Our commitment to security of supply in diagnostics

Why is security of supply important?

Regulatory authorities are putting pressure on immuno- and molecular diagnostic assay developers to have control over their full supply chains from raw material sourcing and supplier management through to delivery of finished products to help protect patients.

Ensuring that materials are available when needed is a key aspect of a supply chain security program, but it is not sufficient to focus on this alone. The raw materials must maintain a high level of quality, and any changes must be communicated in a timely and transparent manner.

The increasing demand for often complex raw materials and restrictions to change approved processes, challenge the entire industry to focus on strategies, in-house expertise, and system resources to manage raw material variability and its impact on process performance.

Supplier risk management program

The diagnostics team understands the importance of using high quality products to deliver reliable and consistent performance in a broad range of applications on an ongoing basis. We take a proactive approach to security of supply with a comprehensive raw material supplier risk management program and risk mitigation plans, through to rigorous product release testing to agreed QC specifications to support performance claims.

Our supplier risk management program

1	**Aims to reduce the number of high risk suppliers and establish secondary suppliers for critical raw materials**
2	**Focuses on risk mitigation through improved knowledge and assessment of potential incidents**
3	**Uses the most resource effective activities to reduce supplier risks**

A sourcing risk index (SRI) has been established to identify supplier and item risk. The table below illustrates some of the factors considered in evaluating the risks.

Supplier risks		Item risk	
• Financial health rating	• Geographical risk	• Revenue contribution	• Safety stock
• Quality classification	• Supply chain visibility	• On-time delivery	• Identified second source
• Qualification status	• Quality measurement Supplier Corrective Action Request (SCAR)	• Process lead time	• Number of active sources
• Business continuity survey score		• Transfer lead time	

Change control notification

At times, it is necessary to make changes to product manufacture. These might be improvements to our manufacturing processes, changes to raw materials, or specification adjustments. All changes are controlled, reviewed, and assessed by experts prior to implementation. Depending on the change impact assessment, changes may be communicated to customers as standard practice. The level of change notifications can be adapted to meet the needs of each customer.

If you are interested in being notified of these changes, please contact your local sales representative to find out more. We would be pleased to notify you of the changes as an additional level of reassurance for both custom and catalog products.

Our 7 activities to mitigate the levels of risk

Our multidisciplinary team including material scientists, manufacturing engineers, and quality and sourcing professionals play key roles in defining the entire end-to-end supply chain for our products. Our sourcing team is fully trained in a *Sourcing risk finder tool*. This tool allows us to assess supplier lead times, relationships, safety stock, and processes. Using this extensive knowledge and continuous improvement ensures consistent and dependable product delivery through the supply chain. This supports customer processes and gives you the control and confidence in the supply of our products.

Here are the key activities we have started to implement

Sourcing risk finder tool

1

A comprehensive program to identify, screen, and evaluate second suppliers for key raw materials to maintain operations should materials become unavailable from a primary supplier.

2

Established multi-sourcing and multi-manufacturing options for high risk items and identified a plan to expand and/or set up new manufacturing areas for our Sera-Mag™ beads in the unlikely event that something goes wrong.

3

Strict quality and supply agreements are in place with critical suppliers. The agreements are reviewed periodically so both parties are aware of their commitments and expectations.

4

Increased raw material safety stock for all items that show regular consumption (considering shelf life, space, cost, etc.) specially for those where the risk of interrupted supply is rated the highest.

5

Open communication and a clear change notification process with our key suppliers as a means of promoting supply chain transparency.

6

A process for ongoing auditing, buying strategy assessment, testing, and verification of components to confirm the consistent reliability of incoming goods.

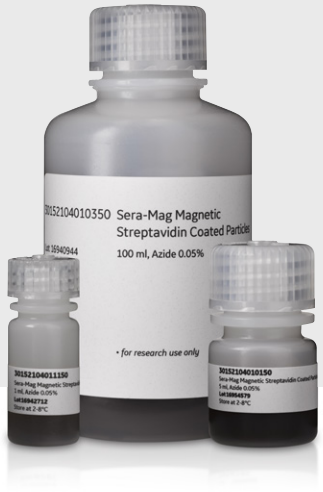
7

Monthly reviews with the sourcing team to identify potential risks and proactively take steps to avoid supply issues. Where suppliers are believed to be unreliable, new suppliers are identified and evaluated.

Modular manufacturing options and business continuity plan

As customer demand for our Sera-Mag™ beads continues to grow, we maintain a very close focus on our manufacturing capacity and work closely with our customers to understand demand trends in advance. Our customer relationship management system and rigorous long-term planning support this process.

We maintain spare capacity in our Center of Excellence facility in Cardiff (UK) to manage unexpected demand increases through investment, expansion, and Lean principles. As we grow, we have to do more in order to maintain that capacity. Our site-wide business continuity plan sets out procedures and outlines alternative production areas to minimize disruption following catastrophic incidents.



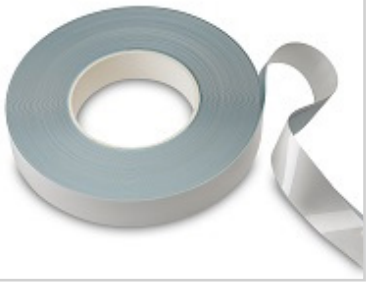
Multi-site manufacturing of membranes, pads, and paper

With manufacturing sites spread across the world, including Tonglu, China; Dassel, Germany; Newquay, UK; and Pensacola, USA, we operate 24/7 production of a vast array of microporous membranes, cellulose and glass fiber substrates, and nitrocellulose membranes. We have the ability to respond to increases in demand as well as support your assay development and scale-up efforts with customized solutions and contract manufacturing.

Our extensive capabilities offered by our ISO-certified manufacturing facilities include:

- Supply chain rationalization
- Sourcing and validating raw materials
- Shelf-life management
- Logistics efficiency
- Streamlined transportation and storage

These capabilities enable you to feel confident in the security of supply of your Cytiva products.



Key questions to ask your supplier

Supply chain sustainability

- What is your strategy for assuring continued product deliveries during challenges to your supply chain?
- What is your change control policy?
- In what ways do you minimize risk of supply disruptions for key raw materials used to manufacture your products?
- Do you have dual suppliers for raw materials?
- What are your lead times for different volumes?
- What does the site master plan look like for each manufacturing site?
- What routines do you have around site master planning and which functions are involved?
- Do you have sufficient manufacturing capacity to meet our needs if we were to increase short- or long-term demand by 25%, 50%, 100%, or 200%?
- Do you have a product discontinuation policy?
- Can you describe your supplier audit qualification program?

Business continuity

- What does your Business Continuity Management (BCM) program look like? Is it accredited?
- What are your biggest business continuity risks and how have you mitigated these?
- Can you give a recent example of your business continuity strategy to enable product deliveries even during manufacturing interruptions?
- How is your inventory management system supporting business continuity? For instance, do you maintain minimum inventory levels of raw materials, intermediates, and final products?
- Where do you store your final products?
- Do you have a strategic reserve to be used only in case of emergencies?
- Do you offer the option of maintaining safety stock dedicated for our use?
- What investments are you making to ensure business continuity?
- In what ways are your higher management involved in enterprise risk management?

Communication

- In what ways do you communicate with other manufacturers?
- Do you have strategic collaborations with customers?
- What happens when a customer contacts you with a technical problem?
- What in-house expertise does your company have to support security of supply and keep customers informed?
- How can you show us that you are responsive to the industry's needs for internal risk assessment when changes must be made?
- How do you handle change control notifications?
- Where can I access regulatory support for your products?

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