

CAPITALIZING ON THE OUTSOURCING OPTION

Why and how to partner with a Contract Development and Manufacturing Organization

► Drug development and manufacturing has become a take-no-prisoners business.

Big pharma companies are merging, acquiring, reducing headcount, and closing manufacturing plants as they recalibrate to either an R&D focus or a bankroller/brand-management function.

Mid-size drugmakers face a recalibration challenge, too, especially those that have older operations infrastructure and less developed IT and automation capabilities. Biotechs are struggling under the burden of clinical trial and drug approval costs. Some drug candidates make it, and these small or virtual companies sell or license their technology and go on to live another day. Most candidates don't make it, though, and increasingly the companies go down with the drugs.

What these pharma company types all have in common is a need to reassess the components of their business and then tune, realign, or eliminate them in line with current strategy. For many, development and manufacturing operations pose a particular challenge due to lack of expertise and absence of infrastructure.

This document explains how and why a contract development and manufacturing organization (CDMO) can help your business thrive under changing market conditions. It also provides tips for initiating, building and maintaining a service provider relationship that benefits both parties. ●

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When to Work with a CDMO



► Having entered the development stage with a promising drug compound, you're likely now facing—perhaps for the first time—the in-house versus contract outsourcing question. With in-house development comes greater control of your resources. But by working with the right contractor, you may be able to tap some expertise unavailable in-house and save time getting to clinical trials.

With in-house development, you're establishing the capabilities that you'll need once the drug is approved and you scale up to commercial manufacturing. But doing so compounds the complexity of your facility. Equipment costs will be high, validation long, and

maintenance and training will be ongoing costs.

On the other hand, expertise and infrastructure are two big reasons to use outside services for drug development and manufacturing. Contract Development and Manufacturing Organizations work with a variety of pharmaceutical companies developing and manufacturing different kinds of drug products. A CDMO therefore has a business imperative to keep both equipment and personnel current and in tip-top condition. Their equipment and expertise needs often surpass those of traditional pharmaceutical companies producing established product brands.

Service providers specializing in development and manufacturing must also keep on top of worldwide regulatory requirements for lab activities, submissions, equipment, and manufacturing

processes across global markets. Pharmaceutical companies must too, but the extent of their research will likely be limited by the scope of their portfolio and market penetration.

Business acumen is another reason to consider using outside help. Chances are, the big changes in the pharmaceutical industry over the past few years have had a big impact on the type, quantity and speed of the work your staff now does. Process-optimized development and manufacturing operations have usually trimmed travel and training to the bone, limiting the potential for networking and first-hand information about product technology and professional capabilities.

Executives at small and mid-size drug companies can hire process, manufacturing, supply chain and regulatory talent, and they can

purchase, maintain and periodically upgrade infrastructure to maintain in-house manufacturing operations. But should you? Are manufacturing operations a strategic imperative for your company?

Perhaps. But given the current pharma environment, take a moment to compare what you're doing against what you know you should be doing to keep your company alive and growing. Then consider whether a CDMO can aid your cause.

The following checklist will help. Find the items that are true for your company. Three or more items mean it's time to consider a strategic discussion on outsourcing:

- ☐ We are much better in some parts of drug development than others.
- ☐ We struggle with project handoffs between discovery and development, and development and manufacturing.
- ☐ We have little or no infrastructure for producing our drug at Phase 2 trial volumes.
- ☐ Our FDA approval is contingent on complex refinements to our development-scale manufacturing processes and CMC preparation.
- ☐ We have two or more products in differing clinical phases and only have resources for one.
- ☐ Staff scientists are expert on our compound, but we have limited expertise on the semi-solid (or other type) formulation that we want to develop.
- ☐ We spend less per year on training per development/manufacturing employee than we did two years ago. ●

CDMO Mythbusters

DON'T BELIEVE EVERYTHING YOU HEAR

► Perhaps you're thinking that development and manufacturing services are worth a closer look. Like all businesses, pharmaceutical outsourcing has been through a lot of changes recently. For one, there's now a separation between the old contract manufacturing organization (CMO) and the more recent contract development and manufacturing organization (CDMO). That separation is a direct result of pharma industry evolution.

For example, an issue of concern in many outsourcing arrangements is handoffs: the passing of a project at one stage to another party for work on the next stage. A CDMO minimizes project handoffs compared with traditional CMOs, particularly at the sensitive step where development gives way to manufacturing.

In addition, service providers now, as in the past, distinguish themselves by areas of expertise or specialty. There are biotech producers, small molecule makers, and those who do both; processors of sterile, non-sterile, and both types of products; solid, semi-solid and liquid dosage form experts, or some combination. And some service providers show greater flexibility than others in the deals they structure with their clients.

Drug sponsors, for their part, have tweaked the client/service-provider model to align outsourcing relationships with their business strategy. And they've become flexible in developing contracts that account for the vagaries of drug development.

The point is that drug development and manufacturing organizations have evolved with the drug business. Perceptions of CDMOs have also evolved, but perceptions often lag the current reality and exclude capabilities developed recently in response to business dynamics.

Here we present some CDMO myths. Make your assessment of their myth or reality status, then check page 14.

- **Handing off a manufacturing operation to a service provider is a straightforward, time-tested process.**
- **Significant problems in outsourcing indicate a job that shouldn't have been outsourced**
- **Outsourcing drug development and manufacturing services is a form of procurement.**
- **The contract is all important.**

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Production Troubleshooting Speeds Anti-fungal Treatment into Phase II

► Troubleshooting is the name of the game in development-stage production. A CDMO that can boast expertise at all stages of development and manufacturing provides a level of operations, process and product quality that is rarely found in-house.

For example, DPT Labs recently contracted to produce and package a topical anti-fungal solution for a Phase 2 clinical trial. The order came from a California drug company: 12,000 vials of the treatment, which contains acetone and ethanol.

"The jump in the number of vials over the Phase 1 quantity (just 400) presented several challenges," says Majid Rafiq, project manager. "First, we were able to hand-package the amber vials with child-proof applicator caps in the earlier phase. But that was no longer an option at a quantity of 12,000."

So DPT introduced the first production change relative to Phase 1: the automated packaging line.

"And because of the automation system, we required a new container closure system," Rafiq continues. Working with a handful of executives from the drug sponsor and two of its consultants, they identified a system appropri-

ate for the trial and the packaging line.

That was the second change relative to Phase 1 production.

"We knew from the Phase 1 experience that the treatment remained stable with the vials packaged vertically. We recommended the same to the client for Phase 2. But the client's consultant wanted a worst-case scenario run in which the bottles were packed horizontally," Rafiq explains.

So horizontal packaging became the third deviation from Phase 1 production. In the event of a Phase 2 batch failure, DPT would have to contend with three suspects.

Seeking the path of least resistance and wanting to keep the project and the upcoming Phase II trial on schedule, Rafiq counter-proposed a run in which some

vials were packaged horizontally and others, vertically. A horizontal-only run would yield the three new variables: use of the automated packaging line, new container closure system, and the horizontal orientation. Failure would lead to head-scratching and very likely several months' delay. A change-out of just the container closure system, for example, would require another round of testing and validation.

Both client and consultant accepted his mixed-orientation proposal. After the run, in accelerated environmental-condition tests, the horizontal vials failed. The treatment was evaporating too quickly, and beyond spec. The selected container closure, it turned out, had less than a 100% seal—okay for vertical shipping, but not for horizontal.

The CDMO advantage is often not a question of product development success versus failure, though in some cases it can be that. It's more often quiet and unnoticed rescue from unplanned downtime and project delays and unexpected costs on the way to market.

"We agreed that, for trials, freight container and service specifications could ensure vertical vial storage," Rafiq says. "Later, given positive trial results, we would locate an appropriate container closure for commercial use."

The mixed vial orientation suggestion is one example of how a

CDMO can assist you with solutions to production problems that you may be unable to find in-house, or even with a traditional CMO. The CDMO advantage is often not a question of product development success versus failure, though in some cases it can be that. It's more often quiet and unnoticed rescue from unplanned downtime and project delays and unexpected costs on the way to market.

As this example shows, each new phase of a clinical trial—and in fact each phase of a manufacturing job—may be highly nuanced. Expertise can help you not just troubleshoot but also anticipate production challenges and prepare for them.

"Our suggestion saved time and money for the client," Rafiq says. ●



JEFF HUGHES, TECH LIAISON, ON THE "D" IN CDMO

► "The molecule is just the beginning. Development of the delivery vehicle is equally important."

As senior technical liaison, Jeff Hughes has a job that pulls him in two directions. One is internal, leading DPT groups that specialize in various stages of drug development. The other is external, advising clients on the best solutions to meet their goals. He generally works with process engineers and technical experts.

"We can enter the river with you at any point. One of my teams can start when you bring us a molecule and say you want to produce a cream. Another team of specialists can meet you farther downstream and begin compatibility studies, fine-tuning excipients to make a stable product or optimizing a unique delivery system."

"We don't make tablets; just semi-solids and liquids. Our scientists are specialized. We bring that expertise to the table. We're going to have an opinion and advise you along the way. People come to us because we make suggestions. They don't want just a set of hands."

Hughes has been with DPT since 1997, first as an analytical chemist, rising to group leader in process development, and now is liaison between DPT's R&D scientists and clients. ●

Pharma/CDMO Working Relationships

CLIENT NEED DRIVES TYPE, LEVEL OF ENGAGEMENT

► Pharma needs flexibility. That's what the last few years have taught. They've taught simultaneously that the development/manufacturing/supply-chain operations box that some small and mid-size drugmakers have built as a result of their business constraints—infrastructure, technical, regulatory—now hinders their competitiveness. Likewise, but to a lesser extent, startup and virtual biotechs that have development and manufacturing deals more than 12 or 18 months old can be similarly challenged.

One thing is for certain: It takes time to make the adjustments required to transform a restrictive ops box into a strategic asset. In some cases, a corporate culture shift will have to precede any operations transformation in which staff members embrace and trust their service providers as much as they do their co-workers. In other cases—particularly small and virtual biotechs—it's a simpler matter of redefining the sponsor/service-provider relationship and following up to be sure that the new relationship forms.

To start the process of incorporating a CDMO as a strategic asset into your operations, determine by type

of relationship the role or roles you want to assign to key suppliers. The relationship types fall into two main categories: business flexibility, and tech/regulatory asset.

BUSINESS FLEXIBILITY

CDMOs can play big and small parts in bringing flexibility to small and mid-size drugmakers. A CDMO may become the big cog in your development and commercialization efforts, involved at various stages as tech experts, joint project overseers, hand-off specialists, and supply chain managers. The service provider can become an organization in tune with your objectives and integrated with your internal processes.

In another relationship model, you bring in the CDMO at the optimum time, given the particulars of a project and its constraints. That might be early-phase clinical production, late-stage formulation, manufacturing scale-up, etc.; it might be a large role or a small one.

In the big picture, however, the greatest benefits come from the multiple linkages of an end-to-end collaboration. Such relationships allow your key scientists and managers to focus on what they do best.

This type of collaboration implies something about the length and depth of the relationship. And it recognizes that beyond the technical, regulatory, and specialty expertise of the CDMO is its underlying

benefit of significantly less investment in facilities and equipment and improved flexibility in the use of

scarce financial resources.

It's a safe bet that the internal cost pressures you're under now will be ending no time soon. Neither will the opportunities for drugmakers and CDMOs to optimize their working relationship.

TECH/REGULATORY ASSET

Technology is the nexus of many drug-sponsor/CDMO relationships. A reliable development and manufacturing partner can go a long way toward helping you achieve critical business milestones—not just by freeing resources but by taking the lead on process and regula-

tory activities, for example, which may be fundamental to product advancement yet a distraction to drug sponsors due to competing development priorities.

One longstanding relationship style between drugmakers and manufacturing service providers occurs when the latter simply provides labor, equipment and facilities for production capacity. The contractor functions as another set of hands for the brand-holder. And the brand-holder often benefits from cost efficiencies and quicker time to market relative to in-house capabilities.

Among the newer types of relationships are strategic partnerships, in which the CDMO is also a link with regulatory bodies and supply chain parties around the world. In

such relationships, the CDMO can rise to the level of stakeholder.

An ever-growing population of small-molecule drugs and vaccines has been joined by generics, biologics and now biosimilars and drug/device/diagnostic combinations. Each new technology represents a threat to an existing way of doing business, driving change not only in processes but in skills and sometimes in culture.

Your company can evolve with the technology, of course, but you don't have to do it alone. CDMOs are prepared to develop, evaluate, prototype, test and counsel as well as manufacture.

Another partnering style—this one likely put forth by discovery-oriented small and virtual biotechs—involves a focus on devel-

opment work, up to and including production of clinical trial supplies and even beyond. This partnership lets the sponsor maintain its discovery focus. Sponsor needs will require service provider expertise in a certain technology and likely at various development stages.

Your company can evolve with the technology, of course, but you don't have to do it alone. CDMOs are prepared to develop, evaluate, prototype, test and counsel as well as manufacture.

Regardless of relationship type, all biopharma companies need to be in step with the FDA's inevitable march toward product quality via Quality by Design principles and the use of process analytical technologies in drug development and processing.

The development process itself is increasingly forcing drug technology expertise to be matched with expertise in process technology, compressing the regulatory development cycle. This is a win for drugmakers and regulators alike in terms of cost and efficiency. In addition, the technologies used in solving production problems are evolving quickly, adding yet another technical strain on sponsors. But it does make a case for partnering with a tech-savvy service provider that offers all three types of expertise—development, process, and regulatory—and can pull them together. ●



How to Choose a CDMO in 5 Steps

► Prerequisites for choosing a contract development and manufacturing organization are to understand the strategic reason for the outsourcing and the role you want the service provider to assume

within that strategy. But perhaps the most important prerequisite is your complete acceptance that—no matter what role you assign to a service provider—the FDA holds you responsible for your products, the condition of the

CDMO's production facility and processes if they affect your product, and even the subcontractors engaged by the CDMO on your behalf.

Your due diligence goes well beyond the CDMO, up and down its supply chain.

Of equal importance to understanding the responsibility assigned to you by the FDA is

understanding that contracting with a CDMO is in no way like selecting a vendor for supplies. Each and every outsourced job is individual in nature. Each requires a vast amount of creativity, effort, expertise, commitment, interaction, coordination, planning and execution. Above all, each requires teamwork, sound functional relationships, and flexibility.

Now it's time to get down to business.

1. SELECT CANDIDATES

Listings of CMOs and CDMOs are available from many sources, but there's no better starting point than word-of-mouth recommendations from your own professional network. Get opinions from within your own company and from industry associates. Explain your thinking behind the outsourcing decision to help inform their suggestions. Ask for recommendations that meet a baseline list of capabilities important to you. Among them might be reputation and ratings; performance; expertise with specific dosage forms; capacity; overall expertise in current pharmaceutical manufacturing art, including lean and Six Sigma techniques, Process Analytical Technology, and Quality by Design; niche or specialty capabilities; QA reputation; and standing with the FDA and other regulators.

2. DEVELOP AND SEND RFP

Here is where you translate your strategic thinking into tactical detail. Make the request for proposals (RFP) as detailed and accurate as possible; enlist all relevant expertise within your company.

Accept that you're unlikely to foresee all problems and contingencies—especially in development-stage projects—to be able to include contract-quality specifications. Identify the items for which that's the case; define them as best you can in the RFP. Revisit those items at contract-writing time in collaboration with the service provider you ultimately choose.

Within the RFP, define your requirements in such a way to elicit responses that allow you to make apples-to-apples comparisons.

You'll put a lot of effort into the RFP. Give your candidate service providers enough time to be as thoughtful in their responses as you are in defining your request. Also, work with them, as necessary, to optimize their responses.

3. EVALUATE RESPONSES

This step generally focuses on very quantitative factors such as

You'll put a lot of effort into the RFP. Give your candidate service providers enough time to be as thoughtful in their responses as you are in defining your request.

capabilities, solution and price. Be sure to use consistent measurement tools for evaluating responses. If your RFP garnered those apples-to-apples responses, you'll spend less time clarifying and confirming details.

Be open to considering alternatives suggested by service providers. Look at the big picture as well as the details. Meet with all respondents and encourage them to put their best foot forward.

4. REFINE

Compare your options. Be reasonable. Ask for clarifications, where necessary, and whether the service providers would be willing to make

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Be clear on the development steps remaining. Both parties need to lay their cards on the table; both promises and expectations need to be based in reality.

changes (e.g., equipment and process) to accommodate your needs.

Narrow down the field to the best two candidates. Get to know their organizations, culture and key players. Meet again to discuss next steps.

Clarify and confirm the details in their proposals and get com-

mitments on timing and project process. Detail is good here; the more the better. Work with the CDMO to identify incompatibilities between the work to be done and existing capabilities. Be clear on the development steps remaining. Both parties need to lay their cards on the table; both promises and expectations need to be based in reality.

This is also the time for a risk assessment. Avoid using a checkbox format, if possible. Be thorough, but prioritize risk items based on what's important for your company.

Negotiate where necessary. Although no deal has yet been

made, you've now entered the project-detail level. Strive for the best available deal at the required value threshold, but maintain your focus on the qualitative factors—relationships and corporate cultures—that will yield a positive long-term relationship.

5. SELECT

Then make your choice and work with the CDMO to create a contract. This stage is for assigning responsibilities and building safeguards. It's also for clarifying the fine details and identifying the rights of each company (your right to audit, for example; the CDMO's right to timely payment). Develop-

ing the contract together helps ensure that the document is not viewed as a mandate but rather as a statement of collaboration. And it's your first real test of how well your companies will work together.

For development projects in particular, some details can't be specified until work has begun. Contracts can be broken into pieces, allowing work to begin in a binding way while still providing the flexibility for project-spec evolution. A common type of breakdown includes a master service agreement, a project agreement, and a quality agreement, all of which tie to the initial project quotation. ●

BOB WOOD ON THE CLIENT-SUPPLIER PUSH BEHIND DPT'S ASEPTIC MANUFACTURING FACILITY

► *"Customers come to us because of our expertise and capabilities in semi-solids and liquids as well as our ability to join expertise with equipment. On several occasions, we partnered with component suppliers whose devices we can fill. Those suppliers, in many cases, drive customers to us because they know we have both the expertise and equipment needed."*

DPT works closely with both its customers and key suppliers. In doing so, it has built one of the newest aseptic manufacturing facilities in the industry.

The 175,000-square-foot Center of Excellence for Sterile

and Specialty Products in Lakewood, NJ, specializes in aseptic production of sterile dosage forms. Some 350 employees produce small-volume parenterals, ophthalmic preparations, preservative-free nasal sprays and sterile ointments.

As director for product technical services, Bob Wood is likely who you will meet when you first visit the facility.

"I'm part of the intro team. I tell customers about our capabilities, give them a tour and an overview of our processes that explains all of our capabilities. Clients may not know that we have expertise in small volume

parenterals and ophthalmics, for example."

"We've built expertise and can now offer product development capabilities that our clients are using to exploit new niches. One example involves an ophthalmic dropper bottle that will keep the product sterile throughout its life."

Wood has been with DPT 10 years. He started as a senior process engineer and was promoted to project manager, then manager of product technical services, senior manager, and then director.

He notes that DPT's Center of Excellence for Sterile and

Specialty Products has two counterparts: One is a 450,000-square-foot center for semi-solids and liquids in San Antonio, TX, the workplace of about 400 employees.

The other center, for research and development, covers 40,000 square feet, also in San Antonio. It has 150 scientists and technicians providing services including formulation development, analytical chemistry and quality control testing. ●



How to Kick Off and Run a Project with a CDMO



► Given the importance of sponsor/service provider relationships in successful outsourcing endeavors, pay particular attention to the maintenance and management of your relationship. Acknowledge contributions, celebrate milestones, keep yourself informed, and, when necessary, take action quickly.

To kick off your new relationship, call a meeting of the principals to award the business to the service provider. Congratulate the CDMO for prevailing in a tough competition. Express your great confidence in a successful partnership. Use this opportunity to further build

relationships among members of both teams, including you. Doing so will help ensure that your new partner is as vested in the relationship as you are. Iron out any last-minute or next-step details. Look for clarity and understanding all around.

Give the meeting a congratulatory tone for two well-suited parties joining forces to the benefit of both. But make it a business meeting. Explain the importance and nature of the relationship and how you are relying on those in attendance to perform work essential to your company's success and the service provider's growth. Provide some stats as visuals to show intended consequences of the relationship.

Mention significant upcoming milestones, when they are expected, and the positive consequences of achieving them.

Have a leading member of your team (perhaps yourself) and the service provider team describe their roles. Have them speak briefly, together if possible, on what they see as the advantages to the relationship, whether in terms of career growth, process streamlining, experience using leading-edge process technologies, etc.

Then summarize the activities currently completed and in process; the decisions already made. Describe what's coming next, and when, and what will be expected of both parties. Express great confidence in the ability of both

teams to pioneer their own methods of communicating effectively, to achieve a successful technology transfer and successful working relationship, and to master their individual roles.

Then, thank everyone for their suggestions, research, expertise, time and flexibility in getting this important collaboration underway. State your belief that collectively you will create a roaring collaborative success to the benefit of both the companies and the individuals.

Ask for questions and encourage feedback. When the questions run out, be available for the remainder of the gathering.

MANAGING THE RELATIONSHIP

As the foregoing chapters show, the drug-sponsor/CDMO relationship begins well before this point, as does management of the relationship. By this time, however, terms of the relationship are much better understood by both parties than they were in the earlier stages of contractor selection and contract development.

Establish a reporting format that will keep you apprised of the work and the relationship. Ask for frequent check-ins from key staff members initially. Keep it as informal and unstructured as possible so it doesn't become yet another managerial reporting task.

Make sure you're getting the appropriate data and information required to ensure the project is going as intended, that both companies are on track to meet milestone dates, and that plans are being developed and actions

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CDMO Mythbusters

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- **Handing off a manufacturing operation to a service provider is a straightforward, time-tested process: *Myth.***

There are certainly handoff models you can follow—models that have been refined over time. And the closer your project is to a straight extra-pair-of-hands manufacturing job (rather than one involving development), the more useful those models will be. But even for the simplest of products, every project is unique in its intertwining of manufacturing, business and management processes, not to mention time constraints and supply chain challenges.

Compounding this myth is the commonly held belief among many that they can manage an outsourced project having never done so before.

- **Significant problems in outsourcing indicate a job that shouldn't have been outsourced: *True.***

But it's not necessarily a function of the project. Significant problems are usually caused by a lack of planning or by time constraints that curtail the full benefits of the service provider's expertise. Unheeded warning signs, lack of project management, an ill-defined contract and the selection of an unqualified service provider can all lead to outsourcing difficulties.

- **Outsourcing drug development and manufacturing services is a form of procurement: *Myth.***

If only it were true! Purchasing office supplies and contracting with a CDMO both require you to find a source, place an order, receive the goods and pay the bill. But the similarity ends there. The vagaries of drug development, the complexity of the interactions between client and service provider, and the strictures of production in a regulated environment make the client/CDMO relationship a partnership or team extension rather than buyer/seller pairing.

- **The contract is all important: *Myth.***

The contract is important, and woe be unto the drug sponsor and service provider that skimp on the details. The contract is a description of sponsor and CDMO responsibilities and the final source of dispute resolution, financial and otherwise. But there's plenty of room for clarifying misunderstandings and for negotiating before turning to the contract for a ruling. **The relationship is all important. ●**



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taken quickly when the unexpected occurs. Watch out for bureaucratic slowdowns at both organizations.

Despite the best possible planning, the development stage is loaded with unknowns and fraught with potential for surprise. Make sure the source of slowdowns and conflicts are identified and quickly addressed. Make sure the manufacturing tech transfer gets all the attention it warrants and is documented.

Especially in projects involving biologics, pay close attention to spec and production-yield anomalies. These can sometimes require a review of the contract to identify financial responsibilities. Get involved early in discrepan-

cies; make sure data supports the actions you take.

Continue to check in on the project as it progresses, though your need for reports may become less frequent. Look beyond manufacturing to the rest of the supply chain.

Longer term, conduct periodic product reviews (at least annually), comparing current results with initial expectations and the impact of changes made along the way to help achieve results. Use the review to fine-tune processes and the relationship.

In all conflict resolution, you'll want both parties to continue to view the relationship as mutually beneficial. Broker negotiations rather than issuing mandates whenever possible. ●

The CDMO Premise: Stronger Now than Ever

BY: PAUL JOSEPHS

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► Things change.

And that is why the business premise for contract development and manufacturing organizations is stronger than ever.

A full-service CDMO is a one-stop shop. It has specialists engaged and available to clients in all facets of drug development, from concept to commercialization. We find that drug sponsors are no longer satisfied working with generalists. They want specialists.

The CDMO is a resource for those toiling in early-phase drug development, those in development's latter stages, and those on their way to commercialization.

In pharma-Darwinist theory, the CDMO evolved from the CMO, still a highly regarded and often-used provider of late-stage development and manufacturing support, and from the drug development portion of the contract research organization (CRO). The result is an entity with academic/scientific and industry/process lineage that can operate in both spaces.

Today's CDMO is the closest convergence yet of CRO and CMO. Its chief benefit for drug sponsors: greater project efficiency and continuity through fewer development-step handoffs, which are administratively tedious and prone to mishap.

The day of the fully converged pharma service provider—offer-

ing discovery and early-stage development support, clinical trials and accompanying drug development, and then the latter-stage development, formulation and manufacturing support—may well be in our future. But it's not here yet.

This is the time of the CDMO.

The concept is clearly attractive to small and virtual biotechs, many of which are in academia or have just emerged from it. As discoverers, they have little or no infrastructure or expertise for development and manufacturing. Some don't even like to think about it.

Likewise, CDMO offerings are attractive to the small biotechs and small to mid-size pharma companies that have a few products in the portfolio and a strategy that involves seeing drug candidates through to commercialization as a means of company growth. They have a limited level of process and operations expertise. But financial constraints typically leave both the talent and the infrastructure shy of the levels necessary for scale-up and manufacturing innovation. For these companies, a CDMO lets them contract for services later in the product-development cycle, minimizing costs and tapping a level of expertise they need but are not likely able to afford on their own.

I don't know of a single drugmaker—virtual, small,



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midsize—that has these things figured out now. A full-service and flexible CDMO like DPT gives each of them a chance to try out business models or to begin developing a chosen one.

And that is why the CDMO premise is stronger today than ever. ●

— Paul Josephs, a 14-year veteran of DPT, is Vice President for Sales and Marketing

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