



Getting Ahead of the IVDR Tsunami

Proactive strategies for navigating regulatory upheaval, translation demands, and the evolving landscape of EU in vitro diagnostic compliance.



June 8, 2025

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The Transition To IVDR

The transition to the In Vitro Diagnostic Regulation (IVDR) marks a pivotal moment for the in vitro diagnostics (IVD) industry. This new regulatory framework, implemented in the European Union, has been introduced to address the evolving landscape of diagnostic technologies and patient safety. Compared to the 20 year old In Vitro Diagnostic Directive (IVDD), the IVDR has ushered in stricter and more standardized regulations to ensure the safety, efficacy, and quality of IVD devices. It hasn't been an easy transition.

1.1 What is IVDR?

The IVDR is a comprehensive set of regulations that governs in vitro

diagnostic devices used for testing biological samples outside the human body. This regulation applies to a wide array of tests, including genetic and infectious disease diagnostics, ensuring they meet high safety and performance standards. Effective from May 26, 2022, the IVDR introduces a risk-based classification system, placing devices into four classes (A, B, C, and D) based on their potential risk to patients and public health. Unlike the IVDD, which allowed for some variability in national implementation, the IVDR applies uniformly across all EU member states, enhancing consistency and compliance.

Key elements of the IVDR Include:



- Enhanced clinical evidence requirements for device approval.
- A more rigorous oversight process, particularly for higher-risk devices.
- Increased transparency through the publication of clinical data and safety information.

1.2 From IVDD to IVDR: A Paradigm Shift

The transition from the IVDD to the IVDR signifies a move from a directive to a regulation, a change that has important implications for stakeholders. Directives, such as the IVDD, were open to interpretation and national transposition, leading to inconsistencies across EU member states. Regulations like the IVDR, on the other hand, are binding and directly applicable, creating a unified legal framework.

One of the most significant shifts is the introduction of the risk-based classification system. Under the IVDD, many devices were self-declared as compliant without oversight. The IVDR, however, subjects all but the lowest-risk devices (Class A) to review by notified bodies, entities designated to assess device compliance.

In addition, the IVDR requires extensive performance evaluations and post-market surveillance to ensure ongoing safety and effectiveness. These changes reflect the EU's commitment to addressing advancements in technology and increasing patient trust in diagnostic devices. We have recently posted a blog on this topic [available here](#).

1.3 New Requirements for Manufacturers

The IVDR introduces a range of new obligations for manufacturers, placing greater emphasis on accountability and transparency.

These include:

- Post-Market Surveillance (PMS):** Manufacturers must establish robust PMS systems to monitor device performance and safety once they are on the market.
- Unique Device Identification (UDI):** Devices must carry a UDI to enable traceability throughout the supply chain.
- Notified Body Involvement:** For all but Class A devices, manufacturers must engage notified bodies for conformity assessment.
- Performance Evaluations:** Comprehensive clinical data must be provided to demonstrate the device's safety and effectiveness.
- Economic Operators' Roles:** Clear responsibilities are defined for manufacturers, importers, distributors, and authorized representatives.

The transition to the IVDR poses challenges as well as increased costs. However, it also presents an opportunity for manufacturers to innovate and enhance their operations, ultimately contributing to improved patient outcomes and greater trust in IVD devices.

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Implementation Confusion

“The IVDR was intended to streamline compliance, but for many manufacturers, it has introduced more questions than answers.”

The transition to the In Vitro Diagnostic Regulation (IVDR) has brought with it an array of implementation challenges, creating confusion for manufacturers, regulators, and stakeholders alike. While the regulatory shift aims to enhance patient safety and ensure robust compliance, its execution has been fraught with delays, uncertainties, and hurdles for those navigating the evolving framework.

2.1 Evolution of Timelines and Reasons for Delays

Originally set to be fully implemented by May 26, 2022, the IVDR timeline has undergone multiple extensions. These delays were introduced to provide stakeholders additional time to adapt to the stringent new requirements. The phased approach reflects a recognition of the regulatory bottlenecks, including the limited capacity of notified bodies, which are pivotal in reviewing device compliance.



One key issue has been the lack of preparedness among notified bodies to handle the overwhelming volume of applications. Under the IVDR, many previously self-certified devices now require conformity assessments. The resulting backlog has been accentuated by the fact that only a small number of notified bodies have been designated under the IVDR framework, creating significant delays for manufacturers seeking certification.

Additionally, the COVID-19 pandemic exacerbated the situation by disrupting global supply chains, slowing down operations, and diverting focus away from regulatory compliance efforts.

These challenges forced the EU Commission to stagger the implementation deadlines based on device risk classification, giving higher-risk devices priority while allowing manufacturers of lower-risk devices more time to comply.

REASONS FOR DELAY IN EC IMPLEMENTATION OF THE IN-VITRO DIAGNOSTIC REGULATION FOR LANGUAGE TRANSLATIONS

2.2 CONTINUED CHALLENGES FOR STAKEHOLDERS

Even with delayed implementation timelines, stakeholders continue to face substantial obstacles. For manufacturers, the shift to risk-based classification has been a major adjustment, requiring significant investments in clinical evidence and technical documentation. Smaller companies, in particular, have struggled with the financial and logistical burden of compliance, as many lack the resources to meet the enhanced requirements.

For notified bodies, the increased demand for assessments has highlighted a lack of standardized processes, resulting in inconsistencies in evaluation criteria. This has further contributed to uncertainty and delays, making it difficult for manufacturers to predict the outcomes of their applications.

Distributors and importers are also facing new responsibilities under the IVDR, such as ensuring product traceability and verifying compliance documentation, adding additional layers of complexity.

Furthermore, the continuous evolution of guidance documents has made it challenging for all stakeholders to stay up-to-date. The lack of clear and consistent communication from regulatory authorities has left many in the industry grappling with questions about how to effectively implement the changes.

2.3 INNOVATE AND STAY AHEAD

Despite the hurdles, the implementation of the IVDR also presents an opportunity for stakeholders to innovate and rethink their compliance strategies. Manufacturers who adopt proactive approaches, such as integrating compliance considerations into product development cycles, stand to benefit from smoother transitions and improved market positioning.

Leveraging digital tools and advanced technologies, including artificial intelligence, can streamline data management, enhance post-market surveillance, and facilitate real-time tracking of compliance efforts.

Collaboration is another key to success. Engaging with notified bodies early in the process, participating in industry forums, and sharing best practices can help stakeholders navigate the complexities of the IVDR more effectively.

While the road to IVDR compliance may be challenging, those who embrace adaptability and innovation can not only meet the new regulatory requirements but also gain a competitive advantage in the rapidly evolving diagnostic landscape.



“Manufacturers who embed compliance into product development and embrace AI-driven tools will gain more than approval—they’ll gain market edge.”



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The Critical Role of Language Translations in IVDR Compliance

Multilingual documentation emerges as both a fundamental and intricate necessity within the European Union's enforcement of the In Vitro Diagnostic Regulation (IVDR) standards. Given the European Union's 24 official languages and the authority granted to each member state to implement their own language standards, accurate translation serves as both a logistical requirement and a regulatory obligation. Clear and precise translations of all materials from labeling to post-market surveillance (PMS) reports are crucial for achieving market access while ensuring patient safety and fulfilling legal requirements. This section examines the critical role of language in IVDR implementation and discusses the dangers of translation errors while proposing strategic management methods for manufacturers to navigate changing linguistic requirements.

“With 24 official languages across the EU, precise translation isn’t optional under IVDR — it’s mandatory for market access and patient safety.”

3.1 Multilingual Requirements for Compliance

The In Vitro Diagnostic Regulation (IVDR) mandates that manufacturers provide documentation in multiple languages to ensure accessibility across the European Union (EU). With 24 official languages, compliance requires precise translations of technical documentation, labeling, and post-market surveillance (PMS) reports.

Each EU member state has the authority to define its own language requirements, meaning manufacturers must tailor their translations to meet national regulations. Some countries allow English for professional users, while others require translations into the local language for all users.

Beyond regulatory compliance, multilingual documentation enhances patient safety by ensuring that healthcare professionals and end-users fully understand device instructions. Misinterpretations due to poor translations can lead to incorrect device usage, adverse events, and regulatory penalties.



3.2 Labeling Needs

Labeling is a critical component of IVDR compliance, ensuring that medical devices are used correctly and safely. Labels must be clear, concise, and available in multiple languages to accommodate diverse patient populations.

Key labeling requirements under IVDR include:

- **Device Identification:** Labels must include the name or trade name, UDI carrier, and manufacturer details.
- **Expiration and Sterility Information:** If applicable, labels must indicate the sterile state, sterilization method, and expiration date.
- **Warnings and Precautions:** Labels must highlight critical safety information, including contraindications and usage limitations.
- **Electronic Instructions for Use (eIFU):** IVDR allows manufacturers to provide digital versions of instructions, reducing paper waste while ensuring accessibility.

The introduction of EUDAMED, a centralized database for medical devices, further emphasizes the need for standardized labeling across all EU member states. Manufacturers must ensure that their labels meet traceability and eco-friendliness requirements, including machine-readable identifiers.

COMPLYING WITH EUROPEAN IN-VITRO DIAGNOSTIC REGULATION (IVDR) LANGUAGE TRANSLATION REQUIREMENTS

3.3 PMS Documentation

Post-market surveillance (PMS) is a continuous process under IVDR, requiring manufacturers to monitor device performance and report findings.



PMS documentation must be translated into multiple languages to ensure accessibility for regulatory authorities and healthcare professionals.

Key PMS documentation requirements include:

- **Post-Market Surveillance Reports (PMSR):** Required for Class A and B devices, summarizing surveillance data and corrective actions.
- **Periodic Safety Update Reports (PSUR):** Required for Class C and D devices, including benefit-risk assessments, sales data, and user population estimates.
- **Performance Evaluation Reports:** Manufacturers must provide ongoing assessments of device effectiveness, ensuring compliance with IVDR standards.

Failure to provide accurate translations of PMS documentation can result in regulatory delays, market restrictions, and compromised patient safety.

3.4 Consequences of Poor Translation

Inaccurate translations can have severe consequences, ranging from regulatory non-compliance to patient harm. Misinterpretations in user manuals, clinical data, or labeling can lead to incorrect device usage, increasing the risk of adverse events.

3.4 Key Risks of Poor Translation Include:



Regulatory Penalties

Non-compliant translations can lead to market entry delays, fines, and product recalls.



Reputation Damage

A single mistranslation can undermine trust in a manufacturer, affecting brand credibility and market success.



Patient Safety Issues

Misinterpretations of dosage instructions, warnings, or contraindications can result in serious health risks.



To mitigate these risks, manufacturers must invest in high-quality translation services that specialize in medical and regulatory terminology. Leveraging expert linguists and AI-assisted translation tools can enhance accuracy while ensuring compliance with IVDR standards.



Safety Summary and Performance Reports

4.1 Overall Guidelines and Requirements

The Safety Summary and Performance Reports play a pivotal role in ensuring compliance with the In Vitro Diagnostic Regulation (IVDR). These reports provide a structured overview of the safety, performance, and reliability of diagnostic devices in clinical and laboratory settings. Under IVDR, manufacturers must maintain transparent, well-documented data demonstrating that their products meet stringent regulatory standards.

Key requirements Include:

- Comprehensive Safety Assessments:**

Evaluating risks and ensuring mitigations are in place.

- Performance Validation:**

Demonstrating accuracy, reliability, and intended clinical outcomes.

- Continuous Monitoring:** Conducting Post-Market Surveillance (PMS) to track real-world efficacy.

- Periodic Review and Reporting:**

Updating authorities with safety data and performance trends.

These elements are crucial for compliance and establishing trust between manufacturers, regulators, healthcare providers, and patients.

“Accurate, multilingual Safety and Performance Reports are not just documentation—they’re a regulatory lifeline under IVDR.”

4.2 Language Translation Challenges

An often-overlooked aspect of Safety Summary and Performance Reports is the requirement for multilingual accessibility. As IVDR is enforced across the European Union (EU), manufacturers must ensure reports are available in the appropriate languages to accommodate different regulatory bodies and stakeholders.

Key Translation Challenges:

- **Regulatory Accuracy:** Technical language must be precisely translated to prevent misinterpretation that could impact compliance.
- **Consistency Across Reports:** Maintaining uniform terminology between documents to uphold clarity and correctness.
- **Timely Submissions:** Translation delays can stall approvals, affecting product launches and updates.

To mitigate these challenges, companies should leverage experienced medical translators and AI-powered translation tools to enhance efficiency while maintaining linguistic and regulatory integrity.



4.3 Best Practice Recommendations

To ensure IVDR compliance and streamline reporting, manufacturers should adopt the following best practices:



Data Integrity & Transparency:

1. Maintain a centralized document repository for real-time access and updates.
2. Implement automated tracking systems to monitor performance data effectively.



Strategic Language Management:

1. Use qualified regulatory translators for critical documents.
2. Employ standardized terminology databases to avoid inconsistencies.



Regulatory Collaboration:

1. Engage with Notified Bodies early in the report development process.
2. Stay updated with evolving IVDR interpretations and adjust documentation accordingly.



By following these best practices, manufacturers can reduce compliance risks, strengthen trust of their diagnostics, and ensure smooth regulatory approval processes.

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Using AI For Efficiency For IVDR Compliance

The transition to IVDR represents a monumental shift for manufacturers and stakeholders in the in vitro diagnostic (IVD) industry. Compliance with IVDR entails navigating complex regulatory requirements, which demand significant resources, coordination, and expertise. Artificial Intelligence (AI) has emerged as a powerful tool to bolster efficiency and address challenges associated with IVDR compliance.

“AI is no longer optional—it’s a strategic asset for navigating the complexity and cost of IVDR compliance.”

5.1 Pros of AI



Streamlined Regulatory Analysis:

AI-powered platforms can analyze and interpret regulatory guidelines, ensuring manufacturers adhere to the evolving requirements of IVDR. By automating this process, manufacturers can save time and mitigate the risk of human error.



Enhanced Documentation Management

The IVDR requires comprehensive technical documentation, such as Performance Evaluation Reports (PERs) and Post-Market Surveillance (PMS) documentation. AI can automate the creation, organization, and monitoring of documentation, ensuring accuracy and compliance.



Data-Driven Decision Making:

AI systems can analyze large datasets and identify trends, enabling manufacturers to make informed decisions. For example, predictive analytics can anticipate potential risks or inefficiencies, allowing stakeholders to proactively address challenges.



Efficiency in Language Translations:

Given the multilingual requirements of IVDR, AI-enabled translation tools can produce accurate and efficient translations for labeling and documentation purposes. This minimizes delays while ensuring compliance with local language regulations across different markets.



By following these best practices, manufacturers can reduce compliance risks, strengthen trust of their diagnostics, and ensure smooth regulatory approval processes.

5.2 Challenges of AI



Regulatory Acceptance and Validation:

Regulatory bodies often require manufacturers to demonstrate the validity and reliability of AI-powered tools. This can involve extensive testing and documentation, which may be time-consuming and resource-intensive.



Limitations in Contextual Understanding:

While AI excels in processing structured data, it may struggle with unstructured or nuanced content, particularly in complex regulatory documents. Human oversight remains crucial for addressing any shortcomings in AI interpretations.



Data Privacy Concerns:

The use of AI entails handling vast quantities of sensitive data. Manufacturers must implement robust data protection measures to ensure compliance with privacy regulations, such as the General Data Protection Regulation (GDPR).



Integration Costs

Incorporating AI-enabled solutions into existing workflows and systems may require significant investment in infrastructure and training. Smaller organizations may face challenges in accessing the resources needed for effective integration.



Despite its transformative potential, AI presents several challenges that stakeholders must consider:

5.3 Optimized Approach for IVDR

To maximize the potential of AI for IVDR compliance, manufacturers should adopt an optimized approach that balances automation with human expertise. Key strategies include:



Human Assisted AI

Combining AI-powered tools with manual review processes such as by trained linguists ensures accuracy and reliability. AI can handle routine tasks, while regulatory professionals focus on strategic decision-making and complex evaluations.



Collaborative Ecosystem:

Encouraging collaboration between AI developers, regulatory experts, and manufacturers fosters innovation and creates tailored solutions for IVDR challenges.



Continuous Learning and Adaptation:

As regulations evolve, manufacturers should invest in AI solutions that incorporate machine learning algorithms. This enables systems to adapt to changing requirements and remain aligned with compliance goals.



Proactive Risk Management:

Leveraging predictive analytics and AI-driven insights allows manufacturers to anticipate compliance risks and implement preventive measures. This mitigates potential disruptions and ensures seamless operations.



AI is poised to transform the landscape of IVDR compliance, offering manufacturers a pathway to efficiency, accuracy, and innovation. By embracing AI while addressing its challenges, stakeholders can position themselves at the forefront of the IVDR transition, successfully navigating the complexities of regulatory demands.



IVDR Organizational Roles & Responsibilities

As organizations strive to comply with the In Vitro Diagnostic Regulation (IVDR), clearly defining and understanding the roles and responsibilities of key stakeholders within the organization is critical. The transition to IVDR has brought not only stringent requirements but also the need for a coordinated effort across different departments to ensure compliance. This section of the document outlines the primary roles involved—Regulatory Affairs, Quality, and Corporate Management—and their interdependent responsibilities to navigate the regulatory complexities of IVDR successfully.

6.1 Regulatory Affairs

The Regulatory Affairs team serves as the cornerstone for IVDR compliance. This team's primary responsibility is to interpret and implement the regulatory framework outlined by the IVDR. Key responsibilities include:



Understanding IVDR Requirements:

Staying informed of the evolving regulatory landscape, including classification rules, performance evaluation requirements, and timelines for compliance.



Coordination with Notified Bodies:

Acting as the primary point of contact with notified bodies, ensuring timely responses to queries and resolving potential non-conformities.



Dossier Preparation and Submissions:

Creating comprehensive Technical Documentation and submitting it to notified bodies for conformity assessments.



Post-Market Surveillance (PMS):

Ensuring that PMS documentation is compliant with IVDR standards, including vigilance reporting and performance monitoring.



Effective communication and collaboration with other departments are essential for Regulatory Affairs to fulfill these roles. Additionally, the team must provide training and updates to ensure that all organizational stakeholders understand their compliance obligations.

6.2 Quality

The Quality department plays a pivotal role in embedding IVDR requirements into the organization's processes and ensuring the delivery of safe, high-quality diagnostic products. Responsibilities for this team include:



Quality Management System (QMS):

Establishing and maintaining a QMS that meets the IVDR's stringent requirements. This includes implementing standard operating procedures (SOPs), risk management processes, and continuous improvement initiatives.



Supplier Quality Management:

Ensuring that suppliers and subcontractors comply with IVDR requirements, particularly regarding raw materials, components, and outsourced processes.



Audits and Inspections:

Preparing for and managing internal and external audits to demonstrate IVDR compliance.



Document Control:

Overseeing document management systems to ensure that all records, including labeling and translations, are accurate, up-to-date, and accessible for audits and notified body reviews.



The Quality team's ability to establish robust systems and collaborate with Regulatory Affairs and other departments is critical for ensuring a smooth path to IVDR compliance.

6.3 Corporate Management

Corporate Management bears ultimate responsibility for the organization's IVDR compliance strategy. This leadership role is essential in fostering a compliance-driven culture and allocating resources effectively. Key responsibilities include:



Strategic Oversight:

Defining the organization's vision and approach for achieving and maintaining IVDR compliance, including timelines, budgets, and risk mitigation strategies.



Stakeholder Communication

Ensuring transparent communication with external stakeholders, including notified bodies, suppliers, and regulatory authorities.



Resource Allocation

Providing the necessary financial, technological, and human resources to support compliance efforts across Regulatory Affairs, Quality, and other departments.



Ethical Responsibility:

Upholding the integrity of the organization's products and processes to safeguard patient health and safety.

Corporate Management must act as a unifying force, integrating the efforts of all departments to meet IVDR requirements while maintaining business continuity and innovation.

Compliance with IVDR is a multidisciplinary effort requiring collaboration among Regulatory Affairs, Quality, and Corporate Management. Each department's roles and responsibilities are distinct yet interconnected, forming the backbone of a successful compliance strategy. By defining these roles clearly and fostering a culture of accountability and collaboration, organizations can not only meet IVDR requirements but also leverage compliance as a strategic advantage in the evolving diagnostics industry.



Navigating IVDR and the Recent Tariff Realities

The implementation of the European In-Vitro Diagnostic Regulation (IVDR) has introduced significant challenges for manufacturers, distributors, and other stakeholders in the medical device industry. Coupled with recent tariff changes, navigating this regulatory landscape requires strategic planning and proactive measures. This section explores the latest developments in tariffs, their impact on IVDR compliance, and recommendations for responding effectively.

“With tariffs rising and regulatory demands tightening, accurate multilingual documentation has never been more critical to market access.”

7.1 Latest on Tariffs and Impact on IVDR

Recent tariff adjustments have added complexity to the already demanding IVDR compliance process. These changes affect the cost structure for manufacturers and distributors, influencing the pricing and availability of in-vitro diagnostic devices in the European Union. The tariffs have also heightened the need for accurate and timely translations of regulatory documentation, as compliance with IVDR mandates multilingual support for all materials accompanying medical devices.

The IVDR requires that labeling, instructions for use (IFU), and other critical documentation be translated into the official EU languages of the markets where the devices are sold. Tariff changes may exacerbate bottlenecks in the availability of Notified Bodies (NBs), which are responsible for evaluating most medical devices under IVDR2. This increased workload for NBs, combined with tariff-related financial pressures, could delay product approvals and market entry.



7.2 Recommendations on How to Respond

To mitigate the impact of tariffs and ensure IVDR compliance, stakeholders should adopt the following strategies:



Streamline Translation Processes:

Invest in professional language translation services to ensure accuracy and compliance with IVDR requirements. This includes translating mandatory documents such as IFUs, EU Declarations of Conformity, and Field Corrective Actions.



Leverage Technology

Utilize AI-enabled translation tools to enhance efficiency and reduce costs. While AI can expedite the translation process, it is essential to validate outputs with human expertise to avoid inaccuracies that could compromise compliance.



Collaborate with Notified Bodies:

Establish strong partnerships with NB's to navigate bottlenecks and prioritize high-risk devices for evaluation.



Monitor Regulatory Changes

Stay informed about evolving tariff policies and IVDR timelines to adapt strategies accordingly.





7.3 HOW LANGUAGE SCIENTIFIC CAN HELP WITH IVDR

Language Scientific offers comprehensive solutions to address the language translation challenges posed by IVDR and recent tariff realities. With expertise in medical and technical translations, the company ensures that all documentation meets the stringent requirements of IVDR.

Key services include:



Multilingual Translation

Accurate translations of labeling, IFUs, and other mandatory documents into all required EU languages.



Phone Interpreting

Real-time support for healthcare, legal, and business industries to facilitate communication and compliance.



Regulatory Expertise

Guidance on navigating IVDR requirements and tariff implications to streamline compliance efforts.

By enlisting Language Scientific as your translation services provider for IVDR compliance, stakeholders can proactively address the challenges of IVDR and tariffs, ensuring patient safety, regulatory compliance, and market success.

[Contact Language Scientific](#) to learn more.

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