The content on this webpage was developed by NIH SEED based on its collective experience working with the NIH innovator community. This information has been developed, for informational purposes, to address questions frequently asked by NIH awardees, and represents the experiences of the subject matter experts who contributed to its development.

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.

Guidance from the U.S. Food and Drug Administration

The FDA has guidance 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 Assurance Perspective
Article: D&B Business Information Report on Demand