CAN YOUR IVD SUPPLIER MEET THE IVDR CHALLENGE?

The new IVDR means that manufacturers are responsible for their suppliers' quality management. Choosing an ISO-13485 certified supplier makes this task infinitely easier and more secure.

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The European market has been turned upside down

The EU 2017/746 in vitro diagnostic medical device regulation (IVDR) has turned the world upside down for IVD manufacturers selling into Europe. Until now, self-declaration was the norm for CE countries. Under IVDR, about 85% of IVDs will be actively regulated.[1] The new classification system splits IVDs into classes ranging from A (lowest risk) to D (highest risk), and all B, C, and D devices will require NB oversight. These and other requirements will force dramatic changes in manufacturer business practices, not least of all in supply chain.

In terms of supply chain management, the fastest, least burdensome, and most secure way for manufacturers to continue selling into Europe in the IVDR era is to work with ISO 13485-certified suppliers. ISO 13485 certification ensures that suppliers can readily adapt their quality management systems (QMS) with the manufacturer's QMS and support the ongoing lifecycle product management requirements of the new regulation. "ISO-like" supplier quality control, or ISO 9001 certification, falls far short of what IVDR effectively requires. In this white paper, we explain:

- **How IVDR changes everything about supply chain management**
- **Why ISO 13485 is a critical success factor for IVD suppliers, and**
- **What to look for in an ISO 13485-certified supplier**

IVDR CHANGES EVERYTHING ABOUT SUPPLY CHAIN MANAGEMENT

For a legal manufacturer, IVDR makes it clear you are now responsible for quality control of your suppliers and must be able to document this control. Failure of suppliers to meet IVDR standards may trigger intensive and costly resolution efforts, endangering on-time regulatory approval of new products or the survival of current products in CE-mark countries.

Manufacturer carries all liability

Under IVDR, manufacturers assume responsibility for the performance and behavior of their IVDs throughout the product lifecycle, from conception to decommission. Outsourced services or products must be evaluated and controlled in terms of their impact on the final IVD, and controls must be incorporated into the manufacturer's QMS.

Liability for non-compliance among suppliers lies with the manufacturer *(Art. 10: General Obligation of the Manufacturer.)*

Supplier audits are coming

Article 88: Market Surveillance Activities authorizes the Competent Authority (CA) or Notified Body (NB) to perform announced or unannounced audits at the manufacturer's premises, including suppliers or subcontractors. According to IVDR 2017/746 Annex VII, "if not already covered by the audit programme, audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers."

Technical information must reflect true product lifecycle management

Technical documentation will need to detail the manufacturer's post-market surveillance system (PMS) for monitoring the safety and effectiveness of IVDs already on the market. This includes all actors in the supply chain (referred to as economic operators). In effect, this means that manufacturers will need a network of quality agreements with suppliers, subcontractors, and service providers. Substandard documentation can thus be seen as a red flag for audits. *(Annex II Technical Documentation under Design and Manufacturing Information [3.2].)*

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1. The European Commission. Factsheet for manufacturers of in vitro diagnostic medical devices. 2020.

WHY SUPPLIER ISO 13485 CERTIFICATION IS CRITICAL

When it comes to supply chain management under IVDR, the heart of the matter for manufacturers is integration of supplier quality management systems into the manufacturer's QMS. ISO 13485 establishes the requirements for a comprehensive quality management system for the design and manufacture of medical devices, including IVDs, and compliance with ISO 13485 is often seen as the first step in achieving compliance with European regulatory requirements.

This puts non-ISO 13485 suppliers at a severe disadvantage in understanding and meeting the stringent requirements of IVDR – and the liability for supplier non-conformance rests with the manufacturer. This means that manufacturers must shoulder the burden of ensuring their suppliers' quality systems are up to the stringent new standards and remain that way.

The best way to navigate through this new regulatory maze is to work with ISO 13485-certified suppliers

An "ISO-like" QMS does not cut it anymore

Some suppliers may insist they have an "ISO-like" QMS. They may even truly believe that this is an acceptable choice. But regulatory and quality professionals know – by heart – that a system needs to be regularly audited by an independent entity to maintain its integrity. A consistent track record of renewed certifications (especially ISO 13485) is the gold standard for quality. A supplier without an ISO 13485 certificate may not even be deemed by the NB as having an effective QMS, increasing the likelihood – and considerable expense – of regular NB QMS verification audits.

ISO 9001 may not be an acceptable replacement

Some suppliers may attempt to justify an ISO 9001:2015 certification as an acceptable replacement for ISO 13485 certification. Although Annex B of IS013485:2016 shows the relationship of clauses between IS0 13485:2016 and ISO 9001:2015, the ISO 9001 standard does not incorporate essential medical device quality system clauses such as controlled work environments and product cleanliness, risk management and safety, product development design controls, inspection and traceability of product, process validation, verification of corrective/preventive action effectiveness, monitoring of regulatory requirements, and reporting to regulatory authorities. NBs do not consider ISO 13485 and ISO 9001 as interchangeable.

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WHAT TO LOOK FOR IN AN ISO-CERTIFIED SUPPLIER: 9 QUESTIONS

In the IVDR era, ISO 13485 certification is a basic differentiator for suppliers. But not all certified suppliers are the same. Some may be newly certified or lack a robust regulatory track record outside of certain specific applications. Here are some criteria to consider when evaluating suppliers:

1. Does the supplier know the regulatory requirements?

Supplier IVDR expertise is an invaluable asset. A top supplier will understand and proactively inform their manufacturer client what the client will need in the future, even if the manufacturer doesn't realize it yet.

2. Can the supplier prepare standardized compliance support packages?

These may include documentation for product manufacturing, performance, stability, and/or safety, standardized but adapted to product complexity.

3. How does the supplier control its own suppliers?

ISO 13485 certification ensures that a supplier has control over all implemented processes, with documentation and records to demonstrate it, including control over its own service and raw material suppliers.

4. Can the supplier perform Verification and Validation (V&V)?

Manufacturers should be confident their supplier can perform V&V activities by specialists with a deep knowledge of the product in question. This is an important contribution to planning of the final IVD device V&V at the manufacturer site and saves considerable time and resources.

5. Can the supplier provide "NB-quality" documentation on manufacturing?

When a legal manufacturer is outsourcing manufacturing, the supplier must provide manufacturing-related documentation (e.g., manufacturing process, process validations, flow charts, and batch release records). These would be shared with the NB during audits to demonstrate control over the manufacturing process at the supplier site to ensure compliance with QMS requirements of IVDR.

6. How effectively can the supplier help implement necessary quality control?

Manufacturers need to provide evidence that their product specifications are being respected by suppliers, including details about QC testing, often including a certificate of analysis. Effective communication of QC activities at supplier sites allows manufacturers to identify critical specifications they need to test and may reduce their own QC burden (and product cost). Suppliers should be able to propose QC relative to the risks related to the product.

7. Can the supplier provide information on the origin of substances?

Suppliers should provide data on immunological tests performed during collection of human, animal, or microbiological substances. This information is useful for assessment of need for import permits, reducing the burden at border controls and ensuring swift approvals for customs agents.

8. Can the supplier provide a risk management summary compliant with ISO 14971?

This reduces the manufacturer's time and effort in preparing necessary technical documentation.

9. Is the supplier willing and able to conduct reagent stability studies?

These should be available for reagent shelf-life assessment and demonstration of storage, shipping safety, and in-use performance stability. These studies significantly reduce the manufacturer's workload and are key for identifying the stock stability and estimating the intermediate product stability for additional manufacturer products.

Final considerations

There can be no doubt that IVDR will place a far greater burden on IVD companies selling into Europe; indeed, it will force many to reassess the viability of their EU product portfolios. This spells opportunity for manufacturers who can secure air-tight quality control of their suppliers with the greatest efficiency.

Fortunately, ISO 13485 provides a clear roadmap for doing so. Ironically, IVDR may compel manufacturers to rely on outsourcing more than ever before, as they focus their attention on adapting to a new era in EU regulation.

In such cases, working with non-ISO 13485-certified suppliers would increase the complexity of supply chain quality control exponentially.

With the new IVDR in Europe and regulatory bodies in other geographies raising their standards for review and approval of IVDs, selecting an ISO 13485-credentialed supplier is the safest and most cost-effective criteria to consider when making a final determination for a supplier for the critical components of an IVD. As such, suppliers with an ISO 13485 quality management system, certified by a reputable Notified Body, are the best option for legal manufacturers.

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