

# INSIDE Outsourcing

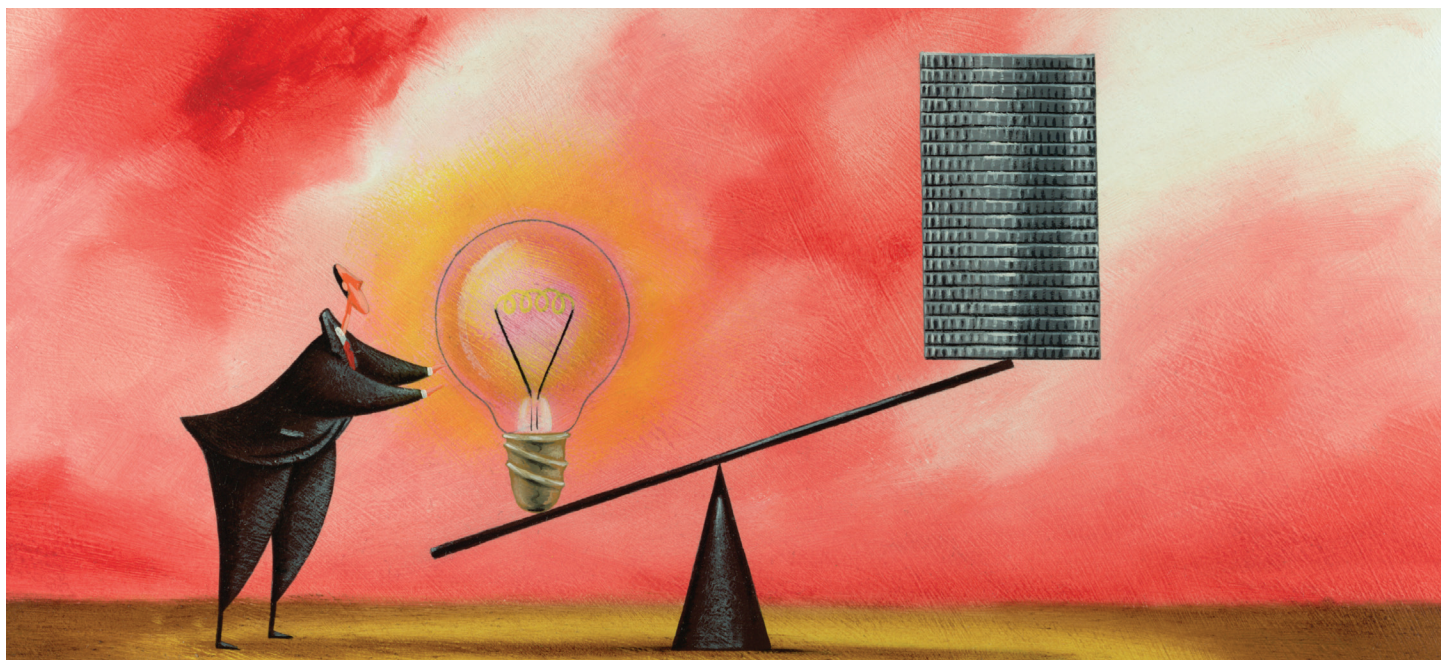
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## 7 KEY PLAYERS ON THE NEW NORMAL

In May Ernst & Young published its annual report on the drug industry. It said that in the wake of the economic crisis a new crisis had taken hold that was fundamentally changing the face of global drug development. They dubbed it the New Normal, which basically means that companies will have to do more with less and fail faster. “Pharma companies will continue to face a challenging funding environment for the foreseeable future,” said Glen Giovannetti, Ernst & Young’s Global

Biotechnology leader. “The firms best poised for success are those that can seize the opportunities latent in the near-universal need for increased efficiency—from capital efficiency to new approaches to R&D and creative models for funding and partnering.”

*Inside Outsourcing* asked 7 top industry leaders from both the pharmaceutical industry and the outsourcing industry to share their insights and analysis on what The New Normal means to them.



## Sven Remmerbach, Ph.D.

### PMP, BAXTER BIOPHARMA SOLUTIONS

From our point of view, we do see a trend toward increased collaboration with contract manufacturing organizations (CMOs), driven by the global economic crisis. Collaboration has always played an important role in drug development, but with the new normal it has become increasingly important. In our experience, there has been an increase in the number (volume) of projects, as well as projects containing more outsourced services (breadth), such as stability studies and formulation development in combination with clinical supply manufacturing. Ernst & Young stated in their report that, "The overall theme is that drug developers need to learn to do more with less." We have seen that companies are looking to outsource services that were previously kept in-house, as outsourcing can be an effective strategy to reduce capital-intensive investments during all phases of development.

We have also seen developers weigh the non-capital costs of building capabilities and expertise within their own organization with the potential advantages of leveraging development and commercialization services that exist within CMOs.

For many biotech and pharmaceutical companies, it can be challenging to manage a large number of outsourcing relationships, so value can be realized through minimizing the number of relationships by partnering with select partners who can offer a broad range of services. An example of this would include a service provider that supports the development of the analytical methods and can also support formulation development, along with providing drug product for clinical trials.

With an increased share of outsourced activities going to fewer partners, the service requirements and critical success factors required for drug developers and their service providers can be clearly defined in a partnership-type approach, rather than being transactional in nature. We have seen that our clients expect experienced, skilled project management staff, the use of advanced project management tools, and mature communication methodologies between the organizations to produce optimal results. When deciding who to partner with, drug developers are asking themselves, "Is there an opportunity for leverage by outsourcing my activities to them? Are we confident that this CMO will deliver on their commitments so that we meet our objectives?" Therefore, it becomes important to find a partner that employs multidimensional strategies and integrates the best practices from project management, customer service, and Lean methodologies, while utilizing continuous improvement and learning principles. We feel these factors provide the most effective basis for partnering and provide the possibility of the CMO becoming a seamless extension of the pharmaceutical company.

Superior service providers are those who offer a depth of services and are able to effectively harness the relevant expertise within their organizations to support their partners' objectives. Certified, experienced Program Management Professionals who are trained and skilled in managing global, intercultural teams are a critical element of this equation. They provide leadership and focus within the CMO in order to help support the partners' objectives.

Maximizing the unique aspects of each partner's contribution to the collaboration is a critical component of the Program Manager's



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role. Those service providers who are able to do this as part of their systemic approach to partnering possess an important differentiator.

Developers understand that the optimal outsourcing solution is an equation identifying quality, service, technical expertise, speed to market, and supply chain safety as variables. All of these factors should be considered as part of the decision-making process, and should be used to determine the total cost of partnering. In other words, the best solution for the developer may not necessarily be the lowest unit-cost option. In our experience, there are unique characteristics to each development program, and the service provider's ability to tailor solutions provides an opportunity to deliver enhanced value. At the same time, drug developers have realized that outsourcing is an opportunity to leverage capabilities and capacity that exist in CMOs. Forming partnerships with CMOs that provide a breadth of services and have the ability to deliver on commitments supports the increased need to do more with less. We feel this trend is likely to continue and agree that this represents the new normal, at least for the foreseeable future.