



eBook

Medical Devices

Navigating the Compliance Landscape

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Introduction

Medical device manufacturers help save lives, but without due diligence, their products and sourcing could cause more harm than good by compromising human health or supporting unethical business practices.

To maintain a strong reputation, companies need comprehensive supply chain sustainability management programs that remain ahead of changing requirements.

This eBook discusses relevant regulatory requirements and the unique compliance challenges medical device manufacturers face: product compliance, vendor management, and corporate social responsibility (CSR) topics. It explains how regulations are enforced and how companies can prepare their programs for success.





CHAPTER 01

Compliance & Due Diligence

Medical device manufacturers are under constant scrutiny from stakeholders, the public, and regulatory bodies. Meeting compliance requirements and managing vendor relationships are key to retaining market access and mitigating reputational risk.

Medical device manufacturers also contend with vast amounts of supply chain data, disparate product lifecycle management, and a lack of industry-specific standardized reporting templates. They must work to remain ahead of evolving requirements and conduct due diligence to mitigate costly product design changes.

EU RoHS Directive

The EU Restriction of Hazardous Substances (RoHS) Directive restricts the use of 10 substances in electronics, including medical devices. In 2015, the directive was amended to add four more phthalates to the list of restricted substances. The current RoHS list is:

- ▶ Lead
- ▶ Mercury
- ▶ Cadmium
- ▶ Hexavalent chromium
- ▶ Polybrominated biphenyls
- ▶ Polybrominated diphenyl ethersBis(2-Ethylhexyl) phthalate (DEHP): max 0.1%;
- ▶ Benzyl butyl phthalate (BBP): max 0.1%;
- ▶ Dibutyl phthalate (DBP): max 0.1%;
- ▶ Diisobutyl phthalate (DIBP): max 0.1%.

In 2017, the directive was updated with the consideration of second-hand medical devices. While the RoHS Directive didn't formerly consider second-hand products, the medical device industry made the argument for medical devices that can sometimes be repurposed. If the amendment is adopted, certain second-hand medical devices could continue to be marketed beyond 2019.¹

¹ National Law Review. (2016, December 19). *EU Expected to Amend RoHS2 Directive for Used and Refurbished Medical Devices*. <https://www.natlawreview.com/article/eu-expected-to-amend-rohs2-directive-used-and-refurbished-medical-devices>



EU Medical Device Regulation & EU In-Vitro Diagnostic Medical Devices Regulation

On May 25, 2017, the EU Medical Device Regulation (MDR), or (EU) 2017/745, and the EU In-Vitro Diagnostic Medical Devices Regulation (IVDR), or (EU) 2017/746, came into force. The EU MDR was initially set to come into effect in spring of 2020, and the IVDR in spring of 2022.² Due to the impacts of the COVID-19 pandemic, however, the European Commission adopted a proposal to grant a 12-month extension to the EU MDR deadline, pushing it to May 26, 2021.

Section 10.4 of the EU MDR has imposed hazardous substances requirements on companies and expanded the scope of products.

EU Waste Framework Directive

In 2017, the EU Waste Framework Directive evolved to align with the EU 2018 Circular Economy package. This established targets for waste recycling and required reporting on substances of very high concern (SVHCs) contained in products. Medical device companies doing business in the EU faced a significant increase in the effort needed to survey their supply chains for the presence of SVHCs.

With the establishment of the Substances of Concern In articles, as such or in complex objects (Products) (SCIP) database for EU waste recyclers to verify SVHC data, any EU company that submits a declaration under the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation must also make the same submission to the European Chemicals Agency (ECHA) for inclusion in the SCIP database. Manufacturers based outside the EU will still need to satisfy this requirement when they sell products into the region.

² European Commission. (n.d.). Regulatory framework.
https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

Figure 1.1: Regulatory Timeline for Medical Device Companies

1986

- ▶ California voters pass the **Safe Drinking Water and Toxic Enforcement Act**, also known as **Proposition 65**

2006

- ▶ The **European Union (EU) Restriction of Hazardous Substances (RoHS) Directive** enters into effect
- ▶ The **Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation** is released

2012

- ▶ Framework for the **Labour Standards Assurance System (LSAS)** is released
- ▶ The United States passes **conflict minerals legislation**

2013

- ▶ Michael Porter publishes the **Value-Based Health Care Delivery** framework, influencing health care providers¹

2014

- ▶ The **EU Public Procurement Directive 2014/24/EU** comes into force

2015

- ▶ The **RoHS Directive** is amended to add four additional substances
- ▶ The **UK Modern Slavery Act** is released
- ▶ MedTech Europe publishes **Key Principles of Smart Procurement for Medical Devices**

2017

- ▶ The **EU Waste Framework Directive** evolves to align with the **EU 2018 Circular Economy package**; medical device companies face new data requirements
- ▶ The **EU Medical Device Regulation (MDR), or (EU) 2017/745**, and **EU In-Vitro Diagnostic Medical Devices Regulation (IVDR), or (EU) 2017/746**, come into force
- ▶ The **Non-Financial Reporting Directive** comes into effect

2018

- ▶ New **Proposition 65** labeling requirements come into effect for products distributed in California

2019

- ▶ Sweden proposes a **new sustainability question set**, which is being introduced across all public procurement sectors
- ▶ The four new **RoHS Directive substances** come into effect, with a transitional period for medical devices
- ▶ MedTech examines the procurement logic set out in the **EU Public Procurement Directive 2014/24/EU**; the development of a **Most Economically Advantageous Tender (MEAT)** tool increases sustainability considerations in public procurement
- ▶ **Australia's Modern Slavery Act** takes effect

2020

- ▶ The **EU MDR** is delayed one year due to COVID-19
- ▶ Increased **sustainability requirements** are expected for public procurement under the **EU Public Procurement Directive**
- ▶ Switzerland's referendum on the freedom of movement of people is due in May 2020, which determines Switzerland's relationship with the EU and could void product approvals

2021

- ▶ The transitional period for medical devices under the **EU RoHS Directive's** four new substances ends
- ▶ The **EU MDR** takes effect
- ▶ A restricted substances list for the Nordic region is being developed by the **Nordic Product Register Group**
- ▶ The **EU Conflict Minerals Regulation** takes effect

2022

- ▶ The **EU IVDR** takes effect

Ongoing

- ▶ Canada and Hong Kong discuss **modern slavery bills**
- ▶ New **REACH SVHCs** added every six months
- ▶ **RoHS exemptions** applicable to medical devices expire



The Data Challenge

Collecting data from suppliers and validating that data are among the biggest challenges companies face in meeting their regulatory requirements. The medical device industry has not adopted any standards that facilitate this data exchange, resulting in inconsistent information that is difficult to validate and lengthy timelines.

Industry Response to Compliance Requirements

Medical device manufacturers often face challenges from a lack of internalized processes and programs as well as data that is siloed and accessible to all stakeholders. Medical device companies often outsource their programs to third-party data and risk management firms that help them demonstrate due diligence and manage data.





CHAPTER 02

Product Compliance

Product compliance is vital to preserving market access, maintaining business continuity, and mitigating reputational risk. The number of restricted substances continues to grow, and companies need to be proactive about meeting their requirements. Medical device manufacturers that remain ahead of changing restricted substance lists and understand the full composition of their products are better equipped to identify which of their products could be in scope of future regulations and avoid costly product redesigns.

Companies face business continuity risks if they are not compliant with the regulations listed here. Supply chain disruptions could occur as a result of non-compliance with a variety of regulations, from discovering hazardous substances in a product to having to source a new key vendor.



EU Medical Device Regulation & EU In Vitro Diagnostic Medical Devices Regulation

The EU MDR (EU 2017/745) and the IVDR (EU 2017/746) entered into force on May 25, 2017. These regulations each replace existing directives, resulting in additional requirements for companies in scope, and recertification of existing and new products by newly-defined notified bodies. There are transitional provisions in place to support the continued availability of the life-saving medical devices on the market today. The transition period for the MDR was spring 2021, and the transition period for products in scope of the IVDR will continue until spring of 2022.

The MDR's broadened scope under Section 10.4 means companies whose products were not formerly in scope — including devices sold online — may now have additional compliance requirements. Section 10.4 also reclassifies medical devices into four main categories: Class I, Class IIa, Class IIb, and Class III.³

This means companies are required to identify if devices fall into the following categories:

- ▶ Devices that “are invasive and come into direct contact with the human body”
- ▶ Devices that “(re)administer medicines, body liquids, or other substances, including gases, to/from the body”
- ▶ Devices that “transport or store such medicines, body fluids, or substances, including gases, to be (re)administered to the body”

To date, notified bodies continue to be established across Europe and added to the Notified Bodies NANDO database once approved.⁴

Increased Requirements on Notified Bodies

Under the MDR and IVDR, notified bodies must make the final approval on data and grant the CE marking to products. When manufacturers assess their products, they must apply to a notified body for approval, which could entail an expert panel review by the European Commission. Hundreds of thousands of products will need to be recertified by notified bodies in order to remain on the market after the May 2022 date of application for in-vitro diagnostics.

3 European Commission. (2019, October 31). Regulatory framework. https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

4 European Commission. (n.d.). Internal Market, Industry, Entrepreneurship and SMEs. https://ec.europa.eu/growth/tools-databases/hando/index.cfm?fuseaction=directive.notifiedbody&dir_id=3

RoHS Directive

When medical device manufacturers build their technical files, they must include data addressing RoHS Directive requirements in order to obtain a CE marking.

Companies will need to identify the presence of RoHS substances in their supply chains and seek substitution where exemptions are not available. They may apply for an exemption, which temporarily allows a restricted substance to be used in certain applications when an alternative is not currently available.

The REACH Regulation

The EU REACH Regulation makes a distinction between medical devices that are chemical substances and those defined as articles. A medical device could qualify as an article under REACH, or be in scope of the regulation based on the substances used within the product. Companies are required to notify the ECHA of any SVHCs contained within their products above the specified reporting threshold.⁵ The obligations for medical device companies in scope include:

- ▶ Registering substances
- ▶ Providing safe use instructions to suppliers, recipients, or consumers
- ▶ Responding to requests for information within 45 days⁶

As the list of SVHCs evolves, companies obligated to report on the substances in their products can face challenges in staying ahead of their requirements.

Case Study: Becton Dickinson EDTA Blood Collection Tubes Recall

Becton Dickinson is a medical device company that produces blood collection tubes used to transport and process blood samples for testing in clinical laboratories. In March 2018, the company recalled their Vacutainer® EDTA Blood Collection Tubes with lavender, tan, pink, and green rubber tube stoppers due to a chemical in the product that interferes with Anodic Stripping Voltammetry (ASV) testing. This type of testing is the methodology used in Magellan Diagnostics' LeadCare Testing Systems; any patient being tested using ASV technology could be impacted by this recall.

The product contains thiuram, a substance used in the vulcanization of rubber, which could release sulfur-containing gases. These gases could potentially dissolve into the blood sample and make it difficult for Magellan lead tests to detect the correct amount of lead in the sample. This could cause inaccurate test results. The FDA has identified this recall as a Class I recall, as the use of these devices could cause serious injury or death.⁷

⁵ Packing Digest. (2011). Medical devices under REACH and RoHS. <https://www.packagingdigest.com/sustainable-packaging/pmp-medical-devices-under-reach-and-rohs-2011-10-05>

⁶ Fieldfisher. (2011). Legal aspects of REACH and the medical devices sector. <https://www.fieldfisher.com/publications/2011/07/legal-aspects-of-reach-and-the-medical-devices-sector>

⁷ U.S. Food and Drug Administration. (n.d.). Becton Dickinson (BD) and Company Recalls Vacutainer® EDTA Blood Collection Tubes Due to Chemical Interference with Certain Tests. <https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm602479.htm>



Making the Case for Product Compliance

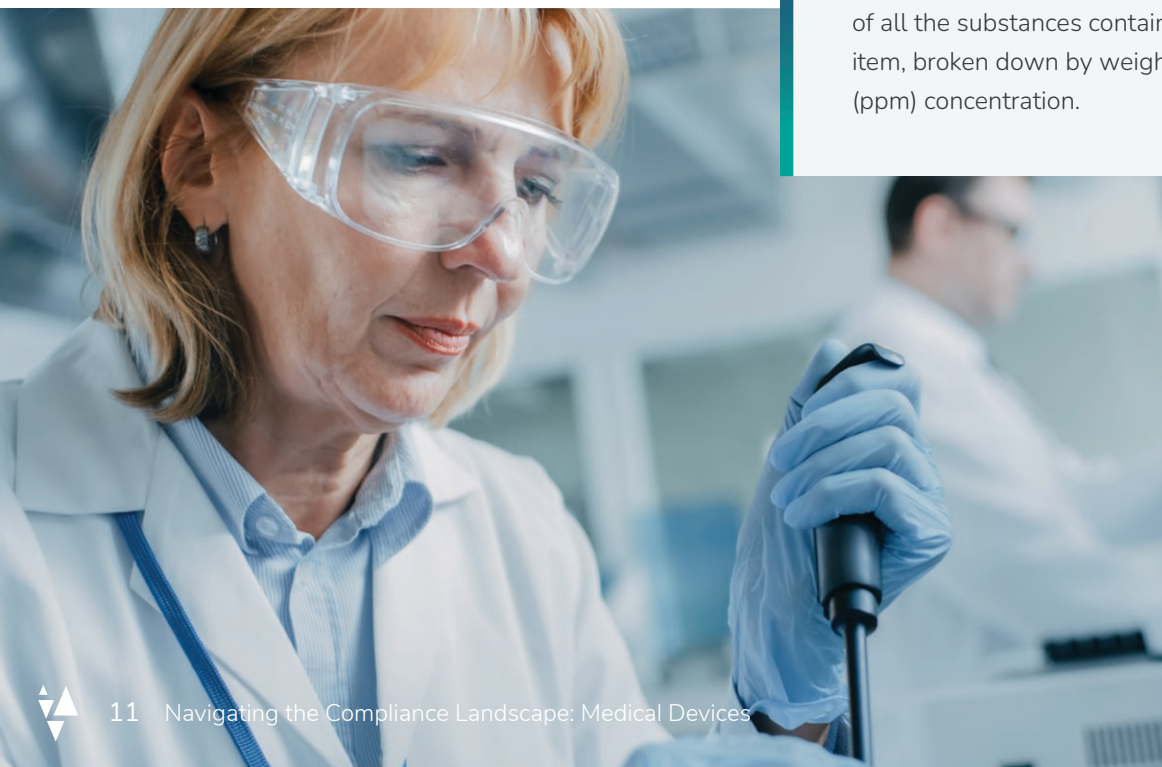
To ensure continued market access and mitigate reputational risk, companies should take a proactive approach to product compliance. Staying ahead of requirements is difficult in the face of constantly changing restricted substance lists.

A comprehensive product compliance program and an efficient supply chain sustainability solution help companies look deep in the supply chain to see what substances are contained in their products. Cross-enterprise and cross-supply chain collaboration, efficient data management, and a thorough understanding of their requirements let companies prepare to comply with regulations.

Vendor management is important to protecting industry relationships with key suppliers and ensuring business continuity. Some suppliers feel there is a risk to working with medical device companies, which can make securing vendors a challenge. Losing a critical vendor is a major setback for medical device companies, with significant financial loss and increased go-to-market time. It is important that medical device companies stay up to date on their vendor management requirements to ensure their operations are not put at risk from supply chain issues.

Full Material Disclosures

Full material disclosures (FMDs) contain a declaration of all the substances contained in a manufactured item, broken down by weight and/or parts per million (ppm) concentration.





CHAPTER 03

Vendor Management

Food & Drug Administration

Medical devices are subject to certain laws and regulations governed by the U.S. Food and Drug Administration (FDA) if they are offered for sale or use in the U.S. Companies that create or import medical devices for commercial distribution in the U.S. are required to register with the FDA, and to verify the registration and listing before they import their products. Medical devices may also have to comply with premarket submission requirements demonstrating or evaluating the safety of their product.

Medical devices are classified as Class I, Class II, or Class III according to their level of risk, with different requirements to import based on this classification. Companies should note the FDA also conducts field examinations and sample analysis to determine if medical devices comply with the standards and labeling requirements they have in place.⁸

⁸ U.S. Food and Drug Administration. (n.d.). Medical Device Overview. <https://www.fda.gov/forindustry/importprogram/importbasics/regulatedproducts/ucm510630.htm#deviceclass>

Case Study: Hernia Mesh Lawsuit Against Atrium & Physiomesh

Atrium and Ethicon, two companies that manufacture hernia surgical mesh implants, faced lawsuits alleging that these companies were aware of the dangers of their products, but did not adequately warn doctors and consumers of the risks. Several of the lawsuits claimed the companies did not perform proper due diligence to ensure their products would function as intended, even though the FDA allowed pre-market clearance.

The FDA has documented adverse event reports against these products and others, and issued product recalls. In 2012, Atrium received warning letters from the FDA because the company did not address known issues with the device. This was followed by a Class 2 recall and an eventual lawsuit against them. In the case of Ethicon, the company voluntarily recalled their product in 2016 for violating FDA guidelines. Companies subject to these lawsuits may have paid millions of dollars in settlements to date due to their products being deemed unsafe or defective.⁹

⁹ ConsumerSafety.org. (2018). Hernia Mesh Lawsuit. <https://www.consumersafety.org/legal/hernia-mesh-lawsuit/>

Trade Compliance

Trade compliance and ensuring conformance with all applicable laws and regulations is an important consideration for medical device companies that import products globally. Importers often take on the majority of the compliance burden, and could be faced with tariffs or sanctions if their products come from certain high-risk areas.

Companies are required to provide authorities with the information they need to accurately assess the product and determine if it is in scope of any additional regulations, and are often subject to a focused assessment. This focused assessment is used to determine a company's level of compliance based on their internal programs and an audit of certain transactions, and helps determine the company's ability to comply with future regulations.¹⁰

Tariff rates are determined by tracking Harmonized Commodity Description and Coding System (HS) codes and country of origin certificates, and cross-referencing or gathering free trade agreement certifications. The country of origin of a product can result in changes in fees. Medical device companies that source their materials from locations embroiled in trade disputes must be prepared to increase their due diligence efforts and supply chain visibility.

¹⁰ Law Offices of George R. Tuttle. (n.d.). Trade Compliance. <https://www.tuttlelaw.com/subjects/~trade/compliance.html>

Harmonized Tariff Schedule Codes

United States Harmonized Tariff Schedule (HTS codes) implement the World Customs Organization's HS codes in the U.S. Products shipped into the U.S. require an HTS code from the U.S. International Trade Commission database to enter into the country. Even small changes to the product can result in a change of code. Companies need to survey their supply chains to determine whether the correct code has been used, or to prepare for new codes as their product composition changes.

Country of Origin

Country of origin certificates certify where a product is manufactured or produced. These certificates, in combination with an HTS code, determine the tariff that companies must pay. If companies intend to bid on federal procurement contracts, they must understand the origin of their products and demonstrate compliance with current regulations. Companies require current information on their suppliers, the origin of their products, and an accurate value of the parts and services implemented into their finished product.

Manufacturers in the medical device industry face expectations from shareholders and the public to prove due diligence, make continuous improvements in their environmental, social, and governance (ESG) and corporate social responsibility (CSR) performance. This means engaging in business practices free from bribery and corruption. Medical device companies must monitor their global supply chains to retain contracts while mitigating reputational risk.





CHAPTER 04

ESG & CSR

Human Trafficking & Slavery

The growing list of human trafficking and slavery legislation includes the German Supply Chain Act, the UK Modern Slavery Act, French Duty of Vigilance Law, the Countering America's Adversaries Through Sanctions Act (CAATSA), the U.S. Trade Facilitation and Trade Enforcement Act, the Dutch Child Labour Due Diligence Law, and the Australian Modern Slavery Act.

U.S. Federal Acquisition Regulation

The U.S. Federal Acquisition Regulation (FAR) governs executive agency procurement contracts, providing uniform policies and procedures for selling to the U.S. government. Medical device companies and their suppliers could be in scope of FAR if they supply to a U.S. federally-owned business through their contract with the government. Companies are required to have a compliance plan in place to ensure they do not have human trafficking and slavery in their supply chains, and must be able to demonstrate they have controls in place. Those who cannot face significant financial penalties and loss of contracts.

Labour Standards Assurance System

The Labour Standards Assurance System (LSAS) is a mandate that reduces the incidence of labor issues in the medical device industry by monitoring standards throughout the supply chain. Companies that are awarded contracts with the UK's National Health Service (NHS) are audited against LSAS requirements and are expected to demonstrate continuous improvement as they progress through the four levels of the LSAS matrix. As part of a company's overall ESG program, compliance with LSAS requirements ensures labor management systems get stronger, and that supply chains meet fair labor standards. Compliance is essential to avoid loss of contracts, and reduce or eliminate instances of human rights abuses in the supply chain.

National Health Service Supply Chain

The NHS Supply Chain is the procurement arm of the NHS, providing end-to-end supply service incorporating procurement, logistics, e-commerce, and customer and supplier support. NHS Supply Chain provides the NHS with cost-effective, quality products while working to improve labor standards throughout the supply chains of its suppliers.

Case Study: Child Labor Used to Produce Surgical Instruments in Pakistan

In early 2018, it was discovered that child labor was used to produce surgical instruments in Pakistan in at least 12 workshops that supply to the NHS. Fears that these workshops supply to the NHS were supported by the fact that three medical device companies that export to the UK admitted to purchasing from these suppliers.¹¹ Although the NHS Supply Chain bans the use of child labor from its first-tier suppliers, the medical device industry faces many risks without deeper visibility into their supply chains, and there may still be human rights violations further down.

¹¹ The Guardian. (2018, January 29). NHS admits doctors may be using tools made by children in Pakistan. <https://www.theguardian.com/global-development/2018/jan/29/nhs-admits-doctors-may-be-using-tools-made-by-children-in-pakistan>





Learn More About LSAS

Learn more about NHS, LSAS requirements, and what companies need to know to comply. Download our eBook, *Understanding the UK Labour Standards Assurance System*.

[Download eBook](#)

Foreign Corrupt Practices Act

Any company that has international sales and business development initiatives, and conducts business with foreign officials, may be in scope of the Foreign Corrupt Practices Act (FCPA). In most cases, medical device companies sell to national, publicly-funded health care organizations, so taking a member of hospital staff to an entertainment event or offering a gift to gain favor could be a violation.

In order to comply with the anti-bribery provision of the FCPA, medical device manufacturers must keep detailed proof of due diligence and be able to provide accurate reports on their transactions and asset dispositions.

UK Bribery Act

The UK Bribery Act 2010 has global jurisdiction, applying to bribery of public officials and businesses around the world. Companies incorporated in the UK, or residents of the UK, are potentially in scope of this act. The requirements are far-reaching: companies in scope must ensure they have the supply chain transparency needed to mitigate the risk of bribery occurring in their operations, or on behalf of their company.

Chinese Anti-Corruption

The Anti-Unfair Competition Law and the Criminal Law of the People's Republic of China (PRC) both include provisions against corruption and bribery. Under the Anti-Unfair Competition Law, bribes may not be given or received during the process of buying or selling goods, while the Criminal Law of the PRC “prohibits giving and receiving money or property ... to obtain an undue benefit.”¹² To ensure compliance with these laws, companies should communicate corporate policies to relevant stakeholders and perform due diligence throughout the supply chain.

Conflict Minerals

Under global conflict mineral laws and expanding responsible minerals sourcing requirements, companies must ensure they are not funding armed conflict in global “high-risk” areas or supporting other human rights abuses when sourcing the minerals used in their products — including tin, tungsten, tantalum, and gold (3TGs).

For medical device companies, responsible mineral sourcing programs are important from a reputational risk perspective. Prioritizing ESG in their business and supply chain demonstrates reduces the risk of contract loss. Medical device companies should leverage the United Nations Guiding Principles to help create and maintain their ESG programs.

Making the Case for Corporate Social Responsibility

Corporate social responsibility is a component of the larger ESG umbrella, focused on protecting your brand value by ensuring your supply chain operates ethically. Today, investors evaluate a company’s entire ESG portfolio, including CSR efforts in addition to other ESG topics. Due diligence for material ESG metrics improves your brand value, while also protecting your supply chain from disruptions and other risks associated with human trafficking, modern slavery, and corruption.

¹² GAN Business Anti-Corruption Portal. (2016). Chinese Anti-Corruption Laws. <https://www.business-anti-corruption.com/anti-corruption-legislation/china/>





CHAPTER 05

Achieving Program Success

While the specifications of each medical device manufacturer program will differ based on program goals and regulatory requirements, the core themes of a successful program for each company remain the same. Companies should focus on optimizing their data management and remaining ahead of the changing compliance landscape.

Efficient Data Management

In the medical device world, where companies must maintain and support numerous systems of bills of materials for different product lines, validating, normalizing and centralizing data; automating collection; and streamlining supply chain communication is the only way to effectively and efficiently conduct due diligence.

An Educated Supply Chain

Educating suppliers on the regulatory requirements their customers face can help them support a successful compliance program. This can result in more accurate data, as suppliers are better able to understand what their client needs to receive. Using a compliance learning management system to educate suppliers can also reduce fatigue in your team caused by repeatedly requesting information and having to bridge supplier knowledge gaps.

Subject Matter Expertise

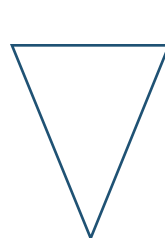
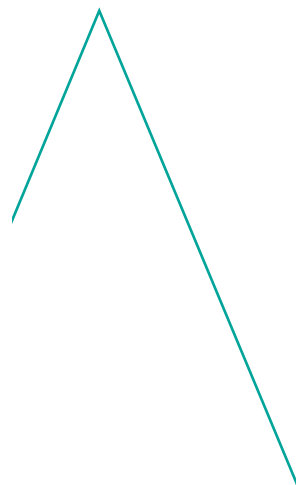
Companies with access to regulatory subject matter expertise are better equipped to proactively handle regulatory changes and plan a more sustainable compliance program. If in-house expertise is not available, companies should partner with service providers with expertise in relevant regulations.

The Right Technology

Technology ensures programs are more efficient and offers a better return on investment than manual methods or internal compliance programs. Look for features such as automation and centralized supply chain sustainability management. Such solutions give companies deep visibility into their supply chains, streamline supplier communications, and ensure companies are better equipped to identify and mitigate risk.

Business Continuity

With the right programs in place, companies can guard against and plan for changes to designs in their products that are subject to regulatory approval and clinical trial evaluations. Thorough supply chain sustainability management also provides manufacturers operational stability, so businesses know their product lines are protected from supply chain risks associated with trade compliance issues or human rights violations and disruptions.



The background of the slide is a photograph of an operating room. In the upper left, a large, circular surgical light fixture is suspended from the ceiling. To its right, another similar fixture is visible. In the lower right, a surgical table with blue padding is partially visible. The overall color palette is light blue and white. Two thin, teal-colored geometric lines, resembling triangles, are overlaid on the right side of the image, pointing towards the text area.

Conclusion

Manufacturers in the medical device industry are subject to a high degree of scrutiny from stakeholders and the public. The manufacturers that win in their markets are the ones with a proactive approach to compliance requirements and deep visibility into their supply chain. Assent is the leading supply chain sustainability management platform, backed by expert support and supplier education, that provides manufacturers with unmatched visibility so they can make data-driven decisions. For more information about how Assent helps medical device manufacturers manage a comprehensive supply chain sustainability program, contact us at info@assent.com.

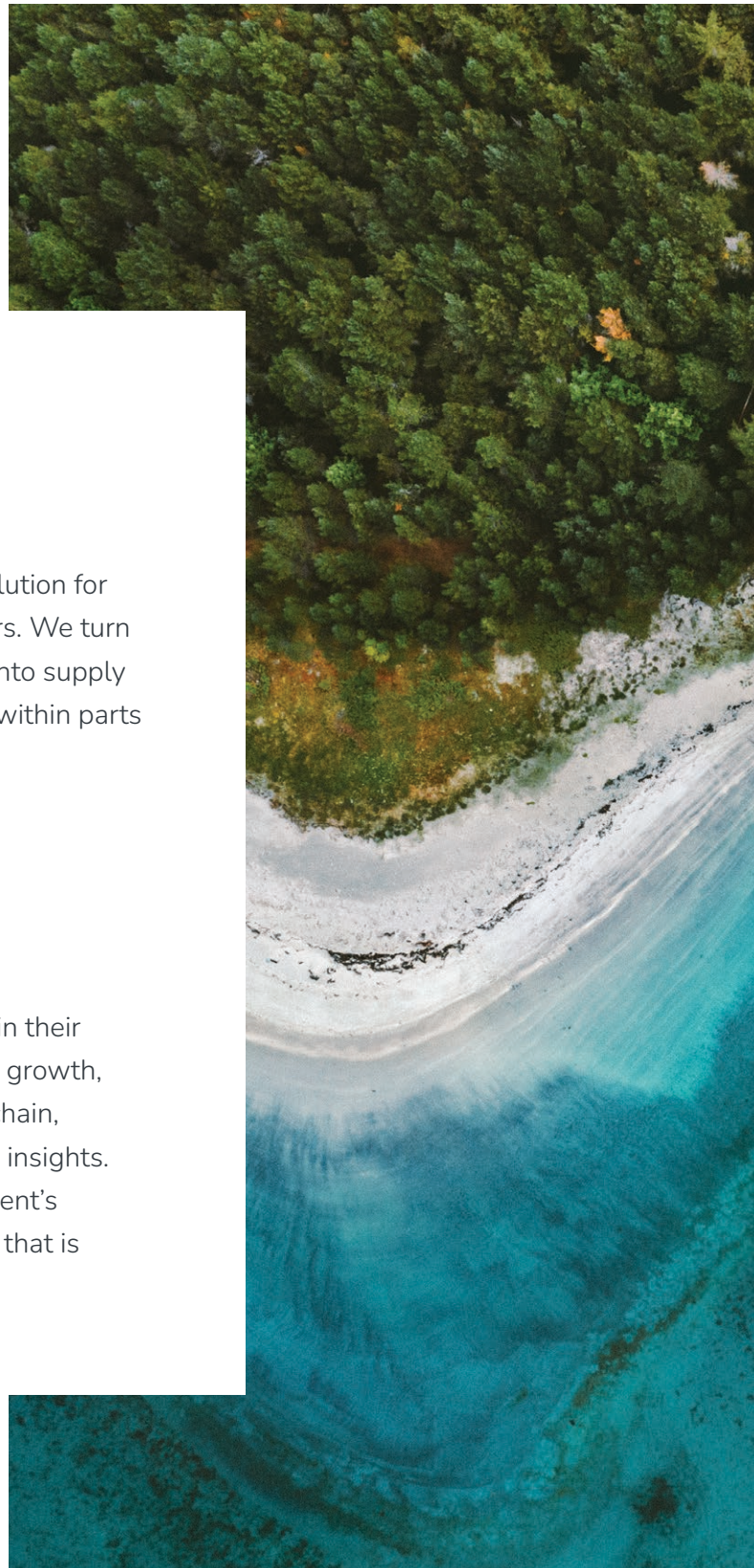


Who Is Assent?

Assent is the supply chain sustainability management solution for the world's most forward-thinking complex manufacturers. We turn sustainability goals into tangible action by delving deep into supply chains, identifying suppliers, parts, and even substances within parts to map the entire complex manufacturing genome.

What We Do

We help companies spot sustainability risks hiding deep in their supply chains and identify new areas of focus to enhance growth, efficiency, and value. By digging deep within the supply chain, we pull and validate more actionable data to provide real insights. Guided by regulatory experts with a diverse skill set, Assent's solution delivers a cross-enterprise view of sustainability that is necessary for true leadership in the field.





[Assent is] a low touchpoint program with very high results and program growth, year in and year out.

— Ryan Zelhofer, Former Product Compliance Manager, Plexus

Over **200,000**
parts managed

80% reduction in staff
management hours



The Assent Solution

The journey toward sustainability demands a new way of thinking about supply chains. Assent turns your supply chain data into a critical tool to make safe, sustainable, and ethical products by providing:

- ▶ Clean data collected from the source using automated engagement techniques that dive deeper into supply chains
- ▶ Crucial, at-a-glance supply chain sustainability data through streamlined dashboards
- ▶ An adaptable program that evolves alongside regulations and industry trends

People are the beating heart of any sustainability program. Assent combines its leading technology with expert guidance, ensuring each program is tailored to your specific needs. Dedicated customer success managers make sure you have a familiar face to speak to about changing program goals or enhancements.

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