifications and usage, and are updated to reflect any changes.



You enhance **patient safety** by ensuring error-free and thorough instructions on proper use, handling, and risks.



Medical device labelling training provides essential information for users regarding appropriate use, handling, and potential risks.



Medical device traceability is vital. The FDA and EU require Unique Device Identifier (UDI) compliance on some classes of medical devices.



The future is digital, and the future is now. Here's a practical guide to everything you need to know about the Digital Transformation of Medical Device Labelling.

Chapter 1

Succeeding in a Highly Regulated Environment

A Deeper Look Into EU and FDA Medical Device Labelling Requirements

Understanding the global labelling regulations for medical devices is essential to achieving compliance. While medical device labelling compliance standards may be relatively simple for a manual toothbrush, labelling requirements for medical devices in high-risk classes are complex and stringently defined.

However, some general medical device labelling alignments stand out for safe operation and identification. These include the device's name and trade name, intended use, lot and serial numbers, the use of recognized symbols, instructions for use, residual risks, and many other medical device labelling specifics.

To fully understand medical device labelling regulations, it's vital to explore two significant regulators:

- U.S. Food & Drug Administration (FDA)
- European Union (EU) Medical Device Regulation (MDR)

FDA Medical Device Labelling Requirements

In the US, the [FDA's Center for Devices and Radiological Health](#)¹ regulates the medical device industry. This oversight applies to “firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States.”

Requirements are stipulated in Chapter V of the [Food, Drug and Cosmetics Act](#),² and general labelling requirements are provided in [21 CFR Part 801](#).³ The FDA's guidance on medical device labelling serves a dual purpose of assisting manufacturers and regulators in the evaluation of medical device patient labelling to “help make it understandable to and usable by patients.”⁴

EU MDR Labelling Requirements

The year 2017 marked a significant change in the regulation of medical devices in the European Union (EU), with [Regulation \(EU\) 2017/745](#) and [Regulation \(EU\) 2017/746](#) coming into force.⁵

These new medical device regulations apply to medical devices placed on the market, made available, or put into service for human use, as well as accessories for medical devices. Regulation 2017/746 relates to in-vitro medical devices. Annexes deal with labelling aspects, notably Annex I Chapter 3 in Regulation (EU) 2017/745.

The EU MDR labelling requirements were introduced to account for scientific and technological advances over the past two decades and also due to problems interpreting previously existing regulations. The regulations divide medical devices into four risk classes, with medium or high-risk classes requiring the involvement of notified bodies—organizations in member states that perform conformity assessments.

Specifics on Medical Device Labelling Compliance

Unique Device Identification (UDI)	Language requirements	Symbol usage
<p>Specific medical devices require unique device identification barcodes and Human Readable Interpretation (HRI).</p> <p>The goal of including a UDI is to improve patient safety, improve traceability, and facilitate innovation.</p> <p>FDA medical device labelling requirements dictate that most devices include a UDI in human- and machine-readable form.⁶ Likewise, the EU requires UDI information on “all devices, except custom-made and performance study/investigational devices.”⁷</p>	<p>When serving international patients, you must understand that there are unique language requirements in each country you do business in.</p> <p>The FDA and EU clearly outline the regulations regarding language.</p> <p>In the EU, each Member State has its language requirements. It is essential to determine the language requirements of manufacturers at a national level for the information accompanying the device.⁸</p> <p>The FDA requires medical device labelling in English except “devices distributed solely in Puerto Rico or a U.S. territory where another language is predominant.”⁹</p>	<p>The FDA and the EU provide guidelines for using symbols on medical device labelling to improve clarity and avoid language barriers.</p> <p>Symbols should be clear and consistent and used alongside or as a substitute for text to convey important information about the device’s use, handling, and warnings.</p> <p>In the U.S., the FDA permits using symbols as long as they are recognized in a standard, such as ISO 15223-1, and include a glossary explaining their meanings if not obvious.¹⁰</p> <p>The EU MDR also encourages using standardized symbols to facilitate understanding across different languages and requires these symbols to comply with the EN ISO 15223-1 standard.¹¹</p>

The medical device industry is highly regulated. Changes to our professional instructions for use must be clearly documented. Text Verification Tool® software by Schlafender Hase® provides reviewers with easy-to-understand and accurate change summaries. This saves time and ensures utmost quality and confidence in change tracking, contributing to streamlined document reviews and error-free document release. ”

Amanda Alegria, Technical Writing Supervisor, Intuitive Surgical, Inc.

Recent Changes and Updates in Medical Device Labelling Compliance and Regulatory Standards

Across many developed markets, the medical device industry is already subject to considerable regulatory change to improve device traceability and patient safety. These measures have been driven by high-profile safety events, such as the PIP breast implant scandal in Europe, technological advances, growth in smart implanted and wearable devices, and an increase in combination products (devices and pharmaceutical products that work in concert).

In today’s rapidly changing regulatory environment, you and your organization must stay updated on the latest regulatory developments to ensure their policies comply with regulations.

To prepare for these regulatory changes, review your current policies to ensure they align with the evolving regulatory landscape. Proactively reviewing and updating policies in response to expected regulatory changes shows a dedication to staying ahead of the curve and building a robust and responsible operational structure.



Explore regulation more thoroughly with our Guide to Medical Device Labelling Requirements.

Chapter 2

Launching Your Medical Device Label Management

A management system for medical device labelling is vital in ensuring regulatory compliance and helping to avoid costly reprints or, worse yet, recalls.

Every organization requires an integrated solution designed to manage the entire labelling lifecycle of medical devices, ensuring compliance with regulatory requirements and enhancing operational efficiency. This system typically includes software tools and processes to create, review, approve, print, and maintain labels for medical devices.

In this chapter, we'll examine the critical components of effective label management, how to integrate it into your other enterprise systems and analyze medical device labelling software solutions for effectively managing your labelling processes

The Benefits of Effective Medical Device Label Management

- ✓ **Compliance Assurance:** Helps ensure that all labels meet the latest regulatory standards, reducing non-compliance risk.
- ✓ **Efficiency and Accuracy:** Streamlines the labelling process, reducing errors and improving turnaround times.
- ✓ **Consistency:** Maintaining uniformity across all labels is critical for brand integrity and user safety.
- ✓ **Traceability:** Provides complete traceability of labelling changes, which is essential for regulatory audits and quality management.

Critical Components of Effective Label Management

Regulatory Compliance	Ensures labels meet the stringent requirements of FDA medical device labelling and EU MDR labelling requirements, including language, symbols, and UDIs.
Label Design and Content Management	Facilitates the creation of standardized label templates that include essential elements such as device names, manufacturer details, and relevant symbols. This helps maintain consistency across all medical device labels.
Version Control and Audit Trails	Tracks all changes to medical device labels, maintaining a history of revisions and approvals. This is crucial for compliance and quality assurance, providing an audit trail for regulatory inspections.
Multi-language Support	Creating and managing labels in multiple languages to meet the requirements of different markets is critical. This is particularly important for compliance with the EU MDR, which mandates translations for various languages depending on the requirements of each member state.
Print Management	Management of the printing process ensures labels are printed accurately and efficiently. This includes handling different label formats and materials based on the device and regulatory requirements.
Quality Control	Implement quality checks to verify the accuracy and compliance of labels before they are finalized and printed. This may include cross-references with regulatory guidelines and product specifications.
Documentation and Record Keeping	Maintain comprehensive records of all labelling activities, including drafts, approvals, and printed labels. This documentation is essential for regulatory audits and internal reviews.
Integration with Other Systems	Label information and data integrate with systems to streamline data flow and ensure product information and labelling consistency.

Integrating Label Management with Other Systems

This checklist is a great way to determine essential system integrations to streamline data flow and ensure consistency between product information and labelling. Integrating these systems allows your medical device label management system to simplify the labelling process, ensure compliance, improve accuracy, and enhance overall operational efficiency. Each integration point helps maintain up-to-date, compliant, and accurate labels critical for regulatory adherence and patient safety.

- **Enterprise Resource Planning (ERP):** Enhance the accuracy of labelling information, synchronize product data, and reduce manual data entry errors.
- **Quality Management Systems (QMS):** Ensures quality compliance, facilitates issue tracking, and streamlines the approval process for label changes.
- **Artwork Management Software (AMS):** Streamlines the artwork approval process, maintains consistency in design, and ensures regulatory compliance of visual elements.
- **Regulatory Information Management (RIM):** Keeps labelling up-to-date with regulatory changes, facilitates easier regulatory submissions, and maintains comprehensive regulatory documentation.
- **Proofreading and Content Comparison Software:** Reduces errors, ensures consistency, and enhances the review process.
- **Content Management System (CMS):** Centralizes content management, simplifies updates and ensures consistency across labels.
- **Electronic Document Management (EDM):** Ensures secure storage, facilitates version control, and supports regulatory compliance.
- **Product Lifecycle Management (PLM):** Synchronizes product information, supports compliance throughout the product lifecycle and enhances traceability

Technology Solutions: Software and Tools for Medical Device Label Management

Document comparison software, like the [Text Verification Tool \(TVT\)](#), minimizes the risk of error by verifying text, spelling, artwork, tables and barcodes in labelling, packaging and documentation before getting printed or published. TVT is used by leading medical device companies and five regulatory authorities, including the EMA and MHRA.

Using document comparison software like TVT eliminates the risk of human error. It does not replace the need for a professional but allows users to quickly identify errors and inconsistencies in their documentation, labelling, packaging, and other materials that can lead to mistakes, misprints, and recalls—ensuring your medical devices meet the highest quality and compliance standards.



Finding the right software solution for compliance with your medical device labelling is essential. This Buyer's Guide will help you understand the journey to getting the ideal software for your needs and goals.

Chapter 3

Designing and Producing Medical Device Labels

Best Practices for Medical Device Label Design

Adequate medical device labelling and design depends on three best practices: clarity, readability, and compliance. By prioritizing these three elements, medical device manufacturers can enhance patient safety, ensure proper device usage, and meet stringent regulatory requirements.



CLARITY

Ensures that the instructions, warnings, and other critical information are easily understood without confusion.



READABILITY

Readability pertains to how easily the written text can be read and understood. This involves factors like font size, typeface, layout, language simplicity, and the use of white space.



COMPLIANCE

Compliance in medical device labelling is vital to ensure that all regulatory standards are met. This avoids legal issues, fines, and recalls, which can be costly and damage the manufacturer's reputation.

Our intention had been to really find the perfect automated proofreading solution for our company, and once we did, we wanted to move forward as quickly as possible so we can really save resources and improve time management for our proofreaders. TVT will really help us in our current expansion into more countries and regions, especially for verifying IFUs in multiple languages. ”

Kejdi Tafili, Senior Regulatory Affairs Specialist, New World Medical

Techniques for Effective Label Printing and Production

Here are 12 essential questions about your organization's Medical Device label printing and production.

Regulatory Compliance	Language requirements	Symbol usage
Do you adhere to regulations such as the FDA's Unique Device Identification (UDI) system and ISO standards relevant to medical device labelling?	Have you implemented strict quality control measures to ensure accuracy and consistency throughout the label production process?	Did you select durable, high-quality materials suitable for the medical device's intended use environment and sterilization methods?
Barcoding and Serialization	Clear and Legible Printing	Color Coding and Symbol Usage
Are you utilizing barcoding and serialization techniques to enable traceability and inventory management?	Have you ensured the label's text, symbols, and graphics are printed clearly and legibly to prevent misinterpretation or errors during device use?	Do you effectively use color coding and standardized symbols to convey critical information such as warnings, precautions, and usage instructions?

(Table continued overleaf)

Techniques for Effective Label Printing and Production (continued)

Variable Data Printing	Testing and Validation	Adhesive Selection
Have you implemented variable data printing technology to personalize labels with unique identifiers, lot numbers, expiration dates, and other relevant information?	Do you thoroughly test and validate label designs, printing equipment, and processes to confirm their suitability and reliability for producing medical device labels?	Are you choosing appropriate adhesives that securely adhere to various surfaces, including packaging materials and medical devices, without leaving residue or compromising sterility?
Integration with Labelling Software	Training and Documentation	Risk Management
Are you integrating label printing systems with labelling software to facilitate centralized control, streamline workflows, and ensure design and content consistency across different product lines?	Do you provide comprehensive training to personnel involved in label printing and production processes and maintain detailed documentation of procedures, materials, and equipment settings for traceability and compliance purposes?	Have you implemented risk management processes to identify and mitigate potential risks associated with label printing and production, such as labelling errors, misprints, and regulatory non-compliance?

Managing Multi-Language Labels for International Markets

Countries have national requirements in their languages for their different markets. Here's a checklist to ensure compliance, accuracy, and efficiency in managing multi-language labels for international markets for medical devices:

- Understand local regulations, including country, including language, symbols, and mandatory information
- Stay informed about changes in international rules to ensure ongoing compliance
- Use advanced labelling software that supports multi-language capabilities and allows for centralized management of label templates
- Implement version control to manage updates and revisions across different language labels consistently
- Employ professional translators with expertise in medical terminology and local language nuances
- Choose legible fonts in multiple languages, including those with special characters or diacritics
- Choosing the right proofreading software that will meet your existing and future needs, including language requirements, reporting, and auditing needs
- Foster collaboration between regulatory, quality, and production teams to ensure cohesive management of multi-language labels
- Review and update labelling processes and systems regularly to incorporate best practices and technological advancements

Technology Solutions: Software and Tools for Medical Device Label Management

Document comparison software, like the Text Verification Tool (TVT), minimizes the risk of error by verifying text, spelling, artwork, tables and barcodes in labelling, packaging and documentation before getting printed or published. TVT is used by leading medical device companies and five regulatory authorities, including the EMA and MHRA.

Using document comparison software like TVT eliminates the risk of human error. It does not replace the need for a professional but allows users to quickly identify errors and inconsistencies in their documentation, labelling, packaging, and other materials that can lead to mistakes, misprints, and recalls—ensuring your medical devices meet the highest quality and compliance standards.



Go digital. Incorporate a medical device e-labelling strategy into your design and production process.

Chapter 4

Validation and Quality Control in Medical Device Labelling

When proofreading comes up, most think of correcting written text in documents like books or school essays. In the **medical device industry**, however, proofreading encompasses much more, including verifying packaging and labelling elements such as instructions for use, company logos, symbols, graphics, and barcodes. Each element must be accurate and serve its purpose before a device goes to market.

Ensuring patient safety is paramount, requiring that all versions of labels, whether online or in print, are accurate. Tracking changes between versions and maintaining a comprehensive audit trail can be challenging, with mistakes potentially leading to corrective actions, recalls, or adverse patient outcomes. If your job involves checking or comparing documents for errors, you are engaged in a critical aspect of proofreading in the medical device field.

Steps for Validating Medical Device Label Accuracy and Compliance

Validating the accuracy and compliance of medical device labels is critical to ensure safety, regulatory adherence, and market acceptance. Here are detailed steps to validate medical device label accuracy and compliance:

1. Understand Regulatory Requirements

This one keeps coming up on every list. The reason is simple: it is essential. Research the specific regulatory requirements for each target market (e.g., FDA in the US, MDR in the EU). Understand the standards for information that must be included on labels, such as UDI, symbols, warnings, and instructions.

2. Develop a Validation Plan

Create a validation protocol by outlining the validation process's objectives, scope, and methodology. Define acceptance criteria based on regulatory requirements and internal standards. Designate roles and responsibilities for the validation team, including regulatory experts, quality assurance personnel, and label designers.

3. Label Design and Development

Develop standardized templates to ensure consistency across different products and languages.

Include placeholders for variable data (e.g., batch numbers, expiration dates). Use professional translation services for multi-language labels. Validate translations through native speakers and regulatory experts in each target market.

4. Content Verification

Ensure all required information is on the label, such as product name, manufacturer details, usage instructions, warnings, and UDI. Verify that symbols and graphical representations meet international standards (e.g., [ISO 15223-1](#)).

Cross-check label content against master documents and product specifications to ensure accuracy. Perform spell checks and proofread all text, especially translated content – **leverage the power of software**.

5. Mock-Up Testing

Create physical or digital mock-ups of the labels. Test the mock-ups on products and packaging to check for fit, readability, and durability. Conduct usability testing with end-users to ensure the label is clear and understandable. Gather feedback on readability and comprehension, especially for multi-language labels.

6. Printing and Material Validation

Choose appropriate printing methods and materials that ensure label durability and legibility throughout the product's lifecycle. Test labels under various conditions (e.g., temperature, humidity, sterilization processes) to remain intact and legible.

Steps for Validating Medical Device Label Accuracy and Compliance (continued)

7. Quality Control Processes to Avoid Common Labelling Errors

Establish checkpoints during the printing process to inspect labels for defects and inaccuracies.

Automated systems are used to verify barcode readability and data accuracy. Perform random sampling and inspection of finished labels to ensure consistency and compliance with the approved design.

8. Document and Review

Document all validation activities, including test results, inspection reports, and approval records. Maintain a detailed audit trail for regulatory audits and inspections. Conduct a final review of the labels by the regulatory and quality assurance teams. Obtain formal approval and sign-off before labels are used in production.

9. Implementing Regular Audits and Compliance Checks

Monitor feedback from the market and users regarding label performance and accuracy.

Investigate any issues reported and implement corrective actions as needed. Review and update label content and design periodically to ensure ongoing compliance with evolving regulations and standards.

10. Training and Education

Provide staff involved in the label design, printing, and inspection processes with training on regulatory requirements and quality standards. Ensure ongoing education to keep up with changes in regulations and best practices.

By following these steps, manufacturers can validate the accuracy and compliance of their medical device labels, ensuring they meet regulatory standards and provide clear, accurate information to users.

Errors were recognized quickly, and the number of correction cycles was significantly reduced. Errors that could have formerly led to expensive reprints were avoided (with TVT). ”

Michael Breiler, Director of Packaging Development, Lohmann & Rauscher



Learn how New World Medical automated proofreading in quality assurance to save days proofreading and devote more time to medical device registrations and company expansion in markets.

Chapter 5

Medical Device Label Management and Supply Chain Integration

Accurate and compliant medical device labelling is crucial for maintaining a flexible and responsive supply chain, especially for medical devices used in critical care, drug delivery, and surgical interventions.

A centralized labelling system that allows suppliers to print approved labels with controlled access can prevent delays and ensure compliance. This approach helps manage labelling risks, especially when switching suppliers and maintains continuity despite disruptions.

The pandemic highlighted the need for flexible and resilient supply chains. Here's how to understand the role of label management in the supply chain, how to ensure compliance and the challenges you could face in label management on an international scale.

The Role of Label Management in the Supply Chain

- **Impact on Supply Chain Efficiency:** Efficient label management is critical for medical device manufacturers to reduce time-to-market, ensure compliance, and streamline supply chain processes.
- **Modernizing Labelling Procedures:** Transitioning from manual, hard-coded label templates to digital, dynamic ones increases agility and reduces IT workloads.
- **Automation and Integration:** Integrating label management systems with ERP, PLM, and MES systems enhances efficiency by providing accurate data for label creation and compliance.
- **Cloud-Based Solutions:** Adopting cloud-based labelling systems allows for centralized management, better version control, and easier compliance with changing regulations.

Coordinating with Suppliers for Label Consistency and Compliance

- **Global Compliance Alignment:** To avoid supply chain disruptions, manufacturers must align labelling with various international standards, such as EU MDR and FDA guidelines.
- **Use of Digital Labelling Systems:** Implementing digital label management systems helps ensure consistent and compliant labelling across all suppliers and production facilities.
- **Cloud Integration:** Moving to cloud-based solutions facilitates real-time updates and compliance checks, ensuring all suppliers meet the latest labelling requirements.
- **Automated Workflows:** Automating label approval and change processes across facilities minimizes manual errors and ensures uniformity in labelling practices.

Challenges in Label Management Across Different Markets

- **Regulatory Variations:** Differences in regulations, such as the requirement for an MD symbol in the EU, can pose significant challenges and require precise label adjustments.
- **Manual Label Changes:** Altering labels to meet specific market requirements can lead to errors and non-compliance, slowing operations down.
- **IT and Labor Demands:** Coding label changes and ensuring compliance often require significant IT resources and labor, which can affect operational efficiency.
- **Staying Up to Date:** Fast-changing regulations necessitate frequent updates to labelling practices, which can be challenging to manage without a centralized digital system.
- **Adoption of Cloud Solutions:** The transition to cloud-based label management can help overcome these challenges by providing a centralized platform for updates, validation, and compliance management.



Biomapas serves 64 European countries, the CIS, and the MENA regions. Here's how they leveraged our Text Verification Tool to ensure compliance globally.

Chapter 6

Risk Management in Medical Device Labelling

Risk management is crucial in medical device labelling because it ensures that the information on the label accurately communicates the risks associated with the device.

Manufacturers must identify potential hazards, assess the severity and likelihood of harm, and implement appropriate mitigation measures. This process helps to minimize the risk of adverse events or misuse of the device by providing precise and comprehensive labelling that informs users about potential risks and how to mitigate them.

In this chapter, we will identify the risks associated with medical device labelling and how to mitigate them, share case studies of labelling errors and the lessons learned, and outline strategies for crisis management related to labelling issues.

Identifying and Mitigating Risks Associated with Medical Device Labelling

Regulatory Non-Compliance

Risk:	Failure to meet regulatory requirements can result in legal penalties, product recalls, and market withdrawal.
Mitigation Strategies:	<ul style="list-style-type: none">• Stay updated on local and international regulations.• Implement a robust regulatory compliance system.• Regularly audit labelling processes for adherence to standards like FDA, EU MDR, and ISO.

Label Inaccuracies

Risk:	Errors in information such as usage instructions, warnings, or expiration dates can lead to device misuse and harm patients
Mitigation Strategies:	<ul style="list-style-type: none">• Use professional translation services for multi-language labels.• Implement a thorough review and proofreading process.• Utilize automated systems to check for errors and inconsistencies.

Mislabelling

Risk:	Incorrect labels on devices can result in the wrong device being used, leading to serious medical errors.
Mitigation Strategies:	<ul style="list-style-type: none">• Separate labelling and packaging operations to avoid mixups.• Use barcoding and serialization to ensure traceability and correct labelling.• Implement stringent quality control checks throughout the labelling process.

Label Durability Issues

Risk:	Labels that degrade or become illegible under normal use conditions can lead to loss of critical information.
Mitigation Strategies:	<ul style="list-style-type: none">• Test labels under various environmental conditions.• Use high-quality materials and printing methods to ensure label durability.• Regularly inspect labels during the product lifecycle to ensure legibility.

Identifying and Mitigating Risks Associated with Medical Device Labelling (continued)

Inefficiencies in Label Management

Risk:	Inefficient labelling processes can delay product launches and increase operational costs.
Mitigation Strategies:	<ul style="list-style-type: none">• Adopt digital label management systems to streamline processes.• Automate label approval and change procedures.• Integrate label management with other enterprise systems (ERP, PLM, MES) for seamless operations.

Supply Chain Disruptions

Risk:	Labelling errors or delays can disrupt the supply chain, causing inventory issues and delayed shipments.
Mitigation Strategies:	<ul style="list-style-type: none">• Implement a centralized label management system to ensure consistency across the supply chain.• Use cloud-based solutions for real-time updates and coordination.• Establish clear communication and quality standards with suppliers and partners.

Security and Data Integrity

Risk:	Unauthorized access or tampering with labelling information can lead to compliance issues, and product recalls.
Mitigation Strategies:	<ul style="list-style-type: none">• Restrict access to labelling systems to authorized personnel only.• Use role-based access controls and audit trails.• Implement robust cybersecurity measures to protect labelling data.

Obsolescence and Change Management

Risk:	Failure to update labels in accordance with new regulations or product changes can lead to the use of outdated information.
Mitigation Strategies:	<ul style="list-style-type: none">• Establish a formal change control process for all labelling updates.• Regularly review and update labels as part of the device lifecycle management.• Ensure all changes are reviewed and approved by relevant stakeholders before implementation.

User Misunderstanding

Risk:	Poorly designed labels can confuse users, resulting in improper device use.
Mitigation Strategies:	<ul style="list-style-type: none">• Design labels with clear, concise, and user-friendly information.• Conduct usability testing with end-users to ensure clarity and understanding.• Provide comprehensive user instructions and training materials.

By proactively addressing these risks through meticulous planning, advanced technologies, and stringent quality control measures, medical device manufacturers can mitigate the risks associated with labelling and ensure the safety, compliance, and efficiency of their products in the market.



Strategies for Crisis Management Related to Medical Device Labelling Issues

By following these strategies and taking proactive measures to address labelling issues, medical device manufacturers can effectively manage crises, protect patient safety, uphold regulatory compliance, and safeguard their reputation in the market.

1. Establish a Crisis Management Team

- Designate Responsibilities: Assign roles and responsibilities to team members to coordinate the crisis response.
- Cross-functional collaboration: Ensure representation from regulatory affairs, quality assurance, legal, communications, and senior management to address various aspects of the crisis.

2. Rapid Assessment and Communication

- Gather Information: Conduct a thorough assessment of the labelling issue, including its scope, impact, and root causes.
- Internal Communication: Immediately notify relevant internal stakeholders, including production, distribution, and regulatory teams, about the issue.
- External Communication: Develop a plan for timely and transparent communication with regulatory authorities, customers, healthcare professionals, and the public.

3. Regulatory Compliance

- Regulatory Engagement: Engage with regulatory authorities to understand their requirements and expectations for addressing the labelling issue.
- Compliance Remediation: Develop and implement corrective actions to address non-compliance with regulatory standards, such as labelling revisions, recalls, or market withdrawals.

4. Product Recall or Market Withdrawal

- **Assess Recall Severity:** Determine the severity of the labelling issue and whether a product recall or market withdrawal is necessary.
- **Recall Execution:** Execute the recall or withdrawal process efficiently, including notifying affected parties, retrieving affected products, and disposing of recalled items.
- **Monitor Effectiveness:** Continuously monitor the effectiveness of the recall or withdrawal actions and adjust strategies as needed.

5. Corrective Actions and Preventive Measures

- **Root Cause Analysis:** Conduct a thorough investigation to identify the root causes of the labelling issue and prevent a recurrence.
- **Implement Corrective Actions:** Implement immediate corrective actions to address the labelling issue and prevent its recurrence.
- **Continuous Improvement:** Establish a system for ongoing monitoring, evaluation, and improvement of labelling processes to prevent future crises.

6. Stakeholder Engagement and Support

- **Customer Support:** Support and assist customers affected by the labelling issue, including replacing or reimbursing affected products.
- **Healthcare Professional Education:** Educate healthcare professionals about the labelling issue and provide guidance on proper product use and handling.
- **Media and Public Relations:** Manage media inquiries and public perception by providing accurate and timely information about the labelling issue and the company's response.

7. Documentation and Reporting

- **Record Keeping:** Maintain detailed documentation of the labelling issue, crisis response activities, and corrective actions taken.
- **Regulatory Reporting:** Comply with regulatory requirements for reporting labelling-related incidents, recalls, or corrective actions to relevant authorities.

8. Learn from the Crisis

- **Post-Crisis Evaluation:** Conduct a post-crisis evaluation to assess the effectiveness of the crisis management response and identify lessons learned.
- **Continuous Improvement:** Use insights from the crisis to strengthen labelling processes, improve risk management strategies, and enhance organizational resilience.



The Ripple Effect: Exploring the Extensive Costs Associated with Product Recalls

Chapter 7

Medical Device Labelling Training and Education

Training is essential for ensuring personnel have the knowledge, skills, and competencies to manage medical device labelling effectively, promoting regulatory compliance, product quality, and overall operational efficiency.

Identifying and Mitigating Risks Associated with Medical Device Labelling

Internal Training Programs

Internal training programs for medical device label management are essential for ensuring that all employees involved in the label creation process understand the regulatory requirements, company procedures, and best practices. Here's why they're essential:

- Regulatory Compliance
- Quality Control
- Risk Management
- Efficiency

Continuous Education

It's essential to stay up-to-date with industry changes. Establish a culture of continuous learning by providing ongoing training opportunities, updates on regulatory changes, and access to relevant resources and tools. Experience the benefits:

- Adaptability
- Improved Performance
- Innovation
- Employee Engagement and Retention
- Risk Mitigation
- Professional Growth
- Organizational Resilience

To implement an effective internal training program for medical device label management, consider the following steps:

- **Identify Training Needs:** Assess the knowledge and skill gaps among employees involved in label management. Determine the specific topics and areas that require training, such as regulatory requirements, label design principles, risk management, and software proficiency.
- **Develop Training Materials:** Create comprehensive training materials tailored to the identified needs. This may include written manuals, presentations, video tutorials, and interactive workshops.
- **Utilize Subject Matter Experts:** Engage experts within the organization or industry professionals to deliver training sessions and provide insights into specific topics.
- **Provide Hands-On Training:** Offer practical, hands-on training exercises to allow employees to apply their knowledge and skills in real-world scenarios. This could involve mock label creation exercises, case studies, or interactive software demonstrations.
- **Evaluation and Feedback:** Regularly evaluate the effectiveness of the training program through assessments, quizzes, and participant feedback. Use this feedback to make improvements and updates as needed.



We believe in continuous learning. Our resource section has everything on medical device labelling compliance and beyond.

Conclusion

Maximizing Compliance and Efficiency in Medical Device Labelling

Nothing is more critical to patient safety than label management. Label management is at the core of the medical device industry's importance. Regulatory compliance, safety, and quality are the foundation of medical device labelling.

The significance of regulatory compliance is highlighted by the potential consequences of incorrect or misleading labelling, which can compromise patient safety and lead to costly recalls.

Proper label management enhances patient safety by providing error-free instructions on device use, handling, and associated risks. Understanding the global labelling regulations for medical devices is crucial to achieving compliance.

Digitalizing labelling processes is essential for adapting to the dynamic supply chain environment and maintaining a flexible and responsive supply chain. It can help prevent delays, ensure compliance, and maintain continuity during disruptions, especially when switching suppliers. Cloud-based solutions and automation play a crucial role in modernizing labelling procedures and ensuring compliance across the supply chain.

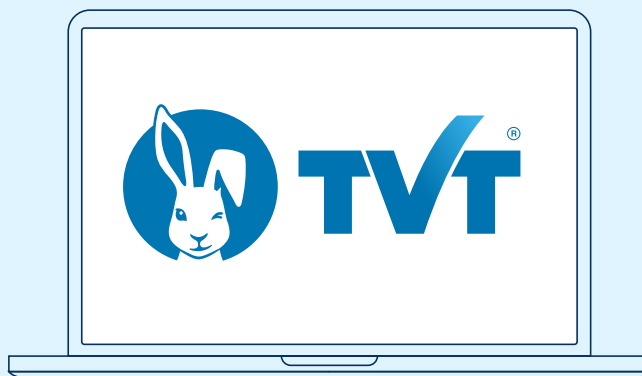


Continually evaluate and improve your medical device label management practices

The **Text Verification Tool (TVT)** by **Schlafender Hase** is an essential solution for medical device labelling in regulated environments like Life Sciences, where accuracy is critical. TVT simplifies the complex document preparation process by automating proofreading across different file formats, multilingual documents, tables, and graphics, ensuring 100% accuracy.

TVT prevents errors, costly misprints, and recalls by enabling easy comparisons of full-page **artwork** and **barcodes** and validating against printer proofs. It supports multiple dictionaries, including medical ones (such as Stedman's), ensuring correct spelling at every review stage.

By consolidating all changes into a comprehensive report, **TVT** provides a fully compliant audit trail, improving workflow efficiency, accuracy, and compliance. Additionally, TVT facilitates the continual evaluation and improvement of label management practices, ensuring that processes remain up-to-date and effective in maintaining the highest standards of accuracy and compliance.



BOOK A DEMO

Appendix

Glossary of terms

ERP (Enterprise Resource Planning)	Integrated management of core business processes, often in real-time and mediated by software and technology.
EU MDR (European Union Medical Device Regulation)	The regulatory framework for medical devices in the European Union.
FDA (U.S. Food and Drug Administration)	The regulatory body responsible for regulating medical devices in the United States.
Label Management	The process of creating, reviewing, approving, printing, and maintaining labels for medical devices to ensure compliance with regulatory requirements.
QMS (Quality Management Systems)	A set of policies, processes, and procedures required for planning and execution in the core business area of an organization.
Quality Control	Ensuring that products meet quality standards and requirements.
Risk Management	Identifying, assessing, and mitigating potential risks associated with medical device labelling.
Traceability	The ability to trace a product's history, application, or location through documented information.
Unique Device Identifier (UDI)	A unique numeric or alphanumeric code that provides a standard way to identify medical devices.

Appendix I

Regulatory Bodies and Contact Information

Region	Regulatory Authority	e-labelling guidelines	HA Link
Australia 	TGA	This guidance refers to requirements set out in clause 13A of Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the MD Regulations). It provides an overview of different types of patient information material (patient information leaflets and patient implant cards)	Link
Canada 	Health Canada	Health Canada Guidance for the Labelling of Medical Devices. To assist manufacturers of non-in vitro diagnostic devices in complying with the labelling requirements under sections 21 - 23 of the Medical Devices Regulations	Link
Europe 	EMA	Regulation (EU) 2017/745 of the European Parliament and Council - 05 April 2017 on medical devices. Chapter III - Requirements regarding the information supplied with the Device states the 'Instructions for Use may be provided to the user in non-paper format (e.g. electronic)'	Link
India 	CDSKO	India has become the latest medical device market where regulators are accepting electronic indications for use (e-IFU)	Link
Japan 	PMDA	Digitization of package inserts, due to the revision of the Act on Securing Quality, Efficacy, and Safety of Products, including Pharmaceuticals and Medical Devices (Act No. 145 of 1960; the "PMD Act") was implemented on 01 August 2019	Link
Saudi 	SFDA	MDS – G5 Guidance on Requirements for Medical Device Listing and Marketing Authorization 23.1. General requirements regarding the information supplied by the manufacturer. Instructions for Use may be provided to the user in non-paper format (e.g. electronic)	Link
Singapore 	HSA	GN-23: Guidance on Labelling for Medical Devices HSA state, for devices not sold to the general public, Instructions for Use may be provided to the user either in paper or non-paper format	Link
Taiwan 	TFDA	The Medical Devices Act (MDA) May 2021 states, for specific medical devices announced by the central competent authority, the instructions set forth in the preceding paragraph may be replaced by electronic instructions. A pilot for replacing enclosed paper labelling with e-labelling is underway [2022]	Link
UK 	MHRA	Regulation 4J of the Medical Device Regulations 2002 [UK MDR 2002] allows manufacturers of certain types of medical devices and accessories to provide electronic Instructions for Use	Link
USA 	FDA	21 CFR Part 801 – General Labelling requirements for Medical Devices. In healthcare facilities, e-IFUs may be made available solely by electronic means [2004]	Link

References

- 1 <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation>
- 2 <https://www.fda.gov/regulatory-information/federal-food-drug-and-cosmetic-act-fdc-act/fdc-act-chapter-v-drugs-and-devices>
- 3 <https://www.fda.gov/medical-devices/overview-device-regulation/device-labelling>
- 4 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labelling>
- 5 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20230320> /
<https://eur-lex.europa.eu/eli/reg/2017/746/2017-05-05>
- 6 <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>
- 7 https://health.ec.europa.eu/document/download/add107c5-0ca8-45d3-b049-63bb84c4ce31_de?filename=md_faq_udi_en.pdf
- 8 https://health.ec.europa.eu/publications/overview-language-requirements-manufacturers-medical-devices_en
- 9 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/labelling-regulatory-requirements-medical-devices-fda-89-4203>
- 10 <https://www.fda.gov/medical-devices/device-labelling/use-symbols-labelling>
- 11 <https://www.medical-device-regulation.eu/category/z-annex-i-general-safety-and-performance-requirements-chapter-3-requirements-regarding-the-information-supplied-with-the-device-part-1/>

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