

10 Strategic Considerations When Outsourcing Production of *In Vitro* Diagnostics

The choice of whether to outsource production of an *in vitro* diagnostic (IVD) or invest and develop in-house capabilities is a foundational business decision. Capacity, capabilities and resources must all be assessed to determine the best course of action. If the decision is made to outsource, selection of a trusted contract manufacturing organization (CMO) that can consistently deliver against key milestones is equally as critical. Below, we highlight 10 important benefits of outsourcing and key considerations that should factor into the evaluation of a partner.

1. Access essential, complementary expertise

Outsourcing provides access to expertise that is complementary to that of the IVD company. CMOs can provide unique process capabilities, capital equipment and QC procedures that smaller organizations may currently lack and would require significant training time and financial expenditures. Look for a highly skilled partner capable of producing components in ISO 13485, ISO 9001, FDA CFR 600 and FDA 21 CFR 820 compliant environments, which is critical for IVD production. An added benefit is that the partner may also be able to offer private label services and reagent manufacturing capabilities.

2. Allow staff to focus on strategic business initiatives

Highly trained staff is always a limited resource. Outsourcing production can make your business more effective and efficient by enabling your human resources to be redirected towards more strategic priorities such as audit preparation, regulatory filings, product innovation, and marketing.

3. Reduce time to market

The use of turnkey contract manufacturing services can accelerate time to market. CMOs produce validated manufacturing processes faster and ensure a rapid and regulatory-compliant journey to market. Your outsourcing partner should offer a wide range of packaging and kitting formats and options tailored

to your specifications. This ensures that your kits are assembled and labeled properly and ready-to-ship to customers without delay.

4. Access a global network

Expanding your IVD distribution internationally can create regional regulatory and storage issues. Look for an outsourcing partner with global manufacturing capabilities and an extensive warehouse network to facilitate getting your finished product to where it is needed – anywhere in the world.

5. Alleviate capacity issues

Manufacturers with existing commercial products may find that outsourcing allows them to free up production capacity. To help ensure success, your CMO partner should have expertise in minimizing potential risks presented by transitions in manufacturing location. Look for a partner with expertise in methods transfer, scale up and validation which ensures your procedures are properly integrated into their quality systems.

6. Safeguard your project

With today's changing markets, it is more critical than ever to manufacture your IVD under solid project management guided by robust risk mitigation plans. Select a CMO that provides a single point of contact and experienced project manager for your internal team. This creates consistent and timely communications, safeguards timelines and ensures the project is executed per your specifications.

7. Align with regulatory requirements

The commercialization pathway for IVD devices is complicated. Partnering with a knowledgeable CMO can save significant time, money, and aggravation by providing insight and expertise related to regulatory guidelines in addition to critical insights related to design and quality. The right CMO partner can smooth bumps in the road, navigate regulatory hurdles and accelerate time to market.

8. Create cost efficiencies

A traditional CMO purchases raw materials to produce reagents, kits and devices from various vendors. Working with a partner whose core business activity is production of raw materials with contract manufacturing as a value-add service can have significant implications for the cost of your materials.

9. Protect your supply chain

An outsourcing partner who is also a raw materials manufacturer has a much stronger and robust supply chain than one who must rely on a network of vendors. A larger, established CMO can also leverage 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, CMOs that manufacture 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.

10. Protect your bottom line

The development, scale to production, and commercialization of your IVD assay is a lengthy and expensive investment. Whether you are producing bottles of reagents or complex multi-component kits, we are an experienced and trusted partner for clinical diagnostics companies planning to outsource their manufacturing projects. We provide contract manufacturing services across a broad spectrum of client needs with proven processes and systems that ensure technical support and reliability at all stages of development. Request a consultation or visit our manufacturing facilities to learn more about our contract IVD manufacturing capabilities.

To learn more about our Contract Manufacturing Capabilities for the clinical diagnostics industry, visit SigmaAldrich.com/OEM

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