

Opening Up Pharma Innovation

Agnes Shanley



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Driven by competitive pressures and using models pioneered in other industries, pharmaceutical companies are extending collaboration efforts well beyond their walls.

Competitive pressures and the move to value-based medicine are changing the nature of partnership and collaboration in the pharmaceutical industry. Like other industries, pharma is moving to more of an “open innovation” model.

The idea of open innovation involves using both internal and external ideas to help solve specific problems or meet unmet needs. The term was coined in 2003 by Henry Chesbrough, a professor at the University of California who had worked in Silicon Valley and saw a need to close the gap between academia and business, at least in the realm of new ideas.

Pharma outsourcing has opened up the traditionally closed world of pharma innovation. When the trend began, pharmaceutical companies would typically outsource specific projects on a transactional basis; today, more are creating strategic partnerships with their contract research, development and manufacturing organization (CRO, and CDMO/CMO) partners, sharing sensitive data, and even financial risks and rewards.

Pharma companies are now more attuned to potential sources of innovation. “Over the past 10–12 years, a lot of the most interesting new ‘disruptive’ technology has been coming from startups,” says Christopher Kulp, executive vice-president of Richman Chemical, Inc., which focuses on small-molecule chemistry and on getting new technologies from innovator companies or academia ready for licensing and/or transfer to larger, partner companies. “Small startups are now preeminent on big pharma’s radar, and some receive preliminary feedback on their IP from big pharma licensing teams,” he says. “This didn’t happen 15–20 years ago when new product development predominantly occurred in-house.”

Companies like Richman serve to bridge the gap between Big Pharma and innovators whose ideas aren’t quite ready for prime time. “There are lots of opportunities to waste time on technology that isn’t going to go anywhere if it is not evaluated properly,” Kulp says. In addition, pharmaceutical manufacturers are sharing more innovation and collaborating more in niche areas (see **Sidebar**).

Big Pharma is moving to a “hub” model for R&D, with companies that include Johnson & Johnson, Eli Lilly, Pfizer, AstraZeneca, and Sanofi basing research centers in specific areas, such as Cambridge, MA, close to university, industry

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collaborators, and contract partners. Recently, a study by Deloitte Consulting suggested that open innovation in biopharma could strengthen new drug pipelines (1). Studying 281 biopharma companies between 1998 and 2012, the research found that drugs sourced via open innovation could have a three-fold higher likelihood of success than those generated traditionally.

The question is: How do you trade off control to get better results? —Matthew Hudes, Deloitte Consulting

Deloitte's study shows an evolution in the open innovation model, from the traditional approach of outsourcing with a university, research institute, or CRO, to licensing. Newer models include the innovation hubs, as well as leading edge partnerships as the transSMART Foundation, the Structural Genomic Consortium, and Asia Cancer Research Group.

In 2014, Deloitte researchers found, of the 12 largest biopharma companies, 54% sourced new drugs via open innovation, 83% of that figure via outsourcing or licensing. Forty-six percent sourced drugs the traditional way (1).

Matthew Hudes, managing principal at Deloitte's biotech consulting division, shared perspectives on the pharmaceutical industry's new open innovation model with *Pharmaceutical Technology*.

Innovation models

PharmTech: Why is pharma changing its models and mindset for innovation?

Hudes: We've seen this coming for some time, with the patent cliff and some recent high-profile failures in pharma's development pipeline. About six years ago, we saw an increased outreach to external sources of innovation. What is remarkable about this is not that it is going on, or even the extent to which it is going on, but the diversity of ways in which this outreach is taking place.

It's a big experiment, and we don't know which model will prevail in the future, but it is rare to see such a diversity of business models. Science is diverse, but not, typically, the business models behind it.

PharmTech: Can you give examples of these models?

Hudes: I think about it as having two main dimensions: control and source (external vs. internal). If you put those two factors together, you get a broad spectrum of what is going on.

In one type of model, large companies are lifting out assets and people from an academic setting and moving them to a place where they can focus on a specific project, and giving them everything they need and access to all their resources, on an exclusive basis. The project is treated like a major product extension, and companies that are taking this approach are having terrific results. They have been picking up intellectual property (IP) that has been, if not languishing in, then bumping up against the limits of what can be achieved in an academic setting.

Another model takes a 'hands-off' approach, in which large pharma invests in an innovation center, in a place where there are many resources and where they are interested in launching companies. They don't own or contribute to the IP, and don't even have first right of refusal.

Through proximity, they get an early, inside look at what these innovations are, but use a community approach. This way, they can invite competitors into that space for collaboration as well.

Niche networking

Open innovation can be spurred by industry groups. The electronics industry already had a good model: Sematech, the consortium for semiconductor manufacturers. Launched in 1986, originally for US manufacturers as a way to help them compete in a market dominated by Asian companies, the group became private in 1996 and is now a global organization focused on improving materials and processes.

For years, observers in the pharmaceutical industry, notably Prabir Basu, former head of The National Institute for Pharmaceutical Technology and Education (NIPTe), have called for the establishment of a group like Sematech in pharma. It may not yet exist, but there has been much more sharing of ideas and best practices in niche areas, by groups such as the International Foundation for Process Analytical Chemistry (IFPAC) and the American Institute of Chemical Engineers (AIChE) for process analytical technology (PAT) and pharmaceutical quality by design (QbD).

One example of an open innovation consortium is Portable Continuous Miniature and Modular (PCMM), devoted to increasing the use of continuous

manufacturing in pharma. Initially involving GEA Process Engineering, G-Con Manufacturing, and Pfizer, the group has extended membership to other pharmaceutical companies and launched pilot programs.

Getting involved at the earliest stages

Consulting services are also being geared more to the small startup and the academic. "We like to get involved at the earliest stages in order to add the most value," says Christopher Kulp, executive vice-president of Richman Chemical, Inc. In the engineering and consulting (E&C) space, Klyo Collaborative was established to offer companies the kind of attention that big E&C companies, focused on billable hours, cannot typically afford. "We can start with a very young bio facility," says cofounder Barry Holtz, a biotech veteran who established G-Con and Caliber Biotherapeutics, and handled tech transfer for the new pandemic flu vaccine manufacturing plant in Texas. The result is an ability to help companies grow as their ideas take off. "Very few companies offer a full palette of services, from early to mid-cap biotech," Holtz says.