

NEWS

on diagnostics

2025 Volume 2



In this issue...

- What are Production Materials?
- Why choose production materials?
- Strategic Partnership
- Merck as a Secondary Supplier
- Planning & Scheduling options
- Distribution
- Quality Considerations
- Capacity issues?? What to do next...

Welcome to the second volume of News on Diagnostics 2025. In this edition, we focus on transforming your research into reality.

Research is fantastic, but what happens when you're ready to take it to the next stage - tech transfer and, ultimately, into full scale production? You need a dependable, high-quality product that performs consistently across all stages of your application. Merck's production materials portfolio can support your evolving diagnostics needs.

What are Production Materials?

Production materials for *in vitro* Diagnostic (IVD) assay development are defined as the essential components used in the creation and validation of diagnostic tests. These materials include:

Antibodies: Both primary and secondary antibodies are used for detecting specific biomarkers.

Antigens: These are used to generate immune responses and are critical in the development of assays.

Enzymes: Enzymes like polymerases and reverse transcriptases are used in amplification processes.

Buffers and Reagents: These are essential for maintaining the stability and functionality of the assay components.

Membranes and Filters: Used for sample preparation and purification processes.

DNA/RNA Probes and Primers: These are used for the detection and amplification of genetic material.

These materials are crucial for ensuring the accuracy, sensitivity, and specificity of IVD assays.



The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

Why choose Production Materials?

Advantages of Choosing Designated Production Materials

Innovative Solutions:

Merck offers a diverse portfolio advanced products that enhance manufacturing processes, ensuring high-quality and reliable outcomes.



Expertise and Experience: With decades of expertise in providing essential products for IVD manufacturing, Merck provides extensive knowledge and technical support to optimize production and improve yields.

Comprehensive Offerings: Merck's production materials support IVD manufacturing across molecular diagnostics and Immunoassays workflows.

Customer Focus: Merck is dedicated to meeting stringent customer requirements through ground-breaking products, providing a competitive market edge.

These factors make Merck a trusted partner for companies aiming to enhance their production processes and achieve superior results.

Merck as a Secondary Supplier

Using a secondary supplier in manufacturing can offer several advantages:

Risk Mitigation: Having a secondary supplier helps reduce the risk of supply chain disruptions. If your primary supplier faces issues like natural disasters, political instability, or production delays, a secondary supplier can step in to ensure continuity.

Quality Assurance: Working with multiple suppliers allows you to compare and contrast the quality of products. This can help identify the best practices and potentially improve overall product quality.

Cost Efficiency: Dual sourcing can enhance your negotiating power. By having multiple suppliers, you can leverage competition to secure better pricing and terms.

Flexibility and Scalability:

A secondary supplier provides additional capacity, which can be crucial during peak demand periods or when scaling up production.

Supply Chain Resilience:

Building redundancy into your supply chain makes it more resilient to unexpected disruptions, ensuring that your operations can continue smoothly.



Strategic Involvement Comparison Chart

Transaction Type	Definition	Benefit	Other Considerations
Spot Order	Impromptu purchase order used to fill immediate need, usually pre-packed catalogue items.	Most of the time, prepack materials are in stock at the time the order is placed and there is flexibility in the ordering channel.	If the order quantity is large or will be ordered frequently, talk to your account manager about options such as blanket PO's, reserves and scheduling agreements
Collaborative Forecast Discussion	When supply assurance for a particular material becomes more critical, sharing information regarding the quantity of material needed and projected timing can facilitate improved availability.	<ul style="list-style-type: none"> Improved Product availability Enables Service Level Reporting Facilitates Strategic Collaboration 	We will manufacture or procure materials based on your forecast. For improved service levels, the forecast should be routinely updated and conveyed to your account manager.
Blanket Order/Call Off Order	For a specific material, the needed quantity and a time frame is provided, but specific ship dates are yet to be determined. Usually, an annual commitment to purchase.	<ul style="list-style-type: none"> We have a better understanding of your total quantity requirements Material is committed to a Sales Order, however no delivery schedule is set 	Multiple lots of material may be used to fulfil the order. As an alternative to the Blanket PO, consider using a Scheduling Agreement when the desired delivery dates are pre-determined.
Scheduling Agreement/Standing Order	A Purchase Order with pre-determined quantities and delivery dates arranged at the time of order placement	<ul style="list-style-type: none"> Firm delivery dates facilitate customer planning process Material is committed to a Sales Order with pre-set delivery dates. Enables Customer specific availability reports (i.e. Open Order) 	Inventory availability can be affected if dates or quantities are changed. For commercial customers, the Scheduling Agreement brings together our Supply Chain Resources and is the preferred order mechanism to mitigate risk.
Supply Agreement	Legal commitment to provide materials, usually includes Terms and Conditions of use, Product Specifications, and Delivery Expectations	Pricing, T&C, and Specifications are held firm for a designated period of time.	Supply Agreements work best in conjunction with other tools such as forecasts, scheduling agreements or reserves.

Greener Alternatives

To determine which products qualify as Greener Alternatives, we quantify sustainability improvements across key impact areas. Each Greener Alternative Product falls under one of these four categories:



Design for Sustainability (DfS) Developed Products demonstrate significant sustainability improvements during our product development process.



12 Principles Aligned Products align with at least one of the 12 Principles of Green Chemistry.



Re-engineered Products are improved by our scientists using DOZN™, our Green Chemistry Evaluator.



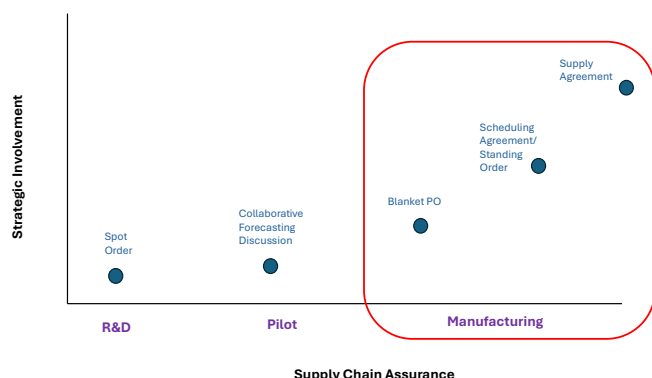
Enabling Products help make science greener through enabling technologies.

Learn or scan the QR-code:
SigmaAldrich.com/ssbi



Planning & Scheduling options

Varying product applications require different approaches to managing the supply chain. The ideal combination of Strategic Partnership and Supply Assurance can be best achieved through ongoing communication and collaboration.



For example, Merck prioritises risk management to ensure the products we market, crucial for developing critical items and scientific research, are continuously supplied. Our procurement team minimises risks within our supply chain through:

- Stocking agreements and dual sourcing with suppliers
- Managing lead times and maintaining extra stock for high-risk items
- Pre-qualifying supplier batches and assessing supplier capabilities for risk planning
- Gathering supply chain transparency data and analysing market trends and external risks

We would encourage all our customers to enter discussions around supply of critical and non-critical raw materials at a very early stage, to determine which factors are key for YOUR manufacturing processes to ensure supply continuity.

Distribution

Distribution is fundamental to ensure that we meet your service needs to deliver products quickly, safely, accurately and compliantly.

Warehouse Space



With approximately 4M square feet of warehouse space, we can safely store our broad selection of products at any scale at the proper temperature and regulatory conditions and have them available to you at any time. We can create regional stored supplies for your local operations as needed.

Order Fulfilment



Our expert worldwide fulfilment team manages more than 4 million customer orders, 8 million order lines, and 16 million units annually. With product volumes varying from grams to tons our team can ensure your order is reliably delivered regardless of changes in manufacturing scale.

Distribution Network



Our global distribution network is comprised of 70 distribution points in 23 countries to satisfy your delivery expectations and empower you to achieve your goals. We work with your team to plan your scale-up demands and coordinate our manufacturing and distribution networks to support delivery of raw materials and products.

When you provide information about the product pipeline including intended use, quantity, and delivery requirements for specific materials, we are able to provide:

- Just-in-Time Delivery
- Regulatory Compliant Shipments
- Import/Export Trade Expertise



For an in depth consultation, please scan the QR Code or contact us.

Quality Considerations

Choose the right product for your manufacturing. Merck's M-Clarity™ Program supports regulatory compliance and supply chain transparency through several key mechanisms:



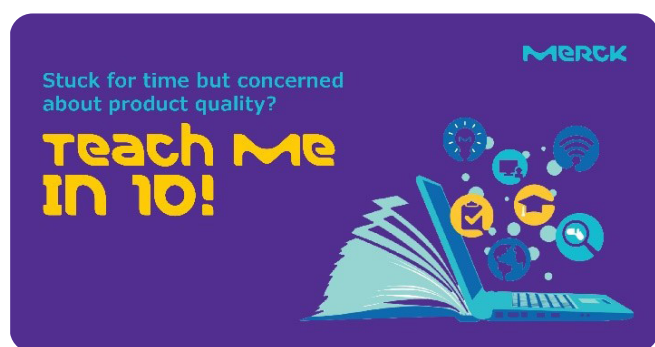
Quality Segments: Products are categorised into different quality segments (e.g., MQ100 to MQ600 for chemicals and consumables). Each segment has specific quality attributes and change notification requirements, ensuring that products meet the necessary regulatory standards.

Change Notification Service: The program includes a robust change notification service that informs users about any changes in product specifications or manufacturing processes. This helps users manage risks and maintain compliance with regulatory requirements.

Documentation and Support: Comprehensive documentation is provided for each product, including certificates of analysis, and regulatory compliance documents. This transparency helps users make informed decisions about product selection.

Enhanced Supplier Quality Support: For highly regulated industries, the program offers enhanced supplier quality support, ensuring that products meet stringent regulatory standards and quality expectations.

You can find out more about our individual site quality accreditation & download certificates [here](#).



Capacity issues?? What to do next...

You have your Star Product, with great market potential, and you've chosen your Production Materials with care. What happens if (when!) demand outstrips your manufacturing capacity? **Merck can support you!**

We offer extensive capabilities in the field of *in vitro* Diagnostics (IVD) and Original Equipment Manufacturing (OEM). Here are some key aspects that could be of interest:

1. ****Contract Manufacturing**:** we provide custom and contract manufacturing services for antibodies, reagents, and IVD kits, ensuring regulatory compliance and quality standards



2. ****Custom Antibodies**:** we can offer customization of catalogue antibodies, allowing manufacturers to tailor products to specific applications

3. ****Microspheres**:** Merck develops custom microspheres for diagnostic and biotech industries, catering to specific needs like particle size, density, and colour
4. ****Packaging Capabilities**:** Our packaging services include sterile filtration, handling hazardous materials, and automated checks in controlled environments

These capabilities help us support the diagnostic industry with reliable, high-quality solutions.

For more information visit:
www.sigmaaldrich.com/oem

MQ300 Level or Higher Products Launched in the Elevate Program

Upgrading our products to meet quality standards of MQ300 and above will raise the bar in support and services that we provide our customers.



The **Elevate Dossier** is available upon request. In the Dossier, you will be provided information on:

- Site Quality Survey self-assessment
- ISO 9001 certificate
- Product Specifications
- Declarations / Statements (animal origin content, latex content, BSE/TSE, phthalates, RoHS, etc.)



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