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An Innovator's Quick Start Guide to Contract Manufacturing Organizations (CMOs) and Contract Development and Manufacturing Organizations (CDMOs)

For innovators starting a new drug development program, outsourcing (i.e., hiring a third-party) can help them acquire specialized services that are not available in-house. This is particularly true of Contract Manufacturing Organizations (CMOs) and Contract Development and Manufacturing Organizations (CDMOs). CMOs offer manufacturing services for clinical products and CDMOs offer both assay and process development and manufacturing services for clinical products. Depending on your company's needs you may contract with one or both types of organizations.

Innovators should consider engaging a CMO or CDMO when they have a viable product but lack the resources, experience, or capital needed for large-scale production. Additionally, if a company wants to accelerate market entry or save on the costs of building out manufacturing capacities and production teams, outsourcing to a CMO or CDMO can be an effective strategy.

CMOs and CDMOs offer several advantages to companies.

- Cost & Time Efficiency Outsourcing to a CMO or CDMO can reduce overall costs and save time. It
 eliminates the need for substantial staffing, facility, qualification/certification, and equipment
 requirements. This is particularly beneficial for smaller companies or startups.
- Expertise & Specialization CMOs and CDMOs have specialized knowledge and experience in large-scale
 production. They can ensure efficient and effective manufacture of small molecule and biological
 products. This expertise is valuable when a company lacks internal staff with experience and
 competence to bring a product from pre-clinical to commercial scale.
- Risk Mitigation Using a CDMO for scale-up support reduces risk and shortens lead times. Investing in buildout of facilities for a product that may fail in clinical trials carries large risk.
- Flexibility Outsourcing allows companies to stay agile and lean while receiving extensive, differentiated, drug development support. It also allows companies to focus on other critical areas like drug discovery and marketing.







Define Your Needs	 Specify the exact service needed: manufacturing, development, research. Define the tasks: e.g., synthesis, formulation, testing, trial material, or commercial production. Establish the project timeline and budget.
Assess Expertise & Capabilities	 Confirm experience related to your product. Examine their regulatory history with bodies like the FDA and the European Medicines Association. Ensure their technological infrastructure matches your requirements.
Quality & Compliance Checks	 Look for certifications such as cGMP or ISO. Explore their regulatory inspection background. Delve into their quality assurance practices.
Communication & Logistical Efficiency	 Favor partners recognized for clear communication and promptness. Account for potential logistical challenges due to location or time zones.
Financial & Technological Stability	 Utilize resources like Dun & Bradstreet reports for financial health checks. Evaluate the resilience of their tech infrastructure.
Intellectual Property Protection	 Ensure they're willing to sign non-disclosure agreements. Research any previous IP conflicts or issues.
Visit & Engage	 Personally tour potential partner sites. Engage with their former and existing clients for genuine feedback. Measure their standing in the industry.
Contractual Safeguards	 Involve legal specialists in reviewing contractual terms. Clearly outline roles, deliverables, payment terms, and performance benchmarks.

Guidance from the U.S. Food and Drug Administration

The FDA has <u>guidance</u> concerning contract drug manufacturing. This document offers insights into defining, establishing, and documenting manufacturing activities when partnering. The emphasis is on







ensuring all parties adhere to current good manufacturing practices (cGMP). One suggested approach is using quality agreements, establishing responsibilities, and ensuring cGMP compliance.

Resources:

FDA: Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry

Article: CDMOs vs. CMOs and CROs: What's the difference between the three?

Article: How to choose a contract manufacturing organization

Article: What Is Contract Development And Manufacturing Organization?
Article: Key Considerations When Selecting a Medical Device CDMO

Article: What to Look for in Selecting a CRO/CMO and How to Ensure the Right Choice: A Quality

<u>Assurance Perspective</u>

Article: <u>D&B Business Information Report on Demand</u>



