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Global Biologics Contract Development and Manufacturing Organizations Growth Opportunities

Asset Co-Development with Clinical-stage Biopharmaceutical Companies and Disruptive Technologies Present Future Growth Potential

Global Transformational Health Research Team at Frost & Sullivan

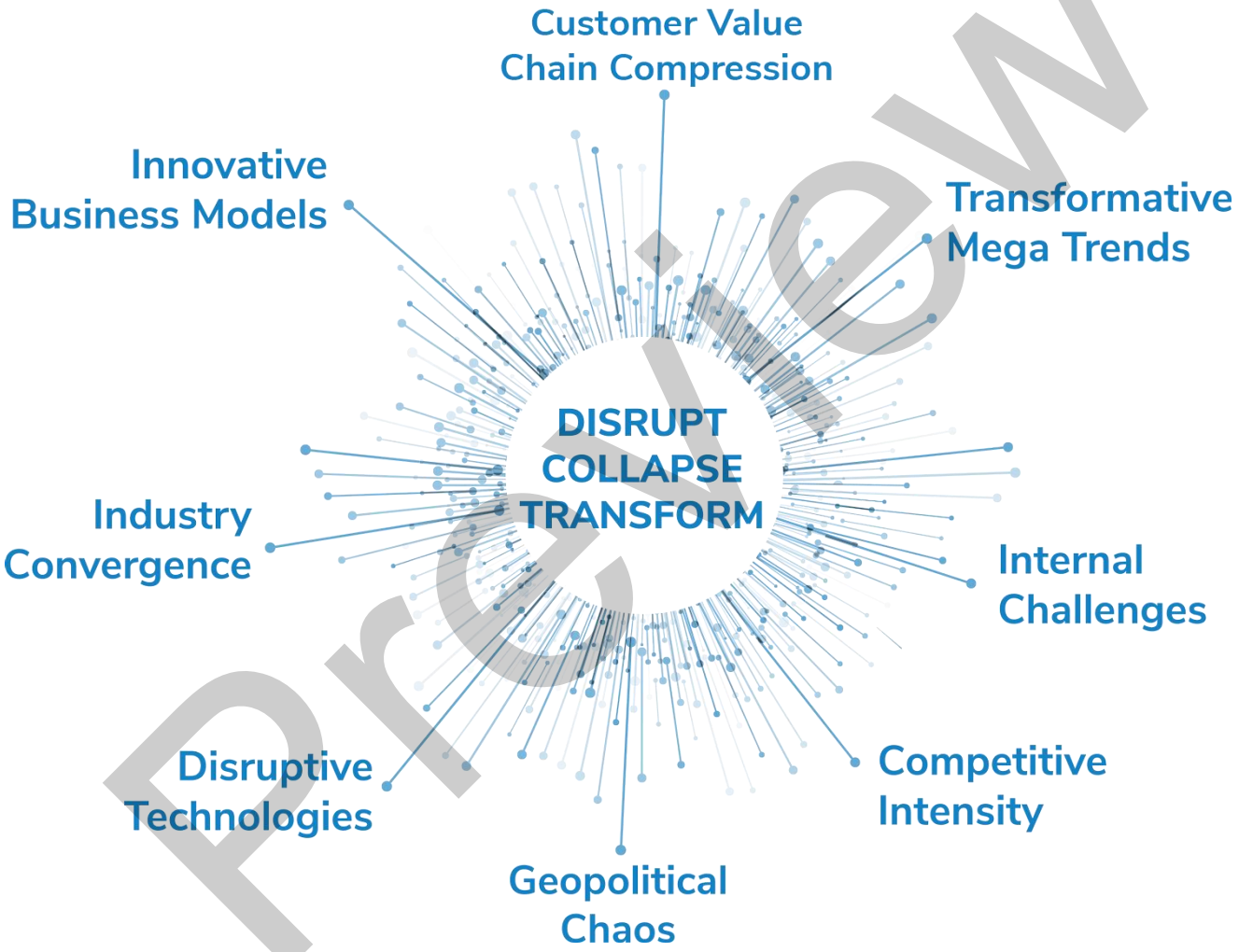
Preview

The Growth Pipeline™ Company
Powering clients towards a future shaped by growth

MG0C-52

Why is it Increasingly Difficult to Grow?

The Strategic Imperative 8™: Factors Creating Pressure on Growth



Preview

Source: Frost & Sullivan

The Strategic Imperative 8™

Innovative Business Models

A new revenue model that defines how a company creates and capitalizes economic value, typically impacting its value proposition, product offering, operational strategies, and brand positioning

Customer Value Chain Compression

Customer value chain compression as a result of advanced technologies, internet platforms, and other direct-to-consumer models that enables reduction in friction and the number of steps in customer journeys

Transformative Mega Trends

Global forces that define the future world with their far-reaching impact on business, societies, economies, cultures, and personal lives

Internal Challenges

The internal organizational behaviors that prevent a company from making required changes

Competitive Intensity

A new wave of competition from start-ups and digital business models that challenge the standing conventions of the past, compelling established industries to re-think their competitive stance

Geopolitical Chaos

Chaos and disorder arising from political discord, natural calamities, pandemics, and social unrest that impact global trade, collaboration, and business security

Disruptive Technologies

New, disruptive technologies that are displacing the old, and significantly altering the way consumers, industries, or businesses operate

Industry Convergence

Collaboration between previously disparate industries to deliver on whitespace cross-industry growth opportunities

Preview

Source: Frost & Sullivan

The Impact of the Top Three Strategic Imperatives on the Biologics Contract Development and Manufacturing Organizations Industry

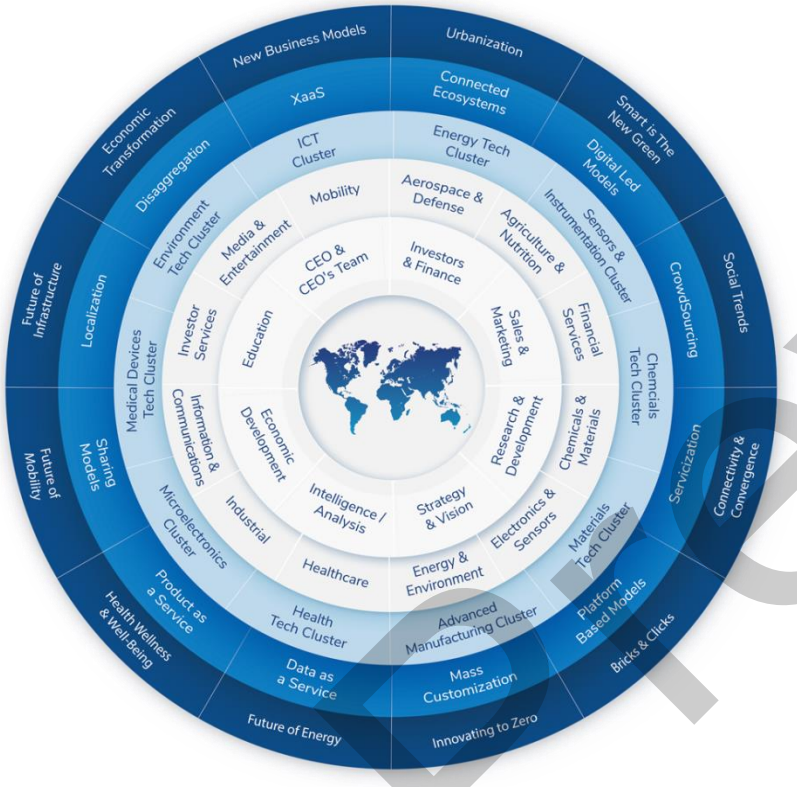
SI8	CUSTOMER VALUE CHAIN COMPRESSION	DISRUPTIVE TECHNOLOGIES	INNOVATIVE BUSINESS MODELS
Why	• Bio-CDMOs increasingly differentiate themselves from the competition by positioning themselves as one-stop shops that offer value-added services to pharmaceutical companies. Contract manufacturing organizations (CMOs) have redefined and integrated themselves as CDMOs into the pharma companies' value chain.	• Cell line development (CLD) is a critical step in drug development. However, CLD is also expensive and can be beyond the budgetary constraints of small to midsize biopharmaceutical companies. • CDMOs/CMOs that offer CLD services often work with clients from numerous domains, thus building their expertise while also investing in the development of advanced expression systems.	• The past decade witnessed CDMOs/CMOs moving from fee-for-service partnerships to more strategic ones, such as reserved capacity, joint venture, global network enterprise, and a reserved suite model. The primary aim is to build long-term yet lucrative partnerships with pharma industry participants.
Frost Perspective	• The CDMOs' one-stop shop model optimizes the pharma industry participants' supply chain, which holds significance especially in the post COVID-19 business world. • Another value proposition through this customer value compression is the lower risk associated with product development and ease of technology transfer as development and manufacturing is carried out by a single vendor.	• Some examples of CDMOs' advanced/next-generation expression systems are: ○ Apollo X, an advanced mammalian expression system introduced by Fujifilm Diosynth Biotechnologies in Jan 2019 ○ Lonza's advanced microbial expression system, XS Technologies, launched in 2017, which has increased the company's competitive edge in the industry	• Pharma industry participants are moving from reserved capacity type partnerships and engaging with CDMOs/CMOs via emerging business models for benefits like dedicated customer suites, manufacturing de-risking, and lower overall manufacturing costs.

Source: Frost & Sullivan

Preview

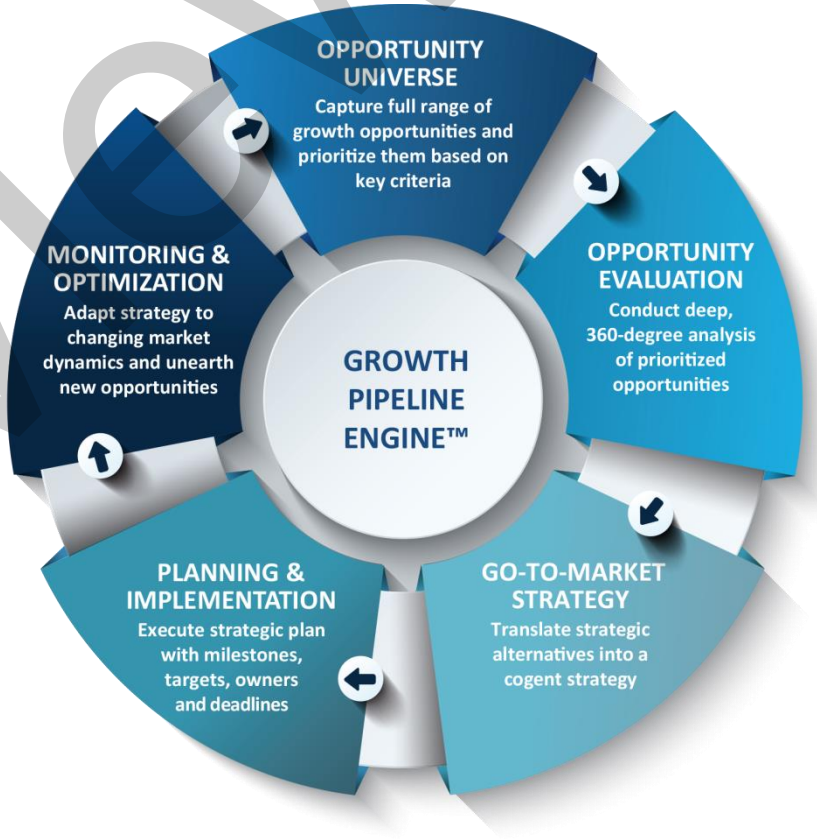
Growth Opportunities Fuel the Growth Pipeline Engine™

The Innovation Generator™



Analytical Perspectives

The Growth Pipeline Engine™



PREVIEW

Source: Frost & Sullivan

Bio-CDMO Market Scope of Analysis

- This research service provides an overview of the global biologics contract development and manufacturing organization (bio-CDMO) market and a 6-year global market revenue forecast from 2020 to 2026.
- This global study's geographical scope focuses on 3 key regions, North America (NA), Europe, and Asia-Pacific (APAC), including Japan.
- The report covers a detailed segment analysis of the bio-CDMO market, including emerging business models set to dominate the traditional fee-for-service model.

Scope	
Geographic coverage	Global
Study period	2020–2026
Base year	2020
Forecast period	2020–2026
Monetary unit	US Dollars

- Forecasts in this study are by product (drug substance vs drug products), cell culture (microbial vs mammalian vs viral vectors and other modalities), and service (commercial manufacturing vs clinical manufacturing) types.
- For this study, the bio-CDMO market includes services encompassing drug development and manufacturing processes, such as product R&D services, analytical support, and manufacturing and packaging services in one integrated process (from drug development to manufacturing).

Preview

Note: Segment-wise growth opportunity analysis is not applicable due to the nature of the bio-CDMO market.

Source: Frost & Sullivan

Key Growth Metrics for the Global Bio-CDMO Market

Bio-CDMO Market: Key Growth Metrics, Global, 2020

Life Cycle Stage	Revenue	Revenue for Last Year of Study Period	Segment with the Highest Outsourcing Penetration
Growth	$11.38 B (2020)	$20.31 B (2026)	Clinical (25% in 2020)

Compound Annual Growth Rate	Number of Competitors	Degree of Technical Change	Concentration
10.1% (2020–2026)	>100 (active competitors in 2020)	8 (scale:1 [low] to 10 [high])	~78% (Revenue share held by top 10 companies)

Preview

Note: All figures are rounded. The base year is 2020. Source: Frost & Sullivan

Growth Drivers for Bio-CDMO Market



Bio-CDMO Market: Growth Drivers, Global, 2021–2026

Driver	1–2 Years	3–4 Years	5–6 Years
Clinical-stage and virtual biopharma companies lack funding and **advanced development and manufacturing expertise**, and so need to partner with bio-CDMOs to develop and commercialize their clinical pipelines.	High	High	High
Commercial **manufacturing deficit** for small and midsize biopharma companies necessitate bio-CDMO services. For example, the cell and gene therapy segment manufacturing capacity is forecast to decrease about fivefold during the forecast period.	High	High	High
There is a need to address challenges, such as **accelerated development, speed to market, cost efficiency, manufacturing complexity, and supply chain deficits** for biopharmaceuticals.	High	High	Medium
Big pharma companies focus their **capital flow** on R&D and marketing to de-risk their supply chain over building up manufacturing capacity.	High	Medium	Medium
Top CDMOs' gradual move toward the **one-stop shop model** that offers **end-to-end services** allows biopharma companies to tackle development and manufacturing needs, from clinical studies to commercialization, and eliminate the need to work with multiple stakeholders for a single project.	High	Medium	Medium
There is a need for **dual manufacturing sourcing**. With drug supply shortages due to the COVID-19 pandemic, the pharmaceutical industry foresees expanding dual manufacturing sourcing to meet demand and prevent unexpected supply deficiencies.	High	Medium	Medium

Source: Frost & Sullivan

Preview

Growth Restraints for the Bio-CDMO Market

Bio-CDMO Market: Growth Restraints, Global, 2021–2026

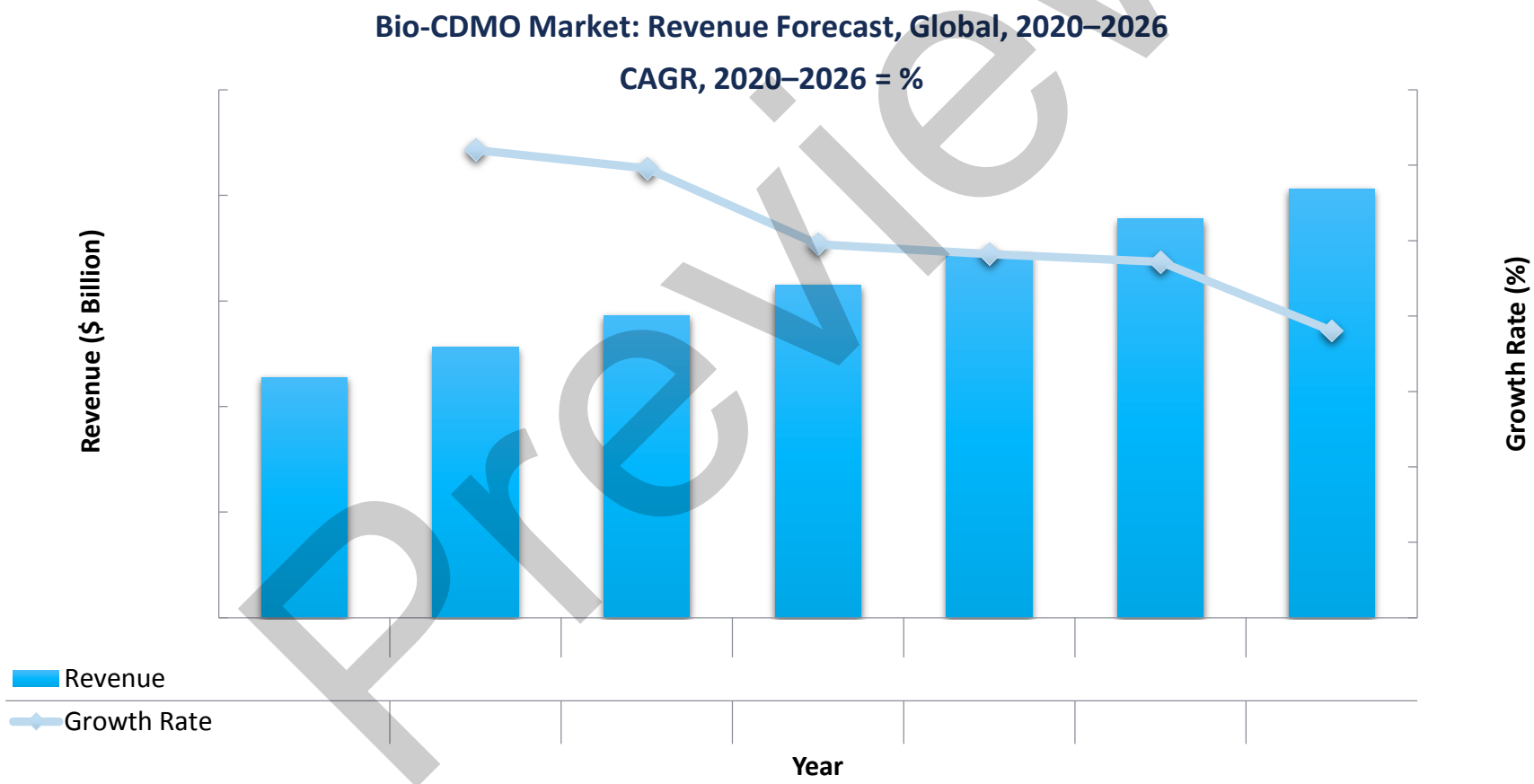


Restraint	1–2 Years	3–4 Years	5–6 Years
Biopharma manufacturing have about 3% batch failure rates. Cell and gene therapy manufacturing has especially high **batch failure rates**, at about 10%; and also records **lower titers** compared to that of mAbs and recombinant protein drugs.	**High**	**High**	**High**
Constant **equipment and process technology upgrades** to increase process output are necessary in the advent of new innovations.	**High**	**Medium**	**Medium**
Bio-CDMOs' **capacity are underutilized**. With aggressive mergers and acquisitions, bio-CDMO market participants continue to increase their manufacturing capacity in anticipation of future market trends. This often results in inadequate or improper utilization of their manufacturing capacity.	**High**	**Medium**	**Medium**
Biopharma companies still have some reservations regarding **patent and intellectual property (IP) sharing risks** with outsourcing partners.	**High**	**Low**	**Low**
In particular, small and midsize pharma companies reliant on their partners for both development and manufacturing have to relinquish manufacturing control to their CDMO partners. They risk being fitted into their CDMO manufacturers' existing process workflow.	**Medium**	**Medium**	**Medium**

Preview

Source: Frost & Sullivan

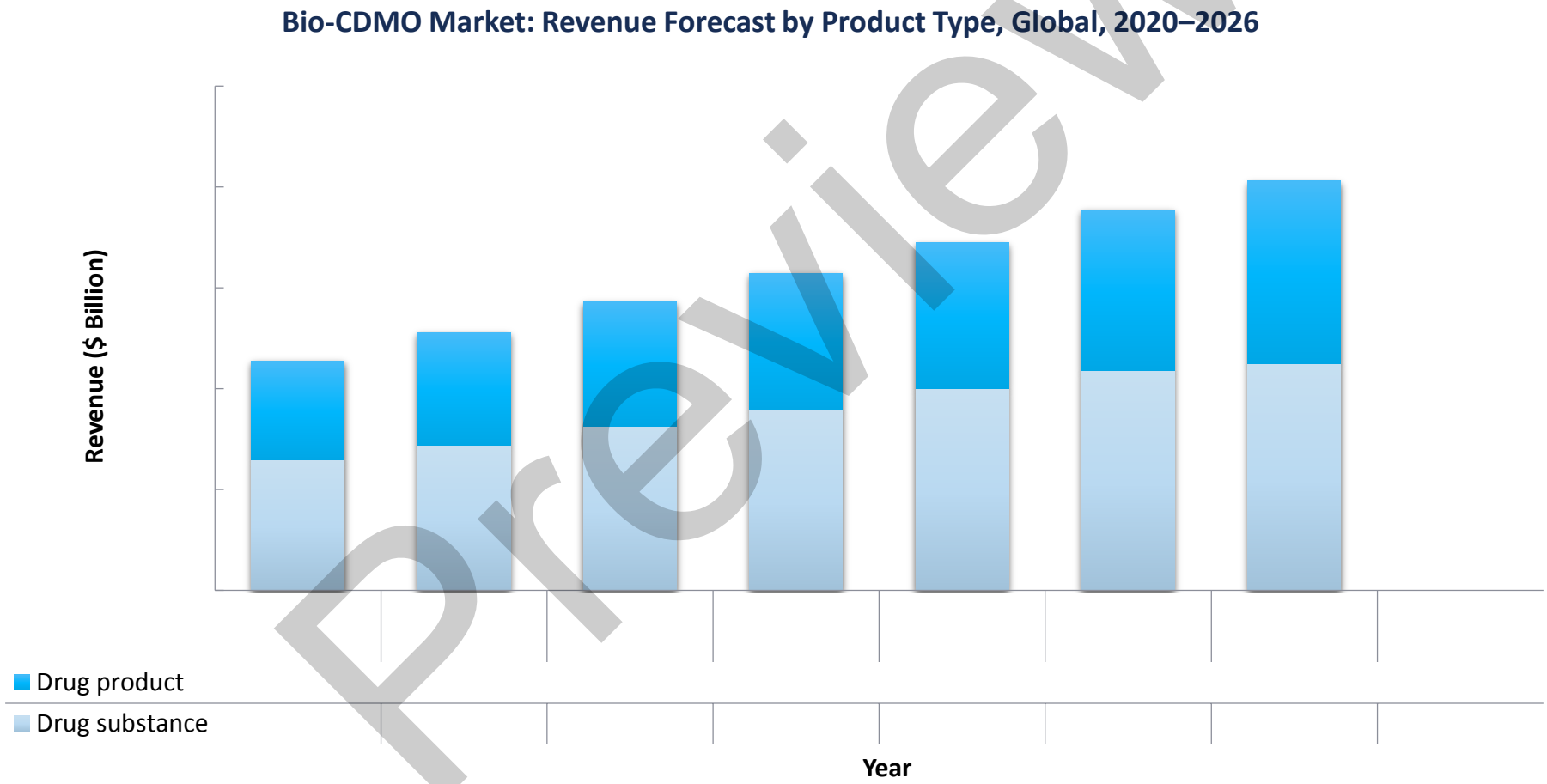
Revenue Forecast, Bio-CDMO Market



Preview

Source: Evaluate Pharma; Frost & Sullivan

Revenue Forecast by Product Type, Bio-CDMO Market

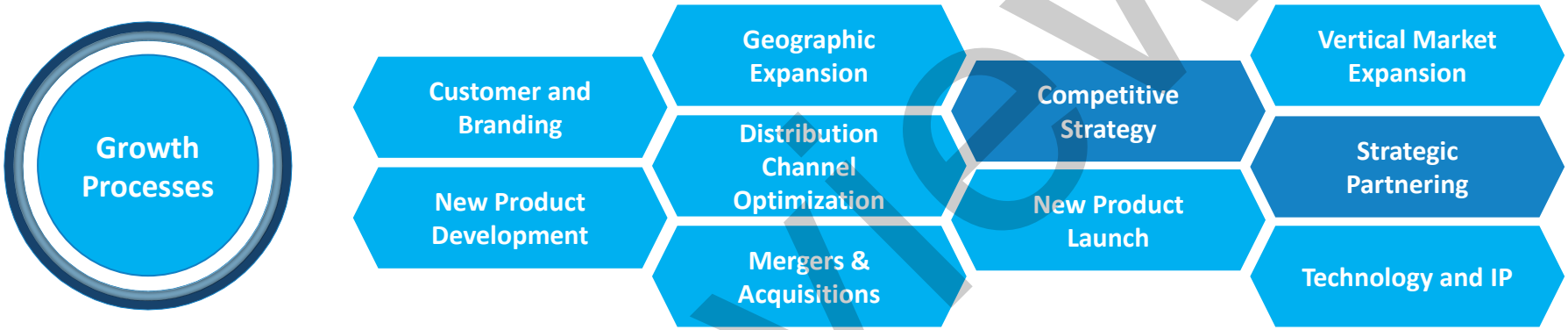


Preview

Source: Evaluate Pharma; Frost & Sullivan

Growth Opportunity 1—Adoption of Single-Use Technology for Cell and Gene Therapy Manufacturing

Frost & Sullivan has identified 10 Growth Processes that serve as levers for determining and evaluating new Growth Opportunities.



Opp. Size in 5 Years	$100 M–$500 M
Timeline for Action	1–2 Years
Base Year	2021

Relevant Industries for this Growth Opportunity

Industrial Automation	Commercial Mobility	Security
Environmental	Chemicals & Materials	Communications Tech
Oil & Gas	Agri., Food & Nutrition	Information Tech
Building Technologies	Test & Measurement	Pharma & Biotech
Consumer Electronics	Aerospace	Advanced Medtech
Consumer Mobility	Defense	Fintech

Applicable Regions

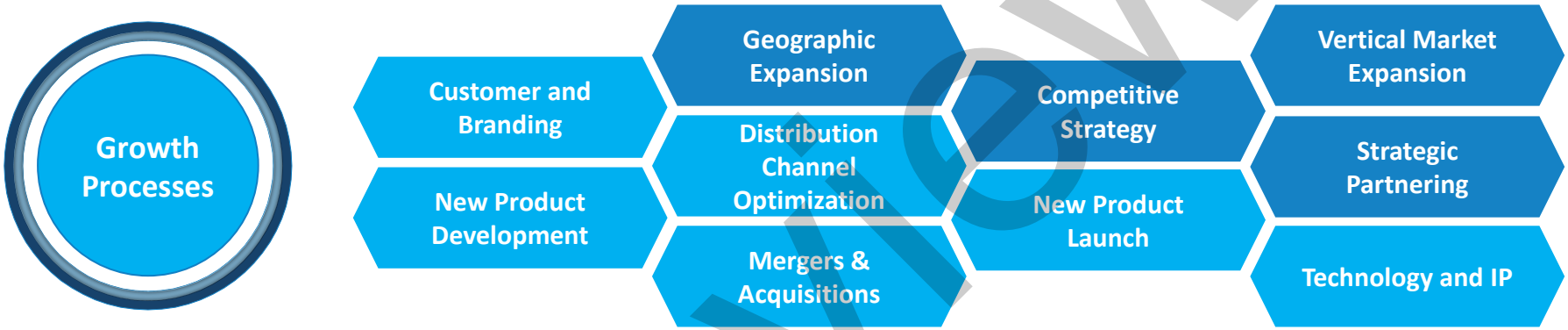
North America	South Asia
Latin America	Middle East
Cent/East Europe	European Union
Asia-Pacific	UK
Africa	Japan
China	Oceania

Source: Frost & Sullivan

Preview

Growth Opportunity 2—Capacity-Building Partnerships for COVID-19 Vaccine Manufacturing

Frost & Sullivan has identified 10 Growth Processes that serve as levers for determining and evaluating new Growth Opportunities.



Opp. Size in 5 Years	$100 M–$500 M
Timeline for Action	0–1 Year
Base Year	2021

Relevant Industries for this Growth Opportunity

Industrial Automation	Commercial Mobility	Security
Environmental	Chemicals & Materials	Communications Tech
Oil & Gas	Agri., Food & Nutrition	Information Tech
Building Technologies	Test & Measurement	Pharma & Biotech
Consumer Electronics	Aerospace	Advanced Medtech
Consumer Mobility	Defense	Fintech

Applicable Regions

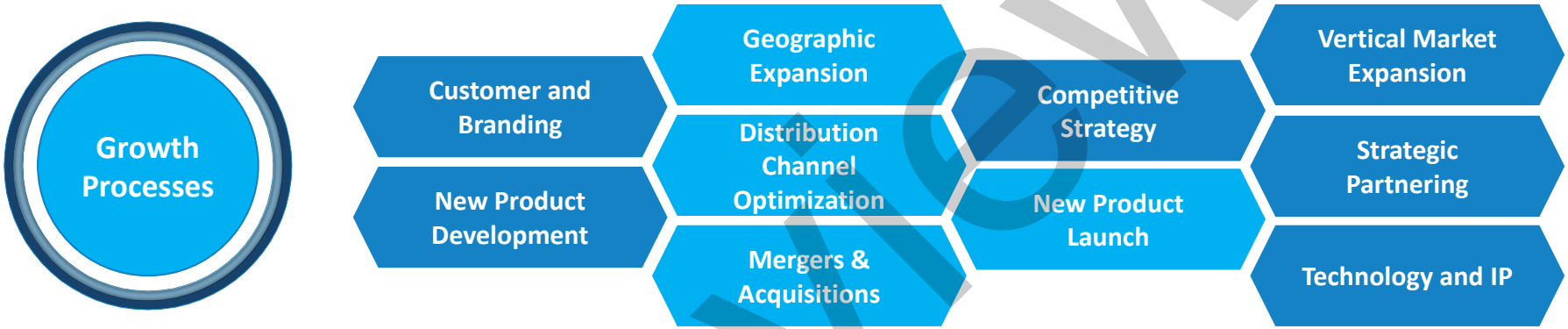
North America	South Asia
Latin America	Middle East
Cent/East Europe	European Union
Asia-Pacific	UK
Africa	Japan
China	Oceania

Source: Frost & Sullivan

Preview

Growth Opportunity 3—Co-Developing Antibody Therapies with Clinical-stage Biopharma Companies

Frost & Sullivan has identified 10 Growth Processes that serve as levers for determining and evaluating new Growth Opportunities.



Opp. Size in 5 Years	$500 M–$1 B
Timeline for Action	1–3 Years
Base Year	2021

Relevant Industries for this Growth Opportunity

Industrial Automation	Commercial Mobility	Security
Environmental	Chemicals & Materials	Communications Tech
Oil & Gas	Agri., Food & Nutrition	Information Tech
Building Technologies	Test & Measurement	Pharma & Biotech
Consumer Electronics	Aerospace	Advanced Medtech
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Applicable Regions

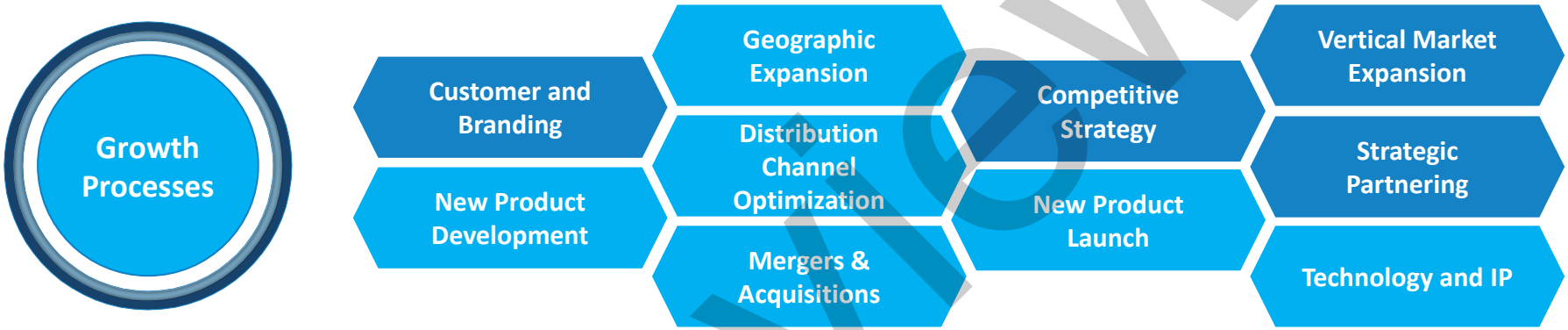
North America	South Asia
Latin America	Middle East
Cent/East Europe	European Union
Asia-Pacific	UK
Africa	Japan
China	Oceania

Source: Frost & Sullivan

Preview

Growth Opportunity 4—Addressing Capacity Scale-up Needs of China's Domestic Biopharma Market

Frost & Sullivan has identified 10 Growth Processes that serve as levers for determining and evaluating new Growth Opportunities.



Opp. Size in 5 Years	$100 M–$500 M
Timeline for Action	1–3 Years
Base Year	2021

Relevant Industries for this Growth Opportunity

Industrial Automation	Commercial Mobility	Security
Environmental	Chemicals & Materials	Communications Tech
Oil & Gas	Agri., Food & Nutrition	Information Tech
Building Technologies	Test & Measurement	Pharma & Biotech
Consumer Electronics	Aerospace	Advanced Medtech
Consumer Mobility	Defense	Fintech

Applicable Regions

North America	South Asia
Latin America	Middle East
Cent/East Europe	European Union
Asia-Pacific	UK
Africa	Japan
China	Oceania

Source: Frost & Sullivan

Preview

Why Frost, Why Now?

Our Expertise

EXPERIENCE	• 60 years of proven global experience • Trusted partner of Investors, corporates, & governments
COVERAGE	• Industry convergence through comprehensive coverage • Global footprint to match clients' needs
ANALYTICS	• Innovation Generator™ driving six analytical perspectives • Proprietary growth tools & frameworks
BEST PRACTICES	• Growth Pipeline Engine™ and Companies to Action™ • Ten Growth Processes: best practices foundation

Client Impact

- **FUTURE GROWTH POTENTIAL:** Maximized through collaboration
- **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

Preview

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