VIEW POINT

Transforming Supply Chain risks

into a competitive advantage in the CRO-CDMO space: The Syngene story

Syngene

Putting Science to Work

Introduction

The COVID-19 pandemic, which led to a widespread supply crunch in the life sciences industry, revealed to the world how inadequate existing supply chains are in managing unexpected disruptions of a global scale. The biopharma industry was affected due to unavailability/ shortage of raw materials arising from country-wide lockdowns, border closures, and a sudden spike in demand. This severely impacted the lead times for developing and supplying life-saving drugs to patients worldwide.

The aftermath? Supply chain operations emerging from decades of back-office obscurity to becoming the focal point of board rooms and C-suites today.

The change is visible even in selecting contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs) for outsourced services across drug discovery, development, and manufacturing. Biopharma companies are now critically evaluating their outsourcing partners on supply chain strength to ensure business continuity in the event of similar disruptions in the future.

In this point of view, we discuss the typical supply chain challenges faced by global CROs and CDMOs. You will also learn how Syngene, a leading CRO-CDMO for small and large molecules, has transformed its supply chain to mitigate these risks and turned them into a competitive advantage.

Dynamics of Syngene's supply chain

Syngene manages a complex supply chain that involves procuring materials as diverse as chemicals, animals, biological samples, consumables, infrastructure, information technology, and equipment. The procurement is from over 2000+ suppliers spread across 30+ countries, catering to both cGMP and non-GMP requirements for drug discovery, development, and manufacturing operations.

Syngene's pharmaceutical-biologics supply chain function possesses the required niche sourcing skills to manage the complexities of the supply chain with high operational excellence. Over the years, we have built expertise in sourcing and logistics services and efficiently handling regulatory clearances and hazardous goods shipments. Syngene's special economic zone (SEZ) status offers various benefits, including import and domestic procurement exemptions on duties and taxes. A dedicated customs officer operating within the SEZ (Biocon Park) at Bengaluru enables faster clearance of goods at the airport.

Since FY20, the world has witnessed several global supply chain disruptions, such as the COVID-19 pandemic, the Suez Canal fiasco, the China power crisis, and, more recently, the Russia-Ukraine war. However, Syngene's Supply Chain function managed these crises with minimum disruption to the business. Syngene's multi-geography supplier network, robust business continuity planning, and the learnings from the past three decades have been pivotal in navigating these crises successfully.

Syngene's supply chain has the flexibility to scale up in tune with growing operations and serve evolving client needs. Through digitization and automation initiatives, we have been able to increase our operational agility and efficiency. We have also been able to mitigate supply chain risks in advance by adopting data-driven decision-making. Further, the inclusion of sustainable procurement practices in Syngene's category management framework has helped us retain our focus on maintaining the right balance between cost reduction and compliance, safely and sustainably.

Key supply chain challenges for CROs-CDMOs

CROs and CDMOs face a number of challenges in supply chain management based on which phase of the drug development life cycle they are in — research, development, or manufacturing. It further varies with the nature of the drugs being developed — small molecules or biologics.

Small molecules

While the small molecule supply market is highly fragmented and spread across multiple geographies, the challenges get more diverse as you move up the development life cycle.

Small molecule research usually calls for quick delivery of non-GMP catalog chemicals, whereas development requires strong supply partners for key starting materials (KSMs). This includes the ability to deliver on niche chemistry (custom synthesized) while ensuring first-time right supplies in GMP conditions against tight timelines. Achieving cost competitiveness is yet another challenge in drug research due to the low volume and wide variety of demand for raw materials.

In manufacturing, the challenge is to achieve just-in-time delivery of raw materials at optimum costs while maintaining good manufacturing practices (GMP). Similarly, in the development stage, sourcing KSMs has its own specific set of challenges. These include:

- Limited suppliers catering to made-to-order custom synthesis
- Shortage of suppliers for commercial-scale supply of new chemical entities/novel molecules resulting in increased lead time required for sourcing
- Limited suppliers with niche chemistry experience in areas such as fluorine, highly potent active pharmaceutical ingredients (HPAPI), etc.
- High lead time for vendor qualification for GMP materials due to stringent process and documentation requirements

Biologics

In contrast to small molecules, the supply market is highly concentrated for biologics. We are in a world that is increasingly shifting its focus to biologics-focused drugs. Moreover, with the onset of COVID-19 and the increasing global demand for biologics-related raw materials, delivery lead times have also increased severalfold (up to several months). In view of the biologics industry's high demand and low supply dynamics, supply security and quality are key priorities for the supply chain function.

General challenges

In general, CRO and CDMO partners the world over face the following challenges:

- Difficulty in building strategic supplier relationships due to the nature of material required (a combination of low volume and wide variety of material requirements, which put CROs and CDMOs at a disadvantage because of low buying power)
- Difficulty in forging long-term commitments with suppliers
- Additional hurdle faced by Indian CROs-CDMOs in terms of lack of customer confidence in utilizing domestic infrastructure to support the fast turnaround of deliverables

No matter what the challenge, a client's expectation boils down to just one prerequisite from its partners. How fast can CROs-CDMOs get the required materials delivered to their scientists? Also, whether they can ensure timely delivery with the desired quality.

In order to stay competitive, partners' supply chains need to be agile to quickly cater to the demand, regardless of the business challenges posed by external disruptions.

Supply Chain myths versus facts about Indian CROs-CDMOs

#	Myths	Facts
1	Inordinate delays in customs clearance	Mature organizations like Syngene manage customs clearance of landed consignments on the same day
2	Logistics and connectivity issues with major international airports	Bengaluru is a major international courier hub for southern India, connecting shipments from around the world via global freight forwarders like DHL, FedEx, and World Courier
3	Shortage of high-quality lab chemicals and reagents	Major global suppliers have set up their shops and warehouses in India for a faster supply of input materials
4	Lack of capability among Indian suppliers to supply KSMs and handle difficult chemistry	Indian suppliers have the process expertise to handle all chemistry areas; lack of continuous demand and high capital investment requirements are the key factors that prevent the KSM supply market in India from growing

Questions CROs-CDMOs need to address to ensure a world-class supply chain

In an era of growing demand for outsourcing partners in the Life Science industry, partners need to have a robust supply chain. Only such a system can address the challenges mentioned in the previous sections. A CRO-CDMO partner with a truly world-class supply chain would answer "Yes" to the following key questions:

1. Are your internal teams, processes, policies, and systems (source-to-pay cycle) efficient enough to compete with your global peers in terms of speed and efficiency?
2. Do you have the right upstream supply ecosystem to cater to the needs of each business?
3. Can you extract maximum value from your supply partners by leveraging the relationships and channelling them down to your clients?
4. In the event of external supply risk, is your supply chain robust enough to ensure business continuity with minimum disruption?

How Syngene transformed its supply chain to make it world-class

Syngene has traditionally followed a fulfillment-focused approach to procuring raw materials for its operations which, at one point, was dominated by the small molecule research business. Over the years, when Syngene started expanding its business to cover biologics development and manufacturing, the supply chain complexity increased. This, in turn, necessitated a revised approach to ensure sustainable operations in the future.

As part of the new approach, Syngene embarked on a transformation journey of its supply chain to shift the focus from mere fulfillment to strategic sourcing of supplies. The primary objective was to strengthen the core deliverables of our supply chain and add value to the business by leveraging our relationship with suppliers. The revised procurement approach was designed around the four pillars of people, process, governance & sustainability, and supply ecosystem (Figure 1).

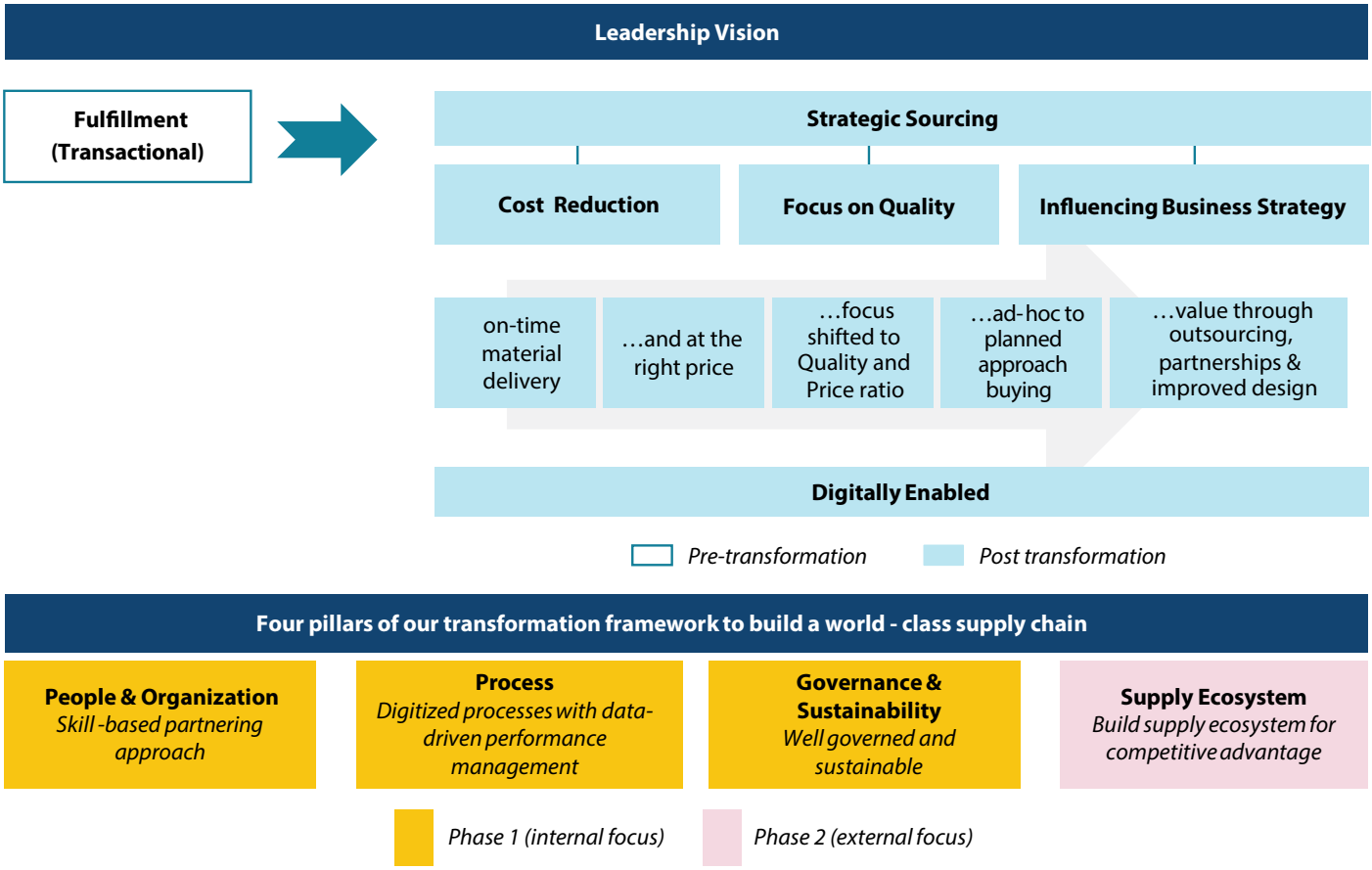

Figure 1: Syngene's multi-year, strategic sourcing transformation program

People

Syngene reorganized its procurement function by segregating its resources based on skills comprising strategic sourcing and procurement operations with an additional layer of business partnering. Strategic sourcing aims to find the right supplier at the right price, quality, and lead time by building subject matter expertise in each area through category management practices. On the other hand, procurement operations focus on increasing the procurement efficiency-to-pay process. We also introduced business partners to act as a bridge between the end users in the operating units and the procurement function for effective planning and crisis management.

Process

Syngene simplified its procurement processes by launching a series of initiatives to enable business scale-up, transparency, and accountability. We implemented automation and digitalization initiatives to manage the exponential growth in business. For instance, we developed a data-driven decision-making culture using an automated management information system (MIS). The automated system enhances supply chain performance via continuous improvement. The MIS periodically generates two types of reports: lagging and leading indicators (Figure 2).

- Lagging indicator reports provide an understanding of the historical performance of the Sourcing team and of the suppliers. The key reasons for performance gaps are identified and highlighted through root cause analysis. Based on these reports, appropriate corrective action and preventive action (CAPA) are taken to address the underlying issues.
- Leading indicator reports provide visibility into the upcoming material and service orders and the potential challenges causing delays. It enables business heads and the strategic sourcing team to take appropriate risk mitigation measures jointly.

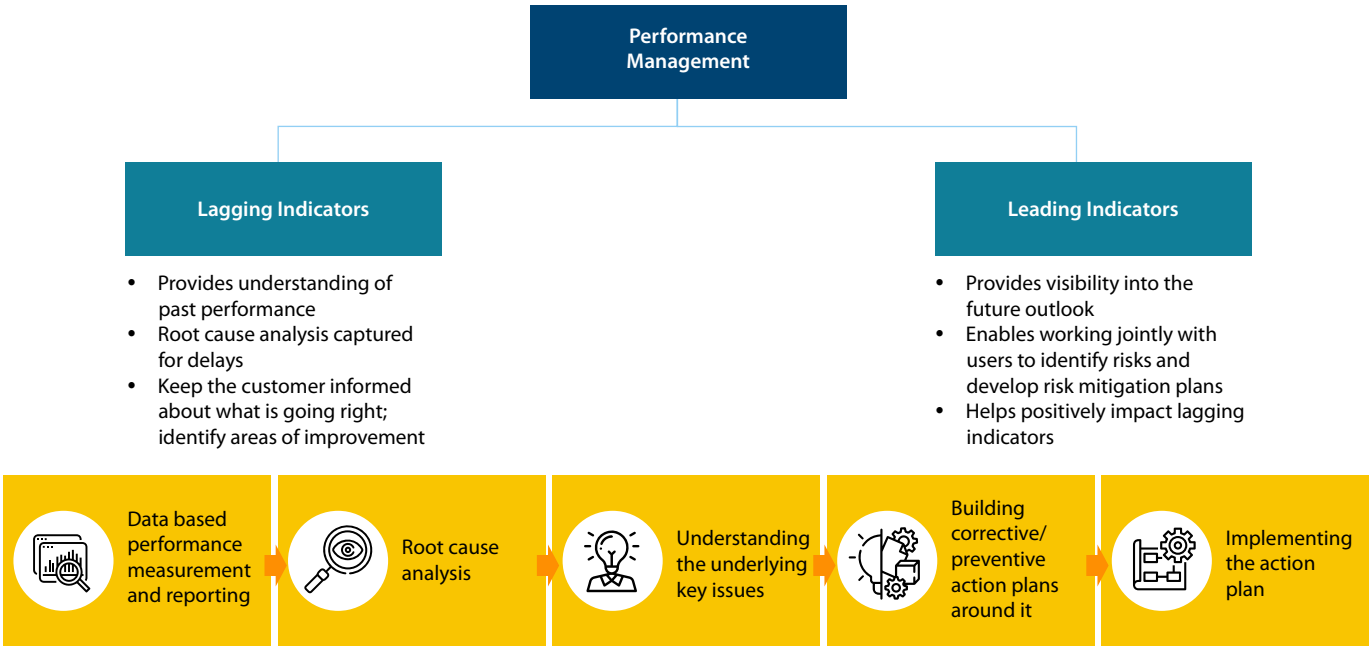

Figure 2: Syngene's Supply Chain Performance Management System

The methodology has helped us identify the gaps in our processes, including vendor selection and internal source-to-pay cycle, to improve supply lead times and formulate risk mitigation measures.

We have also partnered with key suppliers to integrate their catalogs into our SAP system. This has enabled system-to-system connectivity, making the procurement process seamless, fast, and efficient.

Governance & Sustainability

At Syngene, safety, sustainability, and compliance are at the heart of everything we do. As part of our continuous improvement journey, we fortified the governance mechanism by introducing (a) Procurement Committee and (b) Purchase manual.

The Procurement Committee comprises cross-functional representatives to ensure effective decision-making for procurement-related matters. The Purchase Manual, on the other hand, captures the standard practices required to enhance transparency and accountability in procurement.

Further, as a responsible global organization, it has always been Syngene's endeavor to build a sustainable supply chain committed to the environment, social, and governance norms. For instance, Syngene mandates all its suppliers to adhere to its Anti-Bribery Anti-Corruption policy. Close collaboration with a globally renowned organization has also been started to accelerate Syngene's journey towards a sustainable supply chain. We have also translated our vision into a policy document to guide our supply chain partners in conducting business sustainably.

Building a robust supplier ecosystem

Syngene's organizational structure comprises separate business units for drug discovery, development, and manufacturing for small molecules and biologics.

We realized the importance of aligning our sourcing strategy to address the business-specific challenges of each of these divisions separately. Further, we built a tailored supply ecosystem to cater to each business effectively, creating a competitive edge over global peers.

Small molecules

In research, outsourcing partners compete on the speed of delivery to their clients. While there is no dearth of sources to deliver the catalog chemicals (the most critical raw material for research) in a fragmented supply market spread across the globe, it is important to locate ready stock which can be procured in the shortest lead time. Syngene has successfully influenced major global suppliers to set up their warehouses in India and increased stocks of major catalog chemicals to leverage the advantage of proximity.

Further, the world has historically depended on China for the custom synthesis of KSMs required for drug development. Custom synthesis of KSMs on a pilot scale with a first-time-right approach requires expertise in handling niche chemistry. Therefore Syngene has turned its focus on building a strong network of domestic suppliers in India to handle the critical KSM supply as an alternative to China.

To ensure cGMP supply chain integrity for the manufacturing business, we have strengthened our processes and policies across the entire supplier life cycle, from supplier selection and qualification to performance management. We are also building our supply chain capabilities to manage commercial programs involving larger business volumes.

Biologics

From a procurement standpoint, the non-availability of multiple sources for critical materials and the concentration of suppliers in the US and Europe are major hurdles for CROs and CDMOs. Reducing the lead times (stretching up to several months for some materials due to a global demand triggered by COVID-19) and making materials available for operations (supply security) are the key objectives of our supply chain function.

While we have formulated our inventory strategy for long lead time materials, we have also started developing alternative sources in the domestic market/other geographies as a long-term solution. Since the supplier power is typically higher than the buyer power in the CRO-CDMO market, we have started working with other similar buyers to leverage the power of joint negotiations and procurement.

Other initiatives

Logistics Management

Syngene's logistics management framework includes adequate measures to quickly deliver inbound raw materials to its sites and outbound shipments to its customers while ensuring minimum disruption during crises. Listed below are a few highlights of our pharma logistics management framework:

- Partnership with multiple global logistics providers, customs, and freight-forwarding agencies for seamless movement of inbound and outbound shipments
- Shipments having trace and track features connected to Syngene systems, thereby providing visibility to cargo movement
- Special economic zone for faster clearance of consignments along with duty and tax benefits. Syngene is an authorized economic operator (AEO) with tier 2 status – this facilitates a green channel for customs clearance resulting in lead time reduction by one to two days for both imports and exports
- Same-day customs clearance of landed consignments with online Bill of Entry filing and clearance mechanism
- Safety measures in place, including quarantining, sanitizing, and vacuum cleaning for all incoming shipments to avoid contamination
- Booking of cargo space well in advance with major air carriers as a risk mitigation measure during crises

Risk Management

Syngene has identified four major sources of supply risks that could disrupt the on-time delivery of inbound and outbound shipments as follows: (i) environmental, (ii) economic, (iii) geo-political, and (iv) supplier-based. To counter these risks and stay ahead of the competition, Syngene has put in place a strong business continuity plan that is integral to its supply chain (Figure 3).

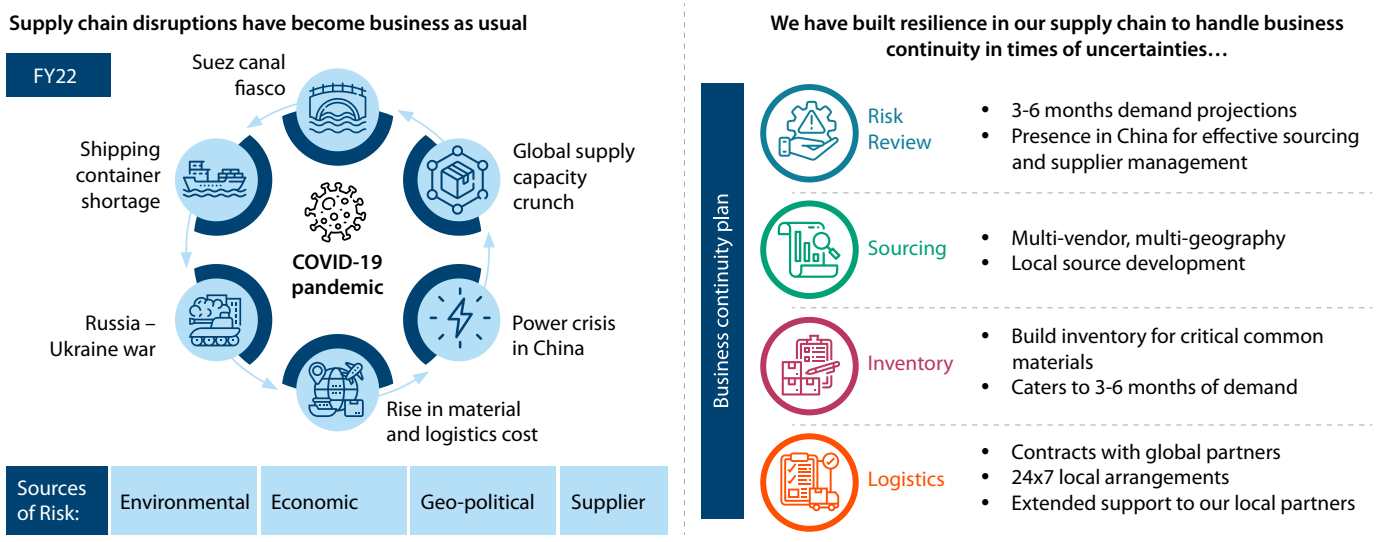

Figure 3: How Syngene demonstrated resilience in FY 22 in the face of multiple disruptions in the global supply chain

Syngene
Putting Science to Work

Key highlights of Syngene's Risk Management framework

- Risk tracker and mitigation status dashboard to quantify the existing risk periodically
- Dual/ multi-sourcing from different geographies for all materials (except sole source materials)
- Identifying and onboarding alternate supplier manufacturing sites for long lead-time materials
- Establishing alternate specifications for long lead time materials, wherever possible
- Managing supplier performance basis a risk scoring system for continuous review
- Enforcing contractual penalties for non-compliance in manufacturing services
- Supplier Quality Assurance function to conduct periodic audits and site visits for evaluation before and after qualification (especially for GMP materials)
- Qualifying and onboarding only direct manufacturers and strictly avoid re-packers/ distributors for GMP requirements
- Adherence to sustainable procurement practices and extending support to our supplier base to follow ''Syngene's policy on Environment, Social, and Governance (ESG) norms

Conclusion

The COVID-19 pandemic acted as a wake-up call for global biopharma and their outsourcing partners (CROs and CDMOs) by exposing the inherent weaknesses in existing supply chain operations. Consequently, there is an urgent need to restructure existing supply chains to become more agile and resilient in coping with uncertainties.

Syngene has built a world-class pharma-biologics supply chain that is fast, resilient, and future-proof. Our supply chain function maintains a fine balance between our investments and managing internal process efficiencies and the external supply ecosystem to enhance the value we bring to our clients. By partnering with Syngene, global biopharma companies can rest assured that their projects will be completed and delivered on time with the desired quality, regardless of external disruptions in the future.

About the authors

Veera Oruganti

Head, Strategic Sourcing – Development & Manufacturing Services, Syngene International Ltd.

Veera spearheads the Strategic Sourcing function and is responsible for building an efficient supply chain organization and supplier ecosystem that supports the aspirational growth plans of Syngene. He strives to create a competitive advantage for Syngene by leveraging supplier partnerships across the globe for both small molecules and biologics. A digital enthusiast, he also leads the Supply Chain Digital transformation at Syngene.

Nikhil Krishnan

Lead – Supply Chain Strategy, Syngene International Ltd.

Nikhil leads the Supply Chain strategy function at Syngene. He is primarily responsible for driving the transformation roadmap of Syngene's supply chain to make it truly world-class while overseeing cross-functional teams and managing timely execution. Formerly a Management Consultant, Nikhil is passionate about solving problems and building practical, sustainable, data-driven solutions.

To know more about our supply chain proficiency or contact our experts for CRO/CDMO services, please click here

Syngene

Putting Science to Work

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

Stay Connected