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
Why is it Increasingly Difficult to Grow?
The Strategic Imperative 8™: Factors Creating Pressure on Growth

Source: Frost & Sullivan
## The Strategic Imperative 8™

<table>
<thead>
<tr>
<th>Innovative Business Models</th>
<th>Customer Value Chain Compression</th>
<th>Transformative Mega Trends</th>
<th>Internal Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>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</td>
<td>Global forces that define the future world with their far-reaching impact on business, societies, economies, cultures, and personal lives</td>
<td>The internal organizational behaviors that prevent a company from making required changes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Competitive Intensity</th>
<th>Geopolitical Chaos</th>
<th>Disruptive Technologies</th>
<th>Industry Convergence</th>
</tr>
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<tbody>
<tr>
<td>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</td>
<td>Chaos and disorder arising from political discord, natural calamities, pandemics, and social unrest that impact global trade, collaboration, and business security</td>
<td>New, disruptive technologies that are displacing the old, and significantly altering the way consumers, industries, or businesses operate</td>
<td>Collaboration between previously disparate industries to deliver on whitespace cross-industry growth opportunities</td>
</tr>
</tbody>
</table>

Source: Frost & Sullivan
The Impact of the Top Three Strategic Imperatives on the Biologics Contract Development and Manufacturing Organizations Industry

**CUSTOMER VALUE CHAIN COMPRESSION**

- 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.

- 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.

**DISRUPTIVE TECHNOLOGIES**

- 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.

- 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

**INNOVATIVE BUSINESS MODELS**

- 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.

- 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.

Why Frost Perspective

Source: Frost & Sullivan
Growth Opportunities Fuel the Growth Pipeline Engine™

The Innovation Generator™

The Growth Pipeline Engine™

Source: Frost & Sullivan
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.

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).

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

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

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

<table>
<thead>
<tr>
<th>Driver</th>
<th>1–2 Years</th>
<th>3–4 Years</th>
<th>5–6 Years</th>
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<tr>
<td>Clinical-stage and virtual biopharma companies lack funding and <strong>advanced development and manufacturing expertise</strong>, and so need to partner with bio-CDMOs to develop and commercialize their clinical pipelines.</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Commercial <strong>manufacturing deficit</strong> 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.</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>There is a need to address challenges, such as <strong>accelerated development, speed to market, cost efficiency, manufacturing complexity, and supply chain deficits</strong> for biopharmaceuticals.</td>
<td>High</td>
<td>High</td>
<td>Medium</td>
</tr>
<tr>
<td>Big pharma companies focus their <strong>capital flow</strong> on R&amp;D and marketing to de-risk their supply chain over building up manufacturing capacity.</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Top CDMOs’ gradual move toward the <strong>one-stop shop model</strong> that offers <strong>end-to-end services</strong> 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.</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>There is a need for <strong>dual manufacturing sourcing</strong>. 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.</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
</tr>
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Source: Frost & Sullivan
### Growth Restraints for the Bio-CDMO Market

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

<table>
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<th>Restraint</th>
<th>1–2 Years</th>
<th>3–4 Years</th>
<th>5–6 Years</th>
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<td>Biopharma manufacturing have about 3% batch failure rates. Cell and gene therapy manufacturing has especially high <strong>batch failure rates</strong>, at about 10%; and also records <strong>lower titers</strong> compared to that of mAbs and recombinant protein drugs.</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Constant <strong>equipment and process technology upgrades</strong> to increase process output are necessary in the advent of new innovations.</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Bio-CDMOs’ <strong>capacity are underutilized</strong>. 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.</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Biopharma companies still have some reservations regarding <strong>patent and intellectual property (IP) sharing risks</strong> with outsourcing partners.</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>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.</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
</tr>
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Source: Frost & Sullivan
Revenue Forecast, Bio-CDMO Market

Bio-CDMO Market: Revenue Forecast, Global, 2020–2026

CAGR, 2020–2026 = %

Source: Evaluate Pharma; Frost & Sullivan
Revenue Forecast by Product Type, Bio-CDMO Market

Bio-CDMO Market: Revenue Forecast by Product Type, Global, 2020–2026

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.

**Growth Processes**

- Customer and Branding
- Distribution Channel Optimization
- Geographic Expansion
- Competitive Strategy
- New Product Development
- Vertical Market Expansion
- Strategic Partnering
- Mergers & Acquisitions
- New Product Launch
- Technology and IP

**Relevant Industries for this Growth Opportunity**

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

**Applicable Regions**

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

Source: Frost & Sullivan
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.

- Growth Processes
  - Customer and Branding
  - Distribution Channel Optimization
  - Competitive Strategy
  - New Product Launch
  - Mergers & Acquisitions
  - Vertical Market Expansion
  - Strategic Partnering
  - Technology and IP
  - Geographic Expansion
  - New Product Development

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
- Chemicals & Materials
- Agri., Food & Nutrition
- Test & Measurement
- Aerospace
- Defense
- Security
- Communications Tech
- Information Tech
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- North America
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- South Asia
- Middle East
- European Union
- Cent/East Europe
- South Asia
- UK
- Japan
- Africa
- China
- Oceania

Source: Frost & Sullivan
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.

- Customer and Branding
- Distribution Channel Optimization
- Geographic Expansion
- Competitive Strategy
- New Product Development
- New Product Launch
- Vertical Market Expansion
- Strategic Partnering
- Mergers & Acquisitions
- Technology and IP

**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
- Communications Tech
- Pharma & Biotech
- Fintech

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

Source: Frost & Sullivan
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.

- Customer and Branding
- Distribution Channel Optimization
- New Product Development
- Geographic Expansion
- Competitive Strategy
- Mergers & Acquisitions
- New Product Launch
- Vertical Market Expansion
- Strategic Partnering
- Technology and IP

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
- Communications Tech
- Pharma & Biotech
- Advanced Medtech
- Fintech

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

Source: Frost & Sullivan
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Our Expertise

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- Industry convergence through comprehensive coverage
- Global footprint to match clients’ needs

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- Proprietary growth tools & frameworks

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- Growth Pipeline Engine™ and Companies to Action™
- Ten Growth Processes: best practices foundation

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Santa Clara, CA 95054

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SILICON VALLEY
3211 Scott Blvd
Santa Clara, CA 95054
Tel 650.475.4500
Fax 650.475.1571

SAN ANTONIO
7550 West Interstate 10
Suite 400
San Antonio, TX 78229
Tel 210.348.1000
Fax 210.348.1003

LONDON
Floor 3 - Building 5,
Chiswick Business Park,
566 Chiswick High Road,
London W4 5YF
Tel +44 (0)20 8996 8500
Fax +44 (0)20 8994 1389