

Syngene

Putting Science to Work



**The Dedicated Center:
Outsourcing's
Answer to the
Innovation and ROI
Challenge in the
Biopharmaceutical
Industry**

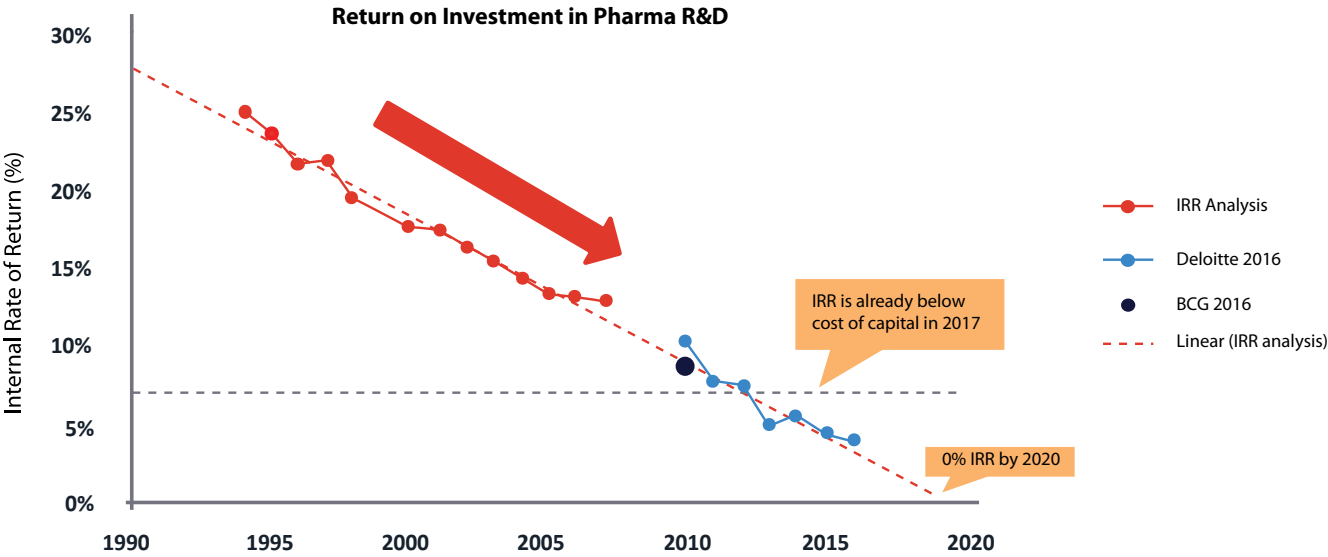
By Mahesh Bhalgat, Ph.D.,
Chief Operating Officer

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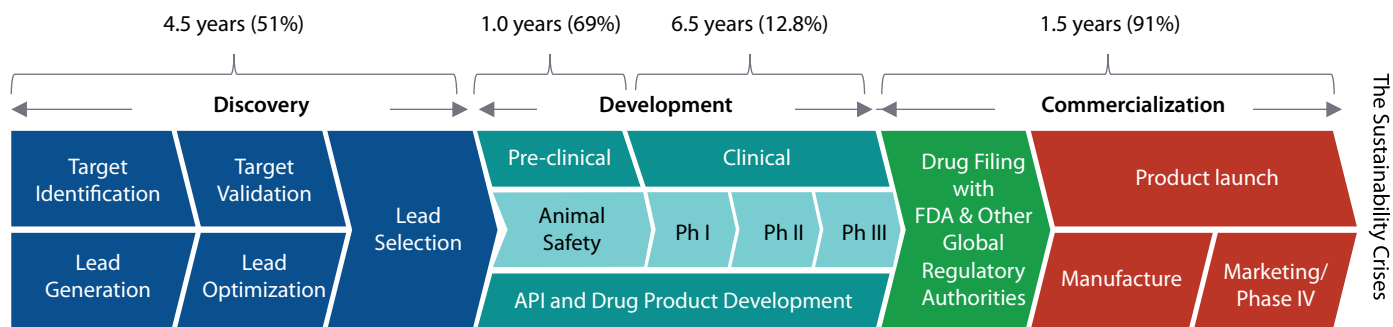




The pharmaceutical industry is facing a sustainability crisis due to dwindling ROI on research and development. Even though the top 20 pharmaceutical companies invested 20.9% of top-line revenues into R&D last year, IRR for pharma R&D is already below the cost of capital and is projected to hit zero.



According to studies, it takes ~14 years and over US\$2.6 Bn to bring a product to market at an overall success rate of just ~4.1%. Recent data also shows an increase in timelines for Pre-clinical (+17 %, 2004–2012) and Phase I development (+58 %, 2004–2012), leading to higher costs.

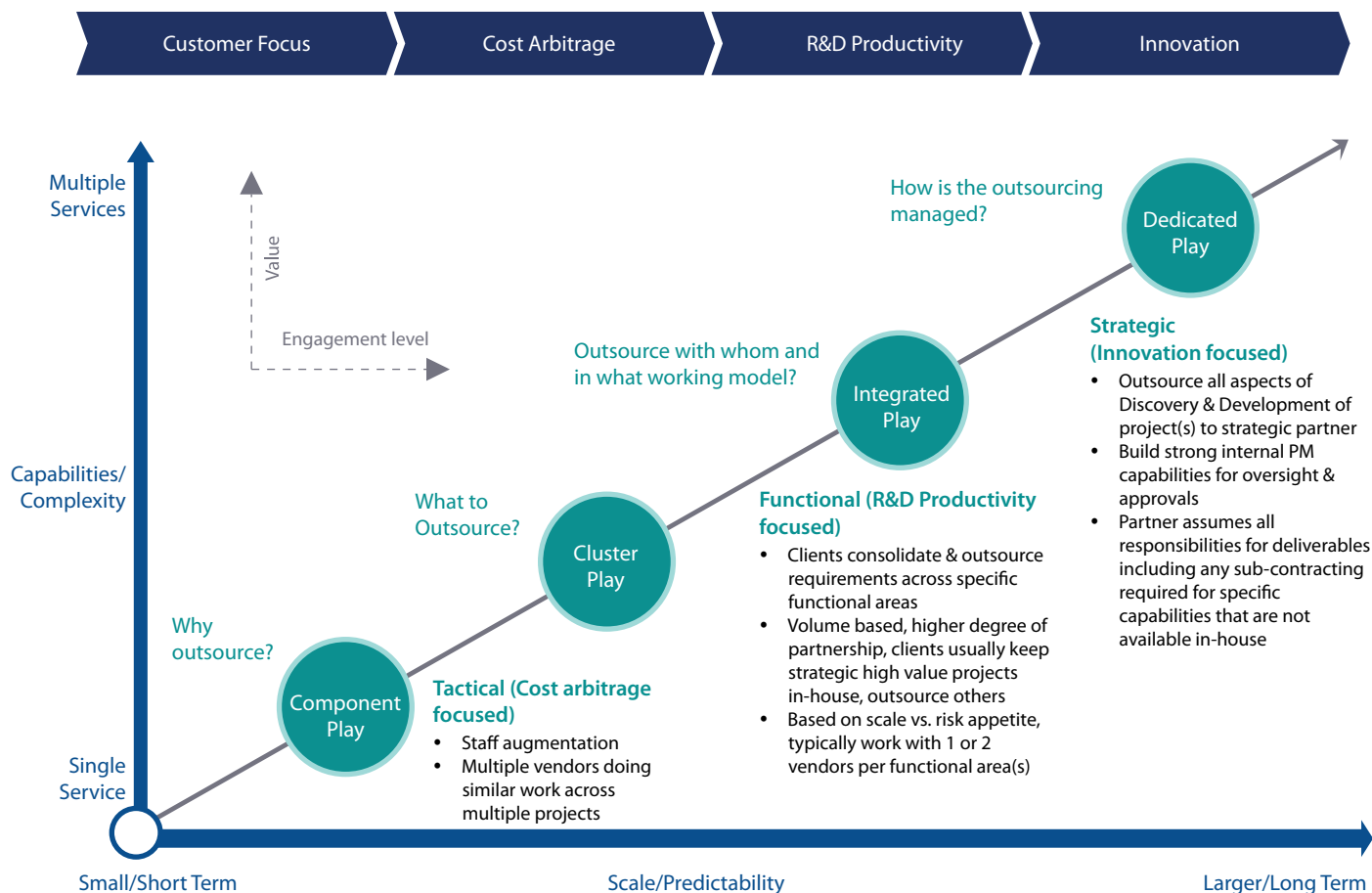


Thus, there is a pressing innovation challenge in the industry today. Organizations are seeking novel strategies to manage expenditure, reduce development timelines and increase returns. Many options have been considered in the quest to bring innovation back, such as academic collaborations, open-source ideation, and M&A. However, two strategies stand out in terms of efficacy and ease of adoption: a) Establishing external R&D partnerships and b) Virtualization and outsourcing.



How can outsourcing drive innovation?

As pharmaceutical companies seek ways to improve research ROI, outsourcing has shifted from being purely a cost arbitrage tactic to an innovation strategy. When organizations mature through the outsourcing lifecycle, the number of outsourced services and the duration of engagements increase. This is typically accompanied by evolution from component play -> cluster play -> integrated play -> dedicated play. Along with this evolution comes a shift in focus from short term gains to building a knowledge continuum with the outsourcing partner. The integrated play and dedicated play emerge as preferred partnership models when organizations start realizing innovation dividends from close integration between outsourced teams and their internal research.

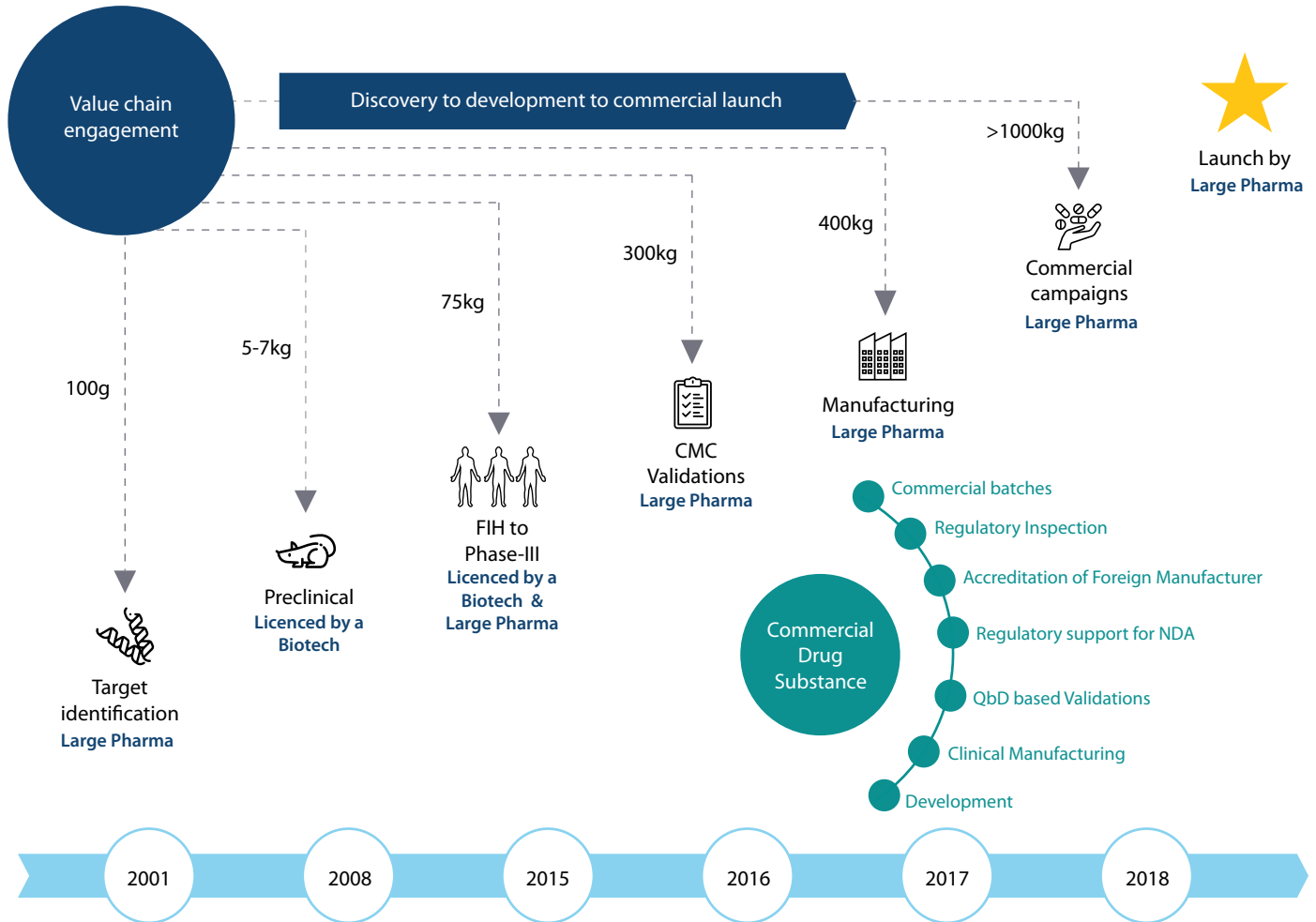


An innovation-focused integrated/dedicated play involves outsourcing all aspects of a research program to a strategic partner. The outsourcing partner assumes responsibility for all deliverables including any sub-contracting for capabilities that are unavailable in-house. A partner with end-to-end capabilities from discovery to commercial manufacturing is essential for such a model to be effective.



Full-scale knowledge integration model

Syngene has had significant success in deploying integrated and dedicated center models for its clients. One such engagement was with a Japanese client on an integrated program spanning over 17 years. This collaboration on a specific molecule began when the client approached Syngene for production at a sub 1Kg scale. Over the years, the scale of the engagement went from <1Kg to >1000Kg, as we followed the molecule through tox, FIH, phase 2, phase 3 and eventually commercial manufacturing.

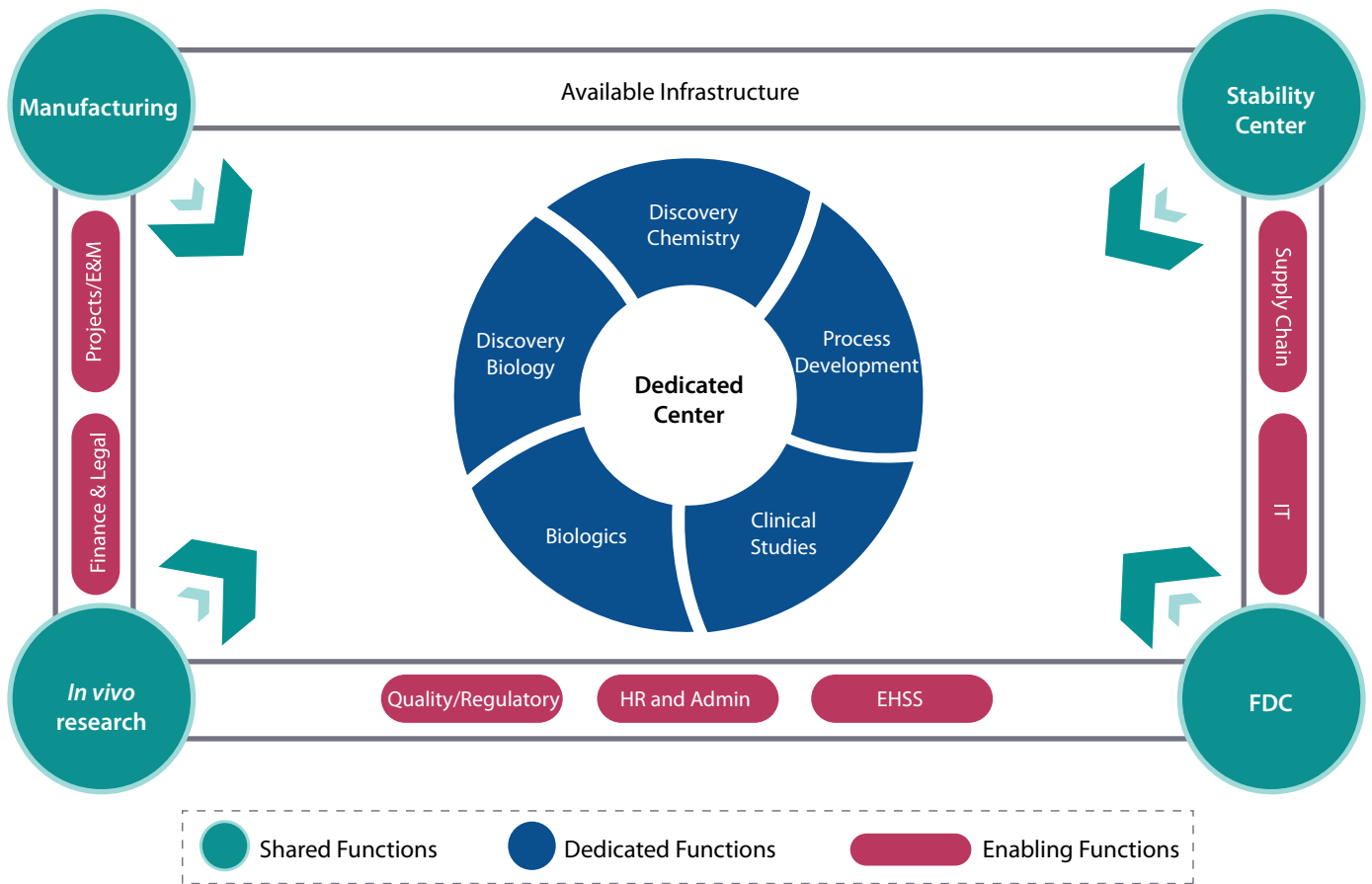


This collaboration was particularly noteworthy due to the contribution made in terms of innovation and process optimization. Even before reaching commercial production, Syngene was able to reduce the no. of steps needed for the synthesis from 17 to 12. Similarly, on one of the steps, the yield was enhanced from 5% to 23%. We were even able to build second sourcing vendors at a much earlier stage in the drug lifecycle, resulting in reduced costs and improved efficiency.



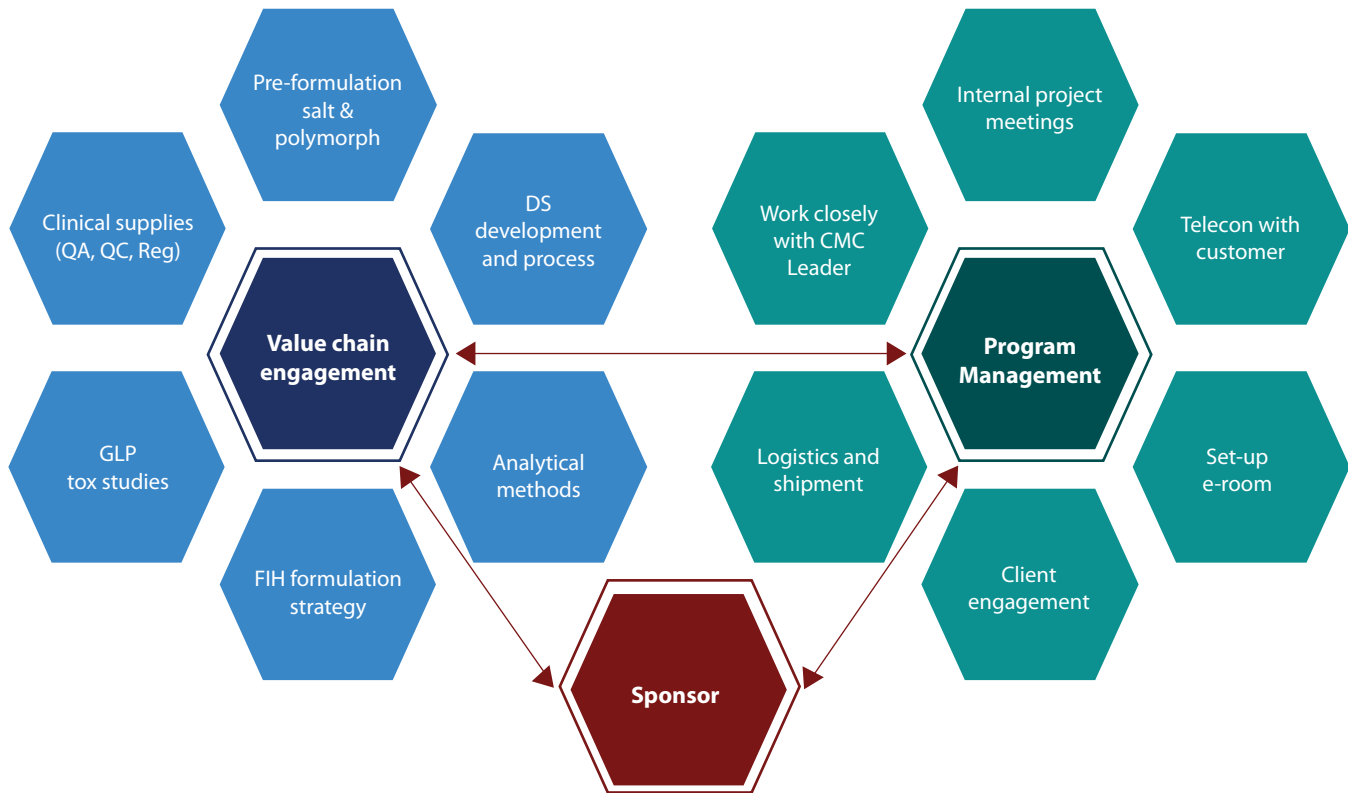


Dedicated centers at Syngene



Under the dedicated center model at Syngene, depending on the program, the sponsor organization will get a set of ring-fenced personnel dedicated to the program as well as access to enabling functions such as HR, facilities management, quality regulation, etc. The innovator company can work directly with the staff at Syngene, while also getting logistics support and audit support from the strong in-house program management team.

The dedicated model is the equivalent of having access to a full-fledged pharmaceutical company entirely housed in a single campus, with capabilities across small and large molecules. What this means is that even niche capabilities that are not part of the dedicated center setup will be available on an as-needed basis as part of Syngene's shared analytical facility.



The BMS dedicated center at Syngene

The first dedicated center at Syngene, BBRC, was established in collaboration with Bristol-Myers Squibb (BMS) in 2007. A 200,000 sq. ft research facility was erected in just 18 months, for under \$200 per sq. ft - far below the cost per sq. ft of a similar facility in the US. The facility has grown over the years into a fully integrated research center for BMS. Today, BBRC contributes significantly to BMS research on immunology in the areas of lupus, inflammatory bowel disease arthritis and endotoxemia, as well, as acting as an exclusive site working on neuropathic pain and depression models.

Three key factors have led to the success of the BMS dedicated center:

- 1. IP protection:** All IP generated is assigned to the sponsor company, thus enhancing the free flow of

information across the partnering companies.

- 2. Scalability:** The dedicated center model gave BMS the capability to expand and use shared resources of Syngene without adding additional CAPEX, converting CAPEX investments to OPEX. It also gave them the ability to maintain an alternate center to ensure a consistent pipeline (2 early nomination candidates per year) to supplement the overall BMS pipeline.
- 3. High-quality talent pool:** The combined brand power of BMS, Biocon and Syngene helped attract high-quality talent, from both within and outside India. The comprehensive training program, world-class shared amenities and well-designed employee policies

helped keep attrition levels low, in comparison to both the Indian market as well as to the rest of Syngene.

In 2009, BBRC became the largest R&D Centre in Asia for BMS. The facility has so far produced >10 drug candidates for further study and advanced new compounds for first-in-human studies, leading to extension of the contract till 2026.



What the dedicated center can deliver for you

The dedicated model delivers manifold benefits for the service seeker:

- 20-25% improvement in operational efficiency per FTE (synthesis of molecules, TAT, assays completed, etc.)
- Employees identify with values of the client organization and become part of an innovation network
- Multi-tiered governance system, direct access to scientists and a framework for leadership level decision making
- Infrastructure and facilities including data security, canteen, supplies, and wellness

Amidst challenges in terms of pipeline, ROI, and innovation, the dedicated center model of outsourcing allows pharmaceutical companies to place strategic bets to achieve long term goals of their research programs. An outsourcing partner such as Syngene, with over 25 years of expertise in advancing the innovation agendas for clients across the globe, can help achieve these goals in a time-bound and cost-effective manner.

About the author



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Chief Operating Officer

Mahesh is a biotechnology and biologics leader with over 25 years of experience and is presently the Chief Operating Officer at Syngene. He has been associated with companies such as Amgen, Sanofi, Celera Genomics, Molecular Probes and Monsanto in the past. He is a member of CII's National Committee on Biotechnology, the Expert committee at United States Pharmacopeia, and the Indian Pharmacopeial Commission. Mahesh holds a Ph.D. in Medicinal Chemistry from the University of Utah (USA) and a B. Pharm from the University of Mumbai.

About Syngene

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development, and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's 5000+ scientists offer both skills and the capacity to deliver great science, robust data security, and quality manufacturing, at speed, to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Baxter, and Bristol-Myers Squibb, as well as 2.2 million sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK, Zoetis, and Merck KGaA.

For more details, visit www.syngeneintl.com or write to us at bdc@syngeneintl.com