NEWS on diagnostics

2026 Volume 1

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Welcome to News on Diagnostics Vol. 1 for 2026!

Effective supply chain risk management is a cornerstone of reliable diagnostic kit manufacturing. When risks are handled proactively, production runs smoothly and efficiently. When they're not, the result can be regulatory issues, product recalls, and significant financial impact. This newsletter can help you to help steer clear of the pitfalls that come with inadequate risk control.

What is Risk Management?

Risk management in IVD manufacturing ensures that every component, process, and decision—from raw materials to final packaging—supports accurate, consistent, and safe test performance. Although IVDs don't act directly on the patient, their results guide clinical decisions, so the primary risk is harm caused by an incorrect result. Effective risk management is a continuous, lifecycle-long discipline that keeps diagnostic tests safe, reliable, and clinically meaningful. When done well, it prevents failures before they reach patients and helps manufacturers remain compliant and competitive.

What tools support *Risk Management*?

Developing and producing Life Science products has become more demanding in recent years. With processes becoming more intricate and regulatory expectations tightening across regions, organisations must be able to identify, evaluate, and mitigate risks while maintaining uninterrupted operations.

Regulations across the industry also stipulate that those products with greater criticality—especially if they're used in highly regulated sectors like pharmaceuticals or *in vitro* diagnostics—require a higher level of supplier quality oversight and support.

In response to this changing landscape, we have developed several tools to help with your risk mitigation strategy.

Merck Tool / Program	How It Supports Risk Management
M-Clarity™ Program	**Provides documentation, supplier transparency, and audit readiness**
Fit for Use IVD Materials (Elevate)	Ensures consistent, qualified raw materials with regulatory support
Technical Expertise	**Reduces design and manufacturing risks**
Assay Development Services & Manufacturing Scale-Up	Assay development & advice

M-Clarity™ Program

The ***M-Clarity™ program*** is one of our most important tools for IVD risk management. It provides:

- Clear quality and regulatory documentation
- Supplier transparency
- Material qualification support
- Guidance on supplier readiness for audits
- Tools to evaluate raw material consistency and supply chain robustness

The structure of the M-Clarity™ Program brings portfolio transparency and consistent quality information across its Life Science products.

M-Clarity™ is a product-classification program that groups offerings into three main categories: Chemicals & Consumables, Equipment, and Spare Parts. It then assigns each product to an M-Clarity™ Segment (a classification level) based on the extent of available documentation and the availability of supporting services—for example change notifications and quality agreements. In practice, a higher Segment indicates more comprehensive documentation and service coverage than a lower Segment.

Fit for Use IVD Raw Materials & Documentation Package

Selecting our ***Elevated Assurance Program*** provides you with enhanced support and reliable, high quality information. It ensures you have the tools needed to meet both internal and external quality requirements with confidence.

We offer fit for use reagents and materials tailored for IVD manufacturing, supported by documentation that aligns with key quality needs, including:

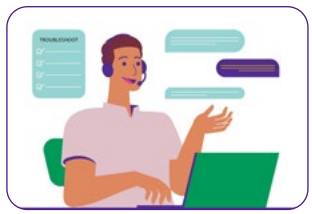
- ISO 13485 compliance
- Risk assessment activities
- Supplier qualification and manufacturing consistency

The Elevated Assurance Program equips you to navigate an increasingly complex regulatory and operational landscape. It supplies the documentation essential for audits and risk assessments, while the products within the program promote supply chain transparency and reinforce manufacturing and quality controls. Each product also meets the standards of an M Clarity™ quality segment of MQ300 or higher, as detailed in the ***Discriminating Quality Attribute table.***

Technical Expertise

Merck further strengthens your risk management efforts by providing a suite of specialised support services that address critical points across the IVD product lifecycle. These include:

- **Technical consulting,** offering expert insights into product performance, process optimisation, and regulatory expectations. This guidance helps you identify potential risks early and implement effective mitigation strategies.



- **Material selection and manufacturing process guidance,** ensuring you choose the most suitable raw materials and establish robust, scalable production workflows. This contributes to consistent product quality and reduces variability during scale up.
- **Assay development support,** helping you refine assay design, select appropriate components, and troubleshoot performance challenges. This reduces the likelihood of design related issues emerging later in development.

Together, these services help minimise design and process risks, streamline development activities, and support a smoother transition from early R&D to full scale manufacturing. They reinforce your ability to deliver reliable, compliant, and high quality diagnostic products.

Assay Development Services & Manufacturing Scale-Up

Merck empowers diagnostic innovators with comprehensive support across assay development and manufacturing. Our teams help refine assay design, optimise performance, and guide the selection of high quality raw materials essential for reliable diagnostic solutions. With deep expertise in process development and scalable production, we streamline the path from concept to commercial ready products. Through our custom assay development capabilities and OEM/CMO manufacturing services, we deliver the technical strength and partnership needed to advance modern diagnostic platforms with confidence.

Key Advantages:

- Expert support to refine assay design and optimise diagnostic performance
- Guidance on selecting high quality raw materials for reliable results
- Scalable process development expertise to streamline manufacturing
- Custom assay development tailored to specialised diagnostic needs
- OEM/CMO manufacturing services to accelerate commercial readiness

Forecasting

Raw material usage forecasting is a critical pillar of IVD (*in vitro* diagnostics) manufacturing, as the field depends on accuracy, strict regulatory standards, and consistent production flow. Weak forecasting can disrupt every stage of the process, while strong forecasting becomes an understated but powerful driver of stability and efficiency across the entire operation.

Investing the time and effort to develop a robust raw material usage forecast:

- Builds a clearer understanding of future material needs and helps prevent supply disruptions.
- Supports cost control by reducing waste, over-purchasing, and last-minute procurement.
- Strengthens overall production stability by aligning purchasing, planning, and manufacturing.

This is explored in more detail in our white paper ***"The Importance of Forecasting for IVD Manufacturing."***

Discover how blending data, experience, and agility can elevate your operations.

Inside, you'll find:

1. Strategies for creating accurate, flexible forecasts
2. How forecasting influences inventory, production, and profitability
3. Approaches to reducing supply chain and compliance risks
4. Real-world forecasting applications in IVD manufacturing

Sustainability

Environmental sustainability is increasingly becoming part of IVD (*in vitro* diagnostic) risk mitigation, even though it is not yet a formal, mandatory element of IVDR risk management. Instead, it is emerging through industry guidance and evolving regulatory expectations that encourage integrating ecological considerations without compromising patient safety.

This includes factors such as:

- environmental impacts of materials, reagents, and disposables
- waste management and recyclability
- energy use in manufacturing
- supply chain sustainability

These elements are now viewed as risk factors that can influence business continuity, compliance, and corporate reputation.

How sustainability is being incorporated in practice

Although not required by regulation, many manufacturers are proactively integrating sustainability into their risk frameworks by:

- Assessing environmental impacts across materials, disposables, and waste-handling in labs and production
- Applying eco-design principles to packaging, components, and overall product lifecycle.
- Integrating sustainability into regulatory monitoring, supplier qualification, and audit processes.

This reflects a broader industry shift toward "green laboratories" and more sustainable diagnostic workflows.

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Bottom line?

Formally: No — environmental sustainability is not yet a required component of IVDR risk mitigation.

Practically: Yes — sustainability is rapidly becoming a material risk factor that manufacturers are expected to address to remain compliant, competitive, and aligned with EU policy trends.

Regulatory Updates!

IVDR: What's new for 2026?

Several updates for the IVDR will come into effect in 2026. As an IVD manufacturer is important to be ready for them, to maintain regulatory compliance.

Mandatory EUDAMED Use Begins *(28 May 2026)*
This means that every IVD device (including Legacy IVDD devices) must be registered in EUDAMED before being placed on the EU market.

Certificates and NB interactions must be handled through the system.

Extended Transition Timelines Continue (Regulation 2024/1860)

Device Class	Application Deadline	Agreement Deadline	New Transition Deadline
IVDD certified devices	26 May 2025	26 Sept 2025	31 Dec 2027
Class D (Self-declared)	26 May 2025	26 Sept 2025	31 Dec 2027
Class C (Self-declared)	26 May 2026	26 Sept 2026	31 Dec 2028
Class B and Class A (sterile)	26 May 2027	26 Sept 2027	31 Dec 2029

New Obligation to Notify Supply Interruptions

- This obligation applies regardless of device class and is part of the EU's effort to prevent shortages – another reason raw material forecasts are so important.

Gradual Roll Out of Remaining EUDAMED Modules

- Four of the six modules become mandatory in 2026 – leading to more structured PMS and vigilance reporting

Ongoing IVDR/MDR Revision Proposal (published December 2025)

- Regulatory changes aim to simplify key processes and reduce the overall administrative burden on manufacturers. They also strengthen coordination with notified bodies and introduce more flexible requirements for low-risk devices.

The Biotech Act (proposal)

The European Commission's December 2025 proposed Biotech Act is designed to strengthen the EU's biotechnology and biomanufacturing environment. At its core, the proposal is about helping the EU stay competitive in the global biotech and health arena.

To do that, the Act looks at key areas, including:

- Expanding the production of essential biological materials
- Improving regulatory coordination for innovative biotech and health products
- Project funding and technology-transfer initiatives.

The Act is predominantly concerned with biopharmaceuticals and advanced therapies. However, it could also indirectly benefit the *in vitro* diagnostics (IVD) sector by improving access to EU-based biologics and reagent suppliers, increasing supply-chain transparency, and allowing more collaboration for R&D.

One thing worth highlighting: the proposal does not make any changes to the IVDR. Its goal isn't to alter device-specific rules but to strengthen the broader biotech ecosystem that all these sectors rely on.

Other EU based regulations

The following legislation will likely hit or are already enforced through the EU. Although they do not impact the IVDR directly, they are expected to impact all manufacturers, irrespective of their sector.

- CSRD (Corporate Sustainability Reporting Directive)
- CSDDD (Corporate Sustainability Due Diligence Directive)
- ESPR (Eco-design for Sustainable Products Regulation)
- PPWR (Packaging & Packaging Waste Regulation)
- CBAM & other Green Deal tools

These frameworks place strong emphasis on sustainable business practices, responsible supply chains, and environmental performance. Key themes include waste reduction, carbon footprint transparency, and broader corporate accountability for environmental and social impacts.

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