

Contract Development and Manufacturing Organization Best Practices

INTRODUCTION

Outsourcing research and development services and manufacturing has historically been an “either/or” choice for pharmaceutical companies looking for efficiencies, expertise and cost savings. But, recent operational shifts in the industry have created new, comprehensive approaches to R&D and manufacturing that have enabled start-up and big pharma companies to recognize benefits inherent in partnering with a single-source provider.

Industry reports identify a growing competitive landscape internationally, which has created a greater demand for outsourced services; but how does one find a contract development and manufacturing organization (CDMO) with the appropriate capabilities, expertise, readiness and proven ability to transition from concept to commercialization?

Key elements in choosing a CDMO should include:

1. **Regulatory Compliance Record** – A stellar compliance record demonstrates the company’s knowledge and understanding of the approval process.
2. **Size and Critical Mass** – A CDMO must have the in-house workforce and technology to meet client needs on time and on budget.
3. **Expertise and Track Record** – Proven expertise in relevant dose forms and successful history of developing and commercializing products.
4. **Interpersonal Chemistry** – With a focus on team chemistry rather than the science of chemistry, the CDMO team assigned to a client must work together to support the project and ensure a successful transition.
5. **Financial and Strategic Stability** – A CDMO must have the financial, strategic, and management stability to remain dedicated to its contract customers and service provider model today and many years down the road.

RATIONALE

The advantages of working with a CDMO ultimately result in time and cost savings. Efficiencies can extend across product development, regulatory approval, packaging, manufacturing and eventually distribution. Minimizing technical transfers between contract organizations also results in quicker deliverables by eliminating delays that often occur when moving from one provider to another.

Regulatory Compliance

A CDMO should ensure a commitment to quality that meets the highest standards in development as well as manufacturing. Involving a CDMO early in the development stage creates a greater understanding of the needs of the client and provides an easier transition from pre-formulation all the way through FDA approval.

The quality of regulatory submissions can be significantly improved by utilizing a CDMO. They provide the essential scientific, manufacturing and quality control module preparation and review services, as well as the scientific basis for the Pharmaceutical Development Report. A CDMO should have thorough knowledge of report preparation and provide a high level of support throughout the process.



Size and Critical Mass

Appropriate infrastructure and talent to support multiple projects simultaneously is essential. Infrastructure encompasses everything from research and development to quality to engineering. A CDMO must be able to show clients that it can handle large projects as well as smaller-size projects and provide the same level of exceptional customer service.

A client relies on the CDMO to deliver on time, every time. In the past, outsourcing was more opportunistic: “I don’t

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have enough capacity in my plant. I'll give you what's leftover." Or tactical: "I have a surge in demand. Can you handle that for me?" Now outsourcing has become more of a strategic decision. The industry has recognized that large pharma's strengths are research, sales and marketing. They generally don't want to tie their money up in development and manufacturing processes; instead they prefer to invest in research and marketing.

Expertise and Track Record

A successful CDMO has technical expertise and infrastructure in place to ensure commitments are being met. The number of launches a CDMO has supported also helps develop a client's trust in the company.

Many CDMOs offer broad capabilities across a wide range of dosage forms. Be sure to understand the CDMO's core dosage form competencies as well as their depth of expertise in these and adjacent areas.

A sustainable operational model calls for a CDMO to look at not only what gets done, but how it gets done. Large and small pharmaceutical companies want to know who they are working with and whether there is a shared, common value system.



Interpersonal Chemistry

Customers need to have confidence in the people who will be executing their project. They are handing off, in many ways, their baby to someone. Customers should trust a CDMO to nurture and take care of that project and bring it to fruition. To provide such intricate, comprehensive services requires an entire team approach and a client must be comfortable with the company and the team. The client should talk to the CDMO's quality department, R&D personnel, operations people and engineering staff before a project is started.

CONCLUSION

The success of a customer's project depends on the CDMO's ability to do what it says it is going to do. In the case of specialty or virtual pharma, it may not be just their project at stake, but their whole company. In some cases, companies are completely dependent on their CDMO to deliver, or the client company no longer exists. This is both the opportunity and the challenge for a CDMO.

A CDMO that provides a broad range of services can eliminate the need for costly site and technical transfers. It is important that the right CDMO be selected as early as possible to seamlessly guide a project from concept to commercial manufacturing.

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About DPT Laboratories:

DPT, a DFB company, is a contract development and manufacturing organization (CDMO) providing companies the best solutions to their sterile and non-sterile pharmaceutical development and manufacturing needs through innovation, technology, and service. Specializing in semi-solid and liquid dosage forms, DPT has a reputation for quality, unmatched technical expertise, extensive manufacturing capabilities, and an exemplary regulatory compliance record. With five cGMP facilities in San Antonio, Texas, and Lakewood, New Jersey, DPT offers full-service outsourcing solutions, including stand-alone development, site transfers, state-of-the-art manufacturing, packaging, and worldwide distribution. For more information, call 210-476-8100 or visit www.DPTLabs.com.