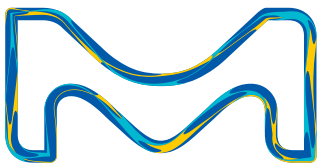


# NEWS on diagnostics

Volume 2, 2022



## In this issue....

- What is the difference between Custom & Contract Manufacturing?
  - Custom Manufacturing & Services
  - Contract Manufacturing (CMO)
- When should you consider a CMO?
- Choosing the right CMO partner

Welcome to the first issue in our series covering Contract & Custom Manufacturing.

We are focused on the unique needs of IVD developers and manufacturers. Our global manufacturing capabilities enable us to develop, deliver, and support an extensive portfolio of raw materials and components as well as offer a range of custom services.

This volume outlines some of the considerations that are needed when determining whether a CMO partner is suitable for your application.

Challenged by the complex task of getting your IVD to market?

Struggling with Supply chain issues?

Lacking manufacturing space and equipment?

Consider collaborating with a  
**CMO partner**



# What is the difference between Custom & Contract Manufacturing?

## Custom Manufacturing & Services

Streamline your processes with our tailor-made services to cover your needs from start to finish:

- Specialty chemicals in bulk quantities and volumes
- Customized chemical solutions and mixtures
- Specific quality control (QC) testing requirements, including customized specifications
- Customized packaging and labeling, custom package sizes, safe and smart packaging solutions
- Chemical contract manufacturing and OEM services

### We can also offer custom QC testing including:

- **Molecular** - qPCR, PCR, western blotting, Southern blotting, electrophoresis, nuclease contamination, bacterial growth, cell component isolation kits (DNA, RNA, protein)
- **Immunological** - ELISA, western blotting, Ouchterlony double diffusion, cell staining, histology, serology
- **Functional** - Plasmid purification, cloning, protein depletion, proximity ligation assays (Duolink® PLA)
- **Other specialized analyses**
  - Endotoxins, hematology, enzymatic activity and contamination, cell culture, tablet testing (hardness, friability, and dissolution)
  - Test method validation for niche QC needs and ability to partner with external testing labs for esoteric tests
  - Functional testing of contract manufactured products on client platform



## Contract Manufacturing (CMO)

Ensure your project success by using our extensive contract manufacturing capabilities for private labelled reagents and kits.

We manufacture single reagents through to finished kits. Our clients have access to our fully traceable supply chain for cost effective sourcing of raw materials. We can maintain your pre-selected raw material suppliers and subcontractors or utilize our global sourcing capabilities on your behalf.

### Our core capabilities include:

- Reagents
- Buffers and solutions
- Consumables
- Tablets
- Standards
- Multicomponent kits



## When should you consider CMO?

The decision to partner with a third party for either custom or contract manufacturing is an important one, that requires due consideration of both the partner, as well as the project for which you need support.

### Are you at the right stage for outsourcing?

There are a few questions that can help you to answer this:

Will outsourcing open capacity for other activities?

Which skills or expertise are currently missing in your portfolio that would allow you to be stronger into the diagnostic market?

Can you avoid capital expenditure to establish or expand existing manufacturing capabilities?

Do you need to contract out non-strategic product (e.g., buffer) to concentrate on higher value components?

## Considering a CMO partner

Choosing a contract manufacturing partner for your clinical diagnostics kit is high on the list of business-critical decisions made during the commercialisation process. Your chosen partner should have excellence in supply-chain management, extensive experience in transitioning assays to production, navigating changing international regulatory requirements, and solid QMS and documentation systems.

Visit [SigmaAldrich.com/cmo](https://SigmaAldrich.com/cmo) for more information and to request a consultation.

Our white paper entitled 10 Strategic Considerations When Outsourcing Production of *In Vitro Diagnostics* gives advice on what to look for in a CMO partner.



Review our short video on Contract Manufacturing [here](#) to help make this important decision

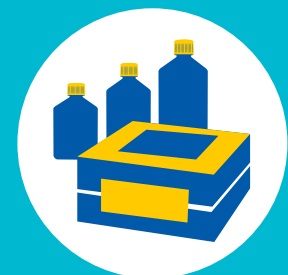
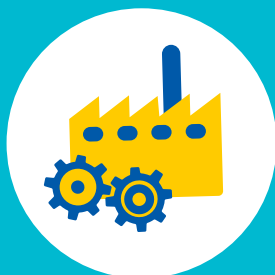
## Here's an excerpt from our whitepaper 10 strategic considerations when outsourcing production of *in vitro* diagnostics

### Consideration #9: PROTECT YOUR IVD SUPPLY CHAIN

Strong supply chain management should be a vital consideration for any potential CMO partner.

One strategy is to choose a CMO partner who is also a manufacturer of raw materials or components required to manufacture the reagent, kit, or device. Practical reasons for this include increased supply chain control and lower raw material costs.

Larger CMO organizations can also leverage their purchasing power to procure raw materials at lower costs and may be better positioned to secure secondary sourcing of critical raw components. During times of supply chain constraints, CMO partners that also manufacture some or all of the raw materials, particularly those with global manufacturing and distribution footprints, are better positioned to maintain sufficient safety stock by mobilizing a global network of secondary and tertiary sourcing.



# Risk Mitigation Workshop

We understand the complexity of manufacturing IVD assays and are committed to offering tailored quality and regulatory support for your product applications.

**Can you answer “YES” to all of the following questions regarding your supply chain risk? If not, meet with us to understand new industry regulations and make sure you are using the correct grade of critical raw materials for diagnostics manufacturing.**

## 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?

## Detailed Topics of Discussion

- Understanding industry regulations
- Defining controlled supply chain
- The common risk factors in a supply chain
- The best available risk mitigation strategies
- Prioritizing your list of critical raw materials
- Current portfolio of our products

## Who should attend?

- Procurement Managers
- Quality Managers
- Tech Operations and Program Management

## Learn About Our M-Clarity Quality Program

- Enhance your understanding of IVD regulatory landscapes and implications for critical raw materials
- Discover factors and controls to reduce overall risks in supply chain
- Optimize your selection of appropriate fit-for-use products

You can request a workshop at [SigmaAldrich.com/ivd-risk-mitigation](https://SigmaAldrich.com/ivd-risk-mitigation), and work with your local account manager to select the meeting time and develop a detailed agenda. We look forward to meeting with you.

