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CMOs, Pharma and Outsourcing: PERCEPTION VS. REALITY

Q&A with *Stuart Needleman*,
President, *Laurus Synthesis*

Pharmaceutical and biotech services company Laurus Synthesis was established in 2015 as a U.S. affiliate of Laurus Labs, one of India's top ten chemistry providers. It operates from a new drug development facility in Woburn, MA, that opened in March 2015.

Laurus Synthesis provides process development, route selection and route optimization, method development and impurity identification services and route selection for API intermediates and starting materials. The company also provides Key Starting Materials (KSMs) and intermediates as well as cGMP manufacturing of APIs for scale up and commercialization through Laurus Labs, India.

Stuart Needleman, president of Laurus Synthesis, recently offered some thoughts around the theme of partnerships between (bio)pharma firms and their contract service providers. Chiefly, what are the nuances that create a successful collaboration, and what are the pitfalls to avoid.

Contract Pharma: Even though pharmaceutical companies and scientists at contract manufacturing organizations (CMOs) both seek to favorably impact patients' lives, there are issues that may stand in the way of their true collaboration. Can you identify what some of these issues are?

Stuart Needleman: It's important that both companies understand each other's culture, mission and values. This goes way beyond the bench level, all the way up the corporate ladder. The intrinsic needs of both partners must be addressed or issues will arise that jeopardize success. Also, there is sometimes a tendency to misread or underestimate each other's motives and competencies. Having a better understanding of misconceptions could foster a more authentic collaboration and deliver more reliable results.

CP: Can you give an example of a misunderstanding that could get in the way of true collaboration?

SN: It is generally assumed, even among CMOs and pharmaceutical scientists, that pharmaceutical companies have generous sums of money at their disposal. Little emphasis is placed on the high cost of R&D at pharma companies of all sizes where outsourcing becomes a small part. CMOs need to be cost competitive in order to survive but to really prosper, they also need to be efficient. It's efficiency that maximizes their ROI on personnel.

CP: Other than misconceptions about financial matters, what else could present a challenge to collaboration efforts?

SN: The high level of competence that CMO scientists bring to

the table is often underrated. In addition, it is an arduous task to assemble pharmaceutical professionals with impressive credentials and a high level of experience. Many are under the false impression that scientists turn to a CMO position because they cannot find work at a pharmaceutical company. That's not the case at all. Many CMO scientists choose the pharmaceutical discovery and development industry because they appreciate the number and variety of active programs and proposals that will regularly come their way. In most cases, this is a far larger number than they would experience if they worked at a pharma company, where the focus on individual therapeutic specialty areas can limit a wider breadth of experience.

CP: Typically, how do the number of ongoing active programs and proposals that scientists experience at the pharma company compare to the CMO experience?

SN: From the experiences of our team—whose backgrounds include both pharmaceutical sponsor and CMO companies—we've learned that CMO scientists really value the variety of programs they touch. It is not unusual for a CMO scientist to see ten different programs in a month, while on the pharma sponsor side, it could take ten years for the scientist to see that many. So the knowledge base and scientific expertise of CMO scientists is continually enhanced. Many of the scientists who establish CMO companies have resumes that would meet the most stringent qualification requirements of the industry's foremost pharmaceutical companies. CMO management teams demonstrate the ability to lead time and time again. Their ability to quickly grasp the challenges of projects that involve different chemistries is remarkable.

CP: Returning to the issue of collaboration, how does it work for the CMO team and the pharma company?

SN: It's important for everyone working on the project to remember that there are different levels of collaboration: internal collaboration at the sponsor, internal collaboration at the CMO and joint collaboration between the two. A strong CMO team recognizes the logistical advantage of internal collaboration that exists within companies. It is far more attainable than what usually exists between the pharma company and the CMO. The opportunity for impromptu meetings and easy accessibility at one location is a decided plus, and the addition of CMO support makes collaboration more challenging, but not impossible. For large-scale collaborative efforts, it's also worthwhile to establish a "Steering Team" that includes multiple layers of personnel and multiple disciplines at both organizations, with governance clearly established.

CP: How can you compensate for not being at one location?

SN: The value of kickoff meetings cannot be overstated. An internal kickoff meeting, where the CMO meets as a team to discuss the overall goal and begin the innovation process, helps ensure that all team members clearly understand the objective. Likewise, the joint sponsor/CMO kickoff meeting confirms expectations, processes, roles, information sharing methodology and other factors that are vital to success. A true vision of the project should be presented, attempting to show each party how and where their

responsibilities apply. Of course, as pointed out, it is easier to see how this understanding continues when collaboration is all under one roof; it's much more difficult when you are somewhat out of the loop (as the CMO team members often are). And it is perhaps harder still for the pharma sponsor to understand that the CMO really needs to know everything about the project, not only at the onset, but also at every step of ongoing development and project evolution. This knowledge is vital if the CMO is going to bring passion and excellence to its work. A high level of communication from initiation through the entire project life cycle is essential. Teleconferences and emails, while efficient, just do not compare with personal meetings that foster unity. Open communication is a two way street—and information should not be withheld.

CP: The challenge of personal meetings must be an important concern when capabilities emanate from China or India. How do you deal with this as a perceived obstacle?

SN: Some sponsors have a built-in preference for U.S. or European facilities as opposed to capabilities in China or India. It's prudent to remember that competencies and quality systems are only as good as the people who oversee them and only as strong as the company culture demands, regardless of location. In this regard, personal dialogue from both the eastern and western perspectives can be a good indicator of where the cultural emphases lie and how effectively the business relationship will evolve.

CP: What are some of the other factors in evaluating potential partners and the prospects of a true collaboration?

SN: Thorough evaluation is critical before you begin any collaborative process. References are of course very important. The CMO's scientific pedigree is also a pretty good indicator of fit between partners, as are the culture and the people. A word of mouth recommendation is helpful in evaluating a CMO. But keep in mind that while it is difficult to build a reputation for excellence, just one unpleasant occurrence could destroy a company's good name.

CP: Can you get an indication of success at the onset of a collaboration?

SN: The CMO/sponsor kickoff meeting is often a great indicator of how companies will work together because the confidence and trust each company has in the other—or lack thereof—is easy to see. When the meeting is over, if either party feels confused or concerned, that's the time to address it or it will surely snowball from there.

CP: How does one determine which CMO is right for a project?

SN: Scientific excellence and expertise of personnel are the obvious answers. There's no substitute for strong technical capabilities and a talented scientific team whose flexibility and fluidity of approach can speak volumes about potential success. But a less obvious answer is to evaluate the energy of an organization. Companies have a "vibe" that is typically pretty consistent with the way they work. If you have a chance to observe the energy, attitude and workflow of a company, you may find it to be the tipping point in a go/no-go decision. **CP**