White Paper

Proactive Solutions for Risk Mitigation

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The last thing any IVD manufacturer wants to occur is a product recall. This has wide-reaching implications, not only for patient care, but also for the individual manufacturer and their ability to provide relevant and useful IVD testing kits onto the market. Product recalls highlight the importance of rigorous quality control and risk management in the IVD industry ensuring patient safety and preventing adverse events.

Global events such as the pandemic and military conflicts have led to supply chain shortages, acutely demonstrating that managing risk is imperative to maintaining a sustainable business. Collaborative proactive risk mitigation with suppliers can better protect a company's ability to reliably deliver their products and services to their customers with the high quality expected.

Risk mitigation is the process of assessing risks and taking one of the following actions: removing the risk, reducing the risk, or accommodating the risk.

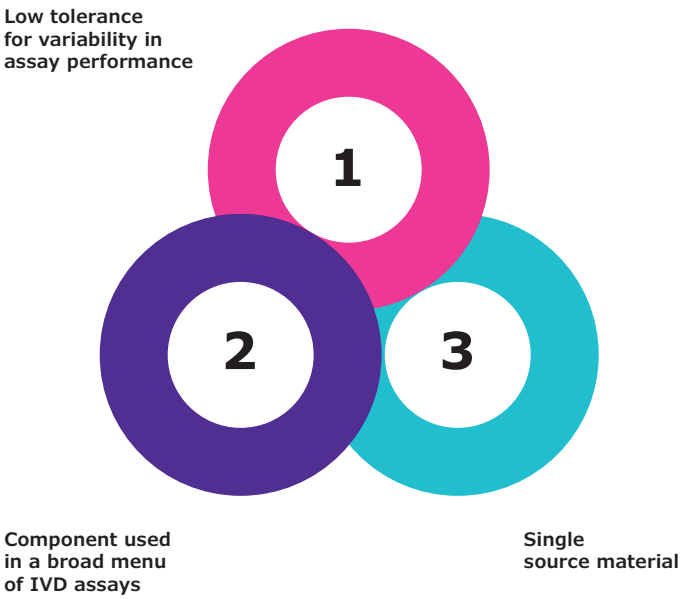
Critical raw materials require active risk mitigation to ensure:

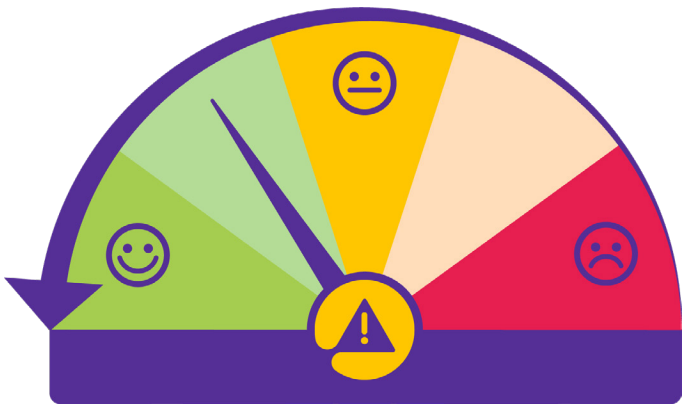
- Manufacturing continuity
- Lot-to-lot consistency
- Regulatory compliance
- Clinical test reliability

Manufacturing and testing organisations actively work to avoid disruption to their operations as the impact could be significant. Such disruptions could include:

- Delays in manufacturing
- Customer backorders
- Batch failures
- Product recalls
- Patient misdiagnosis or harm

Criticality of raw materials can be defined by a broad range of criteria, including:





Risk-o-meter

Identified Risks	Supply Chain	Quality	Contract Manufacturing	Risk Assessment
Supply chain disruptions & delays	●		●	●
Product or manufacturing changes	●	●		●
Lack of manufacturing & packaging expertise	●	●	●	
Supplier inability to support current or future demand	●			●
IVD assay variability	●	●	●	
Incomplete documentation	●	●		●
Specification changes	●	●	●	
Regulatory non-compliance	●	●	●	●

Let's investigate some of these crucial areas of risk mitigation in more detail, and look at solutions to help solve them:

Supply Chain Risks

Ensuring a robust and transparent supply chain for critical raw materials is essential. Collaborative discussions with suppliers help secure key raw materials and prevent disruptions. Risks include delivery delays, supplier inability to meet demands, raw material discontinuation, and unexpected price changes.

Quality Risks

Assessing raw material quality and specifications is crucial. Any unexpected changes in raw material quality or final product can impact IVD performance. Missing QA/QC documentation poses a risk.

Regulatory Compliance Risks

Meeting regulatory requirements is vital. Non-compliance can lead to recalls or other serious consequences.

How Can Suppliers and Manufacturers Work Together to Reduce Risk?

The ideal combination of Strategic Partnership and Supply Assurance can best be achieved through ongoing communication and collaboration between the supplier and the customer. The more critical the application and the raw material, the more controls need to be embedded into the processes, supply chain, and quality management.

Questions to ask the production & purchasing teams:

1. What is a critical raw material for the application(s)?
2. Who defines a material as critical for the organisation and what criteria are used?
3. How are change control and change control notifications managed?
4. What are the expectations from a supplier, and how are these requirements handled?
5. How is supply chain risk managed?
6. What are the most important factors consistency (quality, logistics, etc.), transparency, support, flexibility, and others, to the success of production?

M-Clarity™ Program, your guide for quality and portfolio transparency

The MilliporeSigma M-Clarity™ Program defines product Quality Segments and improves product and service transparency throughout the broad Life Science portfolio.

Let's explore the key features and areas:

1. Understanding M-Clarity™

The M-Clarity™ Program is designed to address the challenges faced during product development and manufacturing in the Life Science sector. *It recognises the increasing complexity of processes, regulatory requirements, and local standards.*

2. Quality Segments

The program classifies products into different Quality Segments based on their attributes and criticality. Chemicals and consumables fall into 6 quality segments (**MQ100-MQ600**), equipment into 4 quality segments (**EQ1-4**), and spare parts into 2 quality segments (**SP1-2**). *Each segment provides specific documentation and services.*

3. Transparency and Compliance

Quality Segments offer transparency regarding:

- Compliance with quality and regulatory standards.
- Portfolio details.
- Change notification services.

Informed product selection becomes easier, ensuring alignment with specific control requirements.

- **Select the right product to meet your needs.**
- **Move smoothly through product development phases.**
- **Ensure compliance by informed product selection.**

4. Risk Assessment and Cost Minimisation

During product development and manufacturing, minimising disruptions is crucial. The M-Clarity™ Program guides the selection of components and raw materials. *By comparing quality support and documentation, costs and delays can be minimised.*

5. Empowering Decision-Making

Leveraging the program allows informed decisions:

- Choose suitable products based on specific needs.
- Opt for controlled and verified processes.
- Navigate compliance requirements effectively.

The M-Clarity™ Program serves as a compass, guiding manufacturers toward quality, compliance, and successful product outcomes.

A final note:

Remember, robust risk management is not just a regulatory requirement; it's a commitment to patient safety and the integrity of the application. Let's continue to prioritise quality and excellence!

Additional Resources on Risk Mitigation & its application in IVD manufacturing.

- Risk Management Page
- M-Clarity™ Program Page
- IVD Development & Manufacturing Page
- Elevate Product Portfolio
- **Webinar:** Risk Mitigation in Cell Line Development: Regulatory Considerations and Impact on Quality Assurance

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