

5 Steps To CDMO Selection

Sponsors will see success in their CDMO partnerships by dedicating time and effort to establish a plan that identifies outsourcing drivers, to select a model that matches company needs and resources, to establish a decision-making process and group, and to designate key selection criteria. Using these steps, drug developers can build strategic outsourcing relationships where their internal expertise is complemented by external CDMO resources.

1. Identify Your Company's Outsourcing Drivers

Recognizing internal outsourcing drivers helps drug developers prioritize their needs from a CDMO.

- Need access to capacity
- Need access to scientific expertise
- Need access to both capacity and expertise
- Other strategic reasons to outsource when capacity/expertise are available in-house

2. Choose the Right Outsourcing Model for the Company or Project

Top level issues like access to capacity vs access to scientific expertise can direct a drug developer towards the right outsourcing model and should inform CDMO selection criteria.

- Tactical Outsourcing
- Preferred Provider Agreements
- Strategic Relationships

3. Establish a Decision-making Process

Company size and available resources often play a role in how outsourcing decisions are made.

- Group approach
- Scorecard
- Board of Directors
- Executive Decision

4. Choose the Decision-making Group Members

Drug innovators that use a group approach for CDMO selection may have as few as 4 high-level individuals (at a virtual biopharma company) or as many as a dozen departments (at a Big Pharma company) represented.

- Operations / Manufacturing
- Executive Management
- R&D Management
- Purchasing / Procurement
- Scientists
- Regulatory / CMC
- Finance / Legal

5. Identify Your CDMO Selection Criteria

Up front communication of needs, the availability of or limits on internal resources at the sponsor organization, and service provider selection criteria with prospective CDMOs enables contract manufacturers to build complimentary teams to balance individual drug developers' specific requirements.

- Ability to smoothly scale up manufacturing and transfer technology
- Experience level of staff
- Facility has most up-to-date manufacturing technologies
- Flexibility to adjust schedule for special requests
- Has capacity to meet our demands
- Low cost
- Offers innovative solutions
- Prior positive experience with service provider
- Reliable, on-time delivery
- Scientific knowledge
- Strong regulatory track record
- Track record for meeting quality performance metric

Reference: [Five Steps To CDMO Selection \(pharmaceuticalonline.com\)](https://www.pharmaceuticalonline.com/2022/10/14/five-steps-to-cdmo-selection/)