FROST & SULLIVAN



2022 COMPANY OFTHE YEAR



Asia-Pacific
Oligonucleotide Contract,
Development, and Manufacturing
Organization (CDMO) Industry

Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. ST Pharm excels in many of the criteria in the oligonucleotide contract, development, and manufacturing organization space.

AWARD CRITERIA	
Visionary Innovation & Performance	Customer Impact
Addressing Unmet Needs	Price/Performance Value
Visionary Scenarios Through Mega Trends	Customer Purchase Experience
Implementation of Best Practices	Customer Ownership Experience
Leadership Focus	Customer Service Experience
Financial Performance	Brand Equity

Overview: Oligonucleotide Contract, Development, and Manufacturing Organization

The pharmaceutical (pharma) industry demands constant innovation to address rising disease incidences. Synthetic-based oligonucleotide therapeutics are rapidly gaining traction. However, manufacturing oligonucleotide active pharmaceutical ingredients (APIs) is relatively new, and capacity expansion to meet the supply bottleneck poses a market challenge. Enhancing analytical methods for oligonucleotide quantification and characterization is another major issue in its synthesis. Also, commercial manufacturing is an industry obstacle as high-volume commercializing programs need to secure right-time procurement with appropriate cost of goods, quality, and compliance. Therefore, top-tier companies are setting up in-house capacity and establishing specialized manufacturing facilities.

Founded in 1983, South Korea-based ST Pharm (STP), a contract manufacturing organization (CMO) and contract, development, and manufacturing organization (CDMO), is one of the world's top three therapeutic oligonucleotide API providers ensuring quality while optimizing price.

Best-in-class Practices Provide Distinct Value

STP started producing small molecules resembling nucleotides and nucleosides as API intermediates and expanded into the small molecule API space. Gaining popularity as the world's largest Zidovudine supplier, the human immunodeficiency (HIV)/acquired immunodeficiency syndrome (AIDS) virus drug to the originator (GSK) and a major Hepatitis-C drug to the originator, the company advanced into the

oligonucleotide space. Its business scope includes messenger ribonucleic acid (mRNA) therapeutics, with active progress in capping management expense ratios and lipid nanoparticles.

STP is also involved in the synergistic set-up of the United States (US)-based biotech subsidiaries and the European Union (EU)-based contract research organizations. Another important area is new drug development, whereby the company is carrying out Phase 1 studies for oncology, HIV/AIDS, and COVID.

"The company [STP] manufactures nucleotides and nucleosides, thus linking them together to create monomers that are a starting point for oligonucleotides. Unlike competitors, its capability to produce small molecules and oligonucleotides distinguishes it in the industry."

- Ojaswi Rana, Best Practices Research Analyst While starting on a small scale, primarily university clients needing minimal scale syntheses, STP partnered with an oligonucleotide API manufacturer, expanding its capability from 100 kilograms to metric tons. International regulatory bodies, including the US Food and Drug Administration, European Directorate for the Quality of Medicines and HealthCare, the World Health Organization, Ministry of Food and Drug Safety in Korea (MFDS), Agência Nacional de Vigilância Sanitária in Brazil (ANVISA), Pharmaceuticals and Medical Devices Agency in Japan (PMDA), Therapeutic Goods Administration in Australia (TGA), and Health Products Regulatory Authority in Ireland (HPRA), have

successfully inspected its products. Prominent global clients, such as Roche, GSK, Novartis, GE Healthcare, and Bristol Myers Squibb have also successfully audited STP for environmental, health, and safety standards.

The company manufactures nucleotides and nucleosides, thus linking them together to create monomers that are a starting point for oligonucleotides. Unlike competitors, its capability to produce small molecules and oligonucleotides distinguishes it in the industry. As a result, if there is a potential raw material (nucleotides) shortage in the market, it can supply its customers without interruptions. Additionally, the company works with its sponsors to find innovative and creative ways to reuse raw materials, decrease wastage, and reduce costs while providing environmental benefits. Therefore, it positions itself distinctively in the market by ensuring greater value than what the customers pay.

Frost & Sullivan commends STP for addressing unmet market needs while implementing best-in-class practices and delivering additional value to its customers.

Customer-centric Approach Demonstrates Growth Potential

Clients laud STP for its quick response rates to inquiries and product and service delivery. The company prioritizes maintaining clear communication and transparency with customers. An example of a use case where STP exceed customer expectations is when the company delivered the blockbuster Hepatitis-C drug API six months prior to the projected timeline.

"ST Pharm has a very good reputation, and its transparency, partnership willingness, and working as a seamless team helps a lot."

-STP client

As a result, 17 of the top 20 global pharma companies work with STP. It conducts detailed annual business reviews with clients, covering all project aspects. Since most of its customers are based in the US and EU while STP's oligonucleotide API technical team is South Korea-based, experts from Korea visit clients to conduct face-to-face meetings and facilitate communication. In addition to audit-related visits, clients also visit its Korean laboratories and facilities. The company has eight operation sites, including API CMOs and CDMOs in South Korea, xRNA services in the US, and a non-clinical and animal CRO in Europe.

"Frost & Sullivan applauds STP's customer-centric approach and commitment towards optimizing the customer experience. The company demonstrates promising potential and commercialization success."

- Ojaswi Rana, Best Practices Research Analyst STP's sales continuously rise, with an approximately 30% increase from 2019 to 2020. Its plans to launch nine new drugs by 2024 will expand its revenue streams, strengthening long-term growth.¹

In December 2021, the API CDMO announced a \$126 million expansion of its oligonucleotide facility.² This second oligonucleotide plant on the Banwol campus at Ansan will house six large production lines. It will maximize efficiency by employing a parallel cross-production process

design to reduce production times. The new facility will also have a solvent recycling system for further cost reduction and an eco-friendly manufacturing process.

Frost & Sullivan applauds STP's customer-centric approach and commitment towards optimizing the customer experience. The company demonstrates promising potential and commercialization success.

Conclusion

With continuous innovations in oligonucleotide synthesis, the oligonucleotide contract, development, manufacturing organization (CDMO) space is exploding. One of the most significant challenges is providing affordable and superior quality products and services on a large scale. The lack of raw materials such as nucleotides is also a challenge in the industry. ST Pharm (STP) effectively leverages its capabilities to deliver top-notch end products and raw materials to customers at low costs. Indeed, STP has exceeded customer expectations by optimizing turnover time. With numerous certifications from regulatory bodies and clients worldwide, it distinguishes itself from market participants. Furthermore, the company prioritizes the customer experience and shows immense growth potential.

For its world-class technology, customer-oriented attitude, and unique industry expertise, ST Pharm earns Frost and Sullivan's 2022 Asia-Pacific Company of the Year Award in the oligonucleotide CDMO market.

¹ Further Expansion of Oligonucleotide Manufacture Capacity, (ST Pharm Presentation, November 2021).

² Cleanroom Technology, "St Pharm Announces \$126M Expansion of Oligonucleotide Facility," Cleanroom Technology, December 8, 2021, https://www.cleanroomtechnology.com/news/article_page/ST_Pharm_announces_126m_expansion_of_oligonucleotide_facility/181126.

What You Need to Know about the Company of the Year Recognition

Frost & Sullivan's Company of the Year Award is its top honor and recognizes the market participant that exemplifies visionary innovation, market-leading performance, and unmatched customer care.

Best Practices Award Analysis

For the Company of the Year Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Visionary Innovation & Performance

Addressing Unmet Needs: Customers' unmet or under-served needs are unearthed and addressed by a robust solution development process

Visionary Scenarios Through Mega Trends:

Long-range, macro-level scenarios are incorporated into the innovation strategy through the use of Mega Trends, thereby enabling first-to-market solutions and new growth opportunities

Leadership Focus: Company focuses on building a leadership position in core markets and on creating stiff barriers to entry for new competitors

Best Practices Implementation: Best-in-class implementation is characterized by processes, tools, or activities that generate a consistent and repeatable level of success

Financial Performance: Strong overall business performance is achieved in terms of revenue, revenue growth, operating margin, and other key financial metrics

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at http://www.frost.com.

The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator $^{\text{\tiny TM}}$.

Learn more.

Key Impacts:

- **Growth Pipeline:** Continuous Flow of Growth Opportunities
- Growth Strategies: Proven Best Practices
- Innovation Culture: Optimized Customer Experience
- ROI & Margin: Implementation Excellence
- Transformational Growth: Industry Leadership

OPPORTUNITY UNIVERSE Capture full range of growth opportunities and prioritize them based on key criteria OPPORTUNITY EVALUATION Adapt strategy to changing market dynamics and unearth new opportunities OPPORTUNITY EVALUATION Conduct deep, 360-degree analysis of prioritized opportunities ENGINETM GO-TO-MARKET STRATEGY Translate strategic alternatives into a cogent strategy

The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.

Analytical Perspectives:

- Mega Trend (MT)
- Business Model (BM)
- Technology (TE)
- Industries (IN)
- Customer (CU)
- Geographies (GE)

