Vetting a Contract Manufacturing Partner for Your Clinical Diagnostics Kit

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Choosing a contract manufacturing (CM) partner for your clinical diagnostics kit is high on the list of business-critical decisions made during the commercialization process. Outsourcing manufacturing is a valid strategic decision due to the significant capital expenditure required for in-house manufacturing. In addition to the costs of equipment, there is also the need to develop a Quality Management System (QMS) aligned with the required regulatory requirements, the hiring of personnel, and the acquisition of the appropriate certifications. Due to the significant capital expenditure required, many companies choose outsourcing in order to redeploy their capital towards growing their business and developing new products. Your CM 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.

Expertise in scaling from assay development through manufacturing

Vetting potential CM partners is as critical as developing your product, and success is dependent on multiple factors. Significantly, your partner's capabilities must align with your needs. Demonstrated expertise with your technology, assay, and format is essential. If your project is early stage, bringing it to market may require significant assistance. An assay that works reliably on the bench top often requires further assay development and reagent reformulations when moved to scale-up. For products early in development, finding a CM partner who not only has expertise with the technology but also the resources to assist with product and assay development can accelerate the time to market significantly. A partner with experience in your assay format can guide you on choosing fit-for-use materials that are aligned with regulatory requirements and supply-chain secure, both of which can save significant time and cost by minimizing the likelihood of costly reworks.

Successful assay commercialization in shifting regulatory environments

Changes in international standards and regulations have created challenges and roadblocks to the commercialization of diagnostic kits. The choice of a CM partner with the expertise to provide guidance and manufacturing capabilities is one strategy clinical diagnostics companies can use to mitigate risk. A well-chosen CM partner can accelerate the commercialization process by anticipating potential roadblocks.

Globally, changes to the regulatory environment need to be considered when choosing a CM partner. In Europe, the transition from IVDD to IVDR has altered the commercialization calculus. Previously, the regulatory hurdles were lower in Europe and many companies would launch a CE-marked kit while waiting on FDA approvals. Under IVDR, it is expected that over 90% of IVDs (up from 10%) will require notified body involvement. If the decision is made to obtain a CE mark, is your CM partner willing and/or able to be compliant with IVDR? This includes being willing to host unannounced audits by notified bodies as required by the new regulations.

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Robust Quality Management System (QMS), document control, and audit response

Beyond the proper certifications, a potential CM partner should also be willing and able to demonstrate a robust QMS and that they have processes and controls in place for documentation. Can they provide you with records of successful audits? Can they guide and assist you with your regulatory submission? Additionally, you should verify that they have experience with preparing a Design History File (DHF), Device History Record (DHR) and Device Master Record (DMR)

While the commercialization pathway for IVD devices is complicated, a knowledgeable contract manufacturing partner can save significant time, money, and aggravation by providing design, quality, and regulatory assistance. Chosen wisely, a CM partner can smooth roadblocks, navigate regulatory hurdles, and speed time to market.

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