NEWS on diagnostics

2020 Volume 2

Highlights of this edition:

- Risk Mitigation & Risk Assessment
- Your Partner from Concept to Clinic
- Risk Assessment
- ISO 13485 and Risk Management
- The M-Clarity™ Program

Risk Mitigation & Risk Assessment

Risk mitigation is a core focus for IVD manufacturers, driven by commercial best-practices and regulatory requirements. Assessment of critical raw material performance, supply and quality is important to minimise risk. Risk must be assessed and mitigated throughout the entire IVD commercialisation process.

This volume of News on Diagnostics will help you to decide whether you need to update your risk assessment procedures, and how Merck as your supplier can support you.

Risk Mitigation Checklist

- □ Do you have change control notification for critical raw materials?
- □ Do your suppliers have compliant quality management systems?
- □ Are you aware of your suppliers' quality policies?
- □ Can your supplier provide manufacturing and supply chain records?
- □ Can you validate your suppliers' testing of raw materials?
- □ Are you and your suppliers prepared for unannounced audits?
- □ Are you confident that your suppliers' raw materials will perform consistently?

Check out this video on 5 ways you may be unprepared for supply disruption

Visit SigmaAldrich.com/ivd-rm-videos

Your Partner from Concept to Clinic

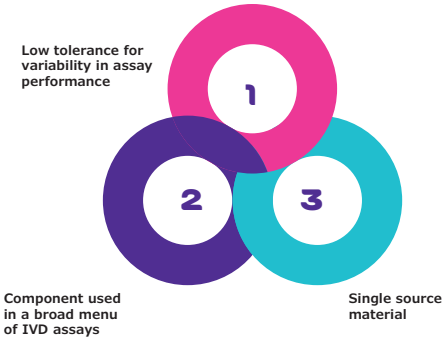
Your critical raw materials require active risk mitigation to ensure:

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

The pillars of risk mitigation are:

- Supply chain
- Quality
- Risk assessment
- Contract manufacturing

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



Below are examples of risks coming from raw material supply and in-house manufacturing capabilities that have been identified by IVD manufacturers and where we have programs in place to support you.

	Our Solutions			
IVD Manufacturer 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	●	●	●	●

Did You Know...?

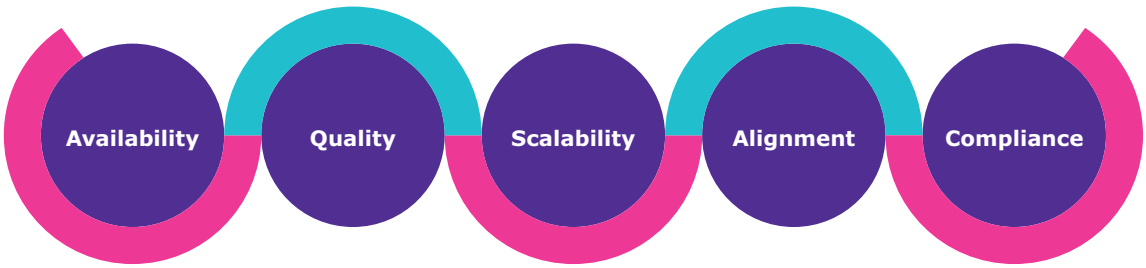
You can learn more by booking one of our Risk Mitigation Workshops?

Schedule your day at: SigmaAldrich.com/risk-mitigation-support

Risk Assessment

Development and manufacture of IVD products is a complex process involving multiple suppliers and raw materials. Minimising disruptions of any kind is vital to supply chain management.

Proprietary assessment of our current supply chain is carried out at the product level within the 5 parameters below. The risk assessment is targeted at general disruption of supply of the current product, ideally a product in development.



Our Supply Chain Risk Assessment Program

This proprietary program helps you to clearly understand these potential risks for critical raw materials and provides recommendations for proactively taking the necessary steps to mitigate risk.

How the program works

IDENTIFY: You compile a list of highly critical materials that we supply to you.

MANAGE: We analyse supply chain risk potential for each material along the 5 key risk categories (above).

MITIGATE: We provide a composite supply chain risk score report accompanied by customised risk mitigation recommendations.

Did You Know...?

You can learn more about our Risk Mitigation and Risk Assessment in our short videos here

SigmaAldrich.com/DXresources

See our Risk Assessment in action at SigmaAldrich.com/ivd-rm-videos

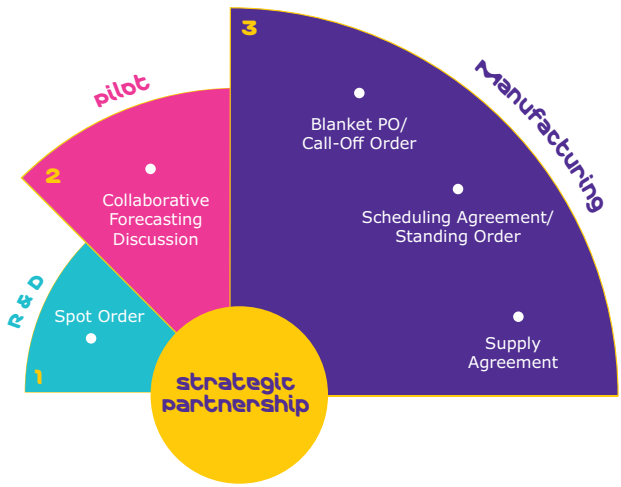
You can also schedule a risk assessment for your company at SigmaAldrich.com/risk-mitigation-support

Best Practices for Mitigating Risk in Your Supply Chain

Risk mitigation strategies include selecting fit-for-use products and a variety of commercial arrangements depending on whether your IVD assay is at the R&D, pilot, or manufacturing stage.

A strategic partnership with us involves continuous communication and collaboration that will assure supply at all stages of your IVD process as an integral part of the IVDR (EU 2017/746)

Learn how to ensure delivery of critical raw materials as well as implement advanced supply security practices in these videos at SigmaAldrich.com/ivd-rm-videos



ISO 13485 and Risk Management

New requirements call for ISO 13485:2016- and BS EN ISO 13485:2016-compliant *in vitro* diagnostic (IVD) manufacturers to manage risk more comprehensively than ever before. Section 4.2.1 of the standard demands that organisations "apply a risk-based approach to the control of the appropriate processes needed for the quality management system."[1] The deadline for meeting these enhanced requirements was February 28th, 2019.

IVD manufacturers can stay compliant with a supplier management program whereby:

1. Suppliers are selected and classified according to the risk level of products or services they provide;
2. Parameters to accept or reject a supplier are defined;
3. Supplier evaluations are executed, and follow-up actions are prescribed based on results;
4. Supplier performance is continuously monitored over time.

Reference

1. BS EN ISO 13485:2016 and ISO 13485:2016. Medical devices – Quality management systems – Requirements for regulatory purposes.

For more information, please visit SigmaAldrich.com/IVD-ISO-Readiness

Working in a global market has its challenges. Find out here how ISO 13485 compares to the FDA CFR820. Download our comparative whitepaper here SigmaAldrich.com/IVD-ISO-CFR-Comparison

Watch this video on quality assurance in IVD manufacturing at SigmaAldrich.com/ivd-rm-videos

The M-Clarity™ Program

Part of risk mitigation is choosing the correct product for the intended application. Our M-Clarity™ program has been developed to address this challenge by classifying the majority of our Life Science products into 6 MQ (Merck Quality) Levels, MQ100 to MQ600:

- Each level provides specific documentation and services
- As MQ levels increase, the quality and regulatory support increases
- Transparency allows you to select the right product for your needs

This added product visibility provides the perfect tool to guide the process of choosing components and raw materials, allowing for comparison of quality support and documentation, that ultimately reduces costs and delays, allowing you to minimise your manufacturing risk.

Learn more about our transparency in supply chain at **SigmaAldrich.com/mclarity-program**

The M-Clarity™ program, in conjunction with our supply chain solutions, is a powerful tool for minimising raw material risks. We keep your needs at the centre of our supply chain through:

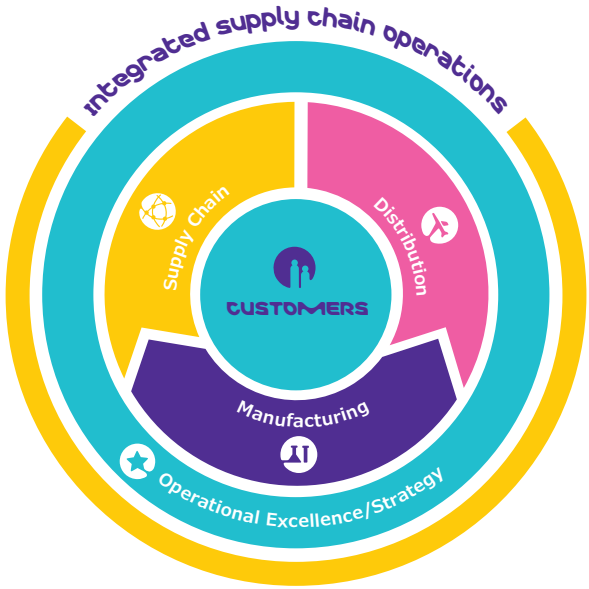
1. Continuous communication and collaboration
2. Understanding the IVD market's needs and expectations
3. Making our supply chain work for you

We understand the importance of your materials being delivered on time, in full, and at the required quality level. By leveraging our global distribution network, you'll receive accurate and compliant delivery from a valued partner.

select the right product to meet your needs

move smoothly through product development phases

ensure compliance by informed product selection



Start your risk assessment at:
SigmaAldrich.com/risk-mitigation-support

Lit. No. MK_NL5173EN
2019 - 27097
01/2020