

Biosimilar Drug Formulations

ANMD-MRS9-085 · Advanced Therapeutics & Biomanufacturing

A Global Sustainability Due Diligence & Market Research Study

History 2020–2024 · Base Year 2025 · Forecast 2025–2032 · Outlooks 2035 / 2040 / 2050 · Currency US\$

WHY THIS REPORT

Biosimilar drug formulations are the affordability engine of the biologics market — the mAb, insulin/hormone, fusion-protein and growth-factor biosimilars that follow originator patent expiry to expand access and cut healthcare costs. This decision-grade study sizes the global market three ways — value, doses/patients treated and production volume — across biosimilar type, regulatory status and application, across seven regions and four scenarios to 2032, with outlooks to 2050.

SUSTAINABILITY & SDG IMPACT — THE ANMD LENS

Sustainability is this report's backbone, not an afterthought. Biosimilar drug formulations deliver measurable cost reduction and expanded access to biologics, while affordability and treatment-economics improvement across major diseases strengthen the health-equity story.

Mapped Sustainable Development Goals:

SDG 3 Good Health	SDG 9 Industry & Innovation	SDG 10 Reduced Inequalities	SDG 12 Responsible Consumption	SDG 17 Partnerships for Goals
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Measurable sustainability outcomes assessed:

- Expanded access and lower treatment cost
- Affordability across oncology and immunology
- Healthcare-system savings as biologics lose exclusivity
- Manufacturing energy, single-use plastics and supply-chain ESG as material risks

Framework alignment: Double materiality mapped to GRI, SASB, ISSB, TCFD, TNFD, CSRD and the EU Taxonomy, with greenwashing and SDG-washing screens applied throughout.

WHAT'S INSIDE AT A GLANCE

53 Chapters	9 Report Parts	7 Regions Covered	40+ Country Markets
2025–32 Forecast Horizon	4 Forward Scenarios	25+ Companies Profiled	5 SDGs Mapped

REPORT COVERAGE

Geographic scope: North America, Europe, Asia Pacific, Latin America, Africa, Middle East and Rest of World — with named country intelligence. North America is the value leader (United States) on pipeline depth and CDMO capacity; Europe is the technology leader (Germany, United Kingdom, Switzerland) on platforms and manufacturing; Asia Pacific is the scale engine; other regions assessed on their own merits.

MARKET OVERVIEW

From patent cliff to access engine — where biologics go biosimilar, interchangeable and lower-cost.

Biosimilars are scaling on a patent-cliff tailwind. Demand is driven by originator expiries, payer pressure for lower-cost biologics, and interchangeability pathways — with manufacturing cost and regulatory navigation central to competitiveness. The market is read three ways — value, doses/patients treated and production volume — and forecast under four scenarios, each region reported separately.

- **North America is the value leader** — United States, on patent-cliff launches and interchangeability
- **Europe is the adoption leader** — Germany, United Kingdom and Nordics, on biosimilar uptake
- **Asia Pacific is the scale engine** — South Korea, China and India, on biosimilar manufacturing
- **Cost and regulation are the differentiators** — interchangeable designations plus manufacturing-cost discipline

REGIONAL OUTLOOK

Across seven reporting regions, the report separates early commercialisation leaders from high-growth and emerging markets — each profiled in full rather than aggregated into Rest of World.

Region	Stage	Lead Markets & Drivers
North America	Value leader	United States — pipeline depth, CDMO capacity, reimbursement
Europe	Technology leader	Germany, United Kingdom, Switzerland — platforms, manufacturing
Asia Pacific	Scale engine	China, Japan, South Korea — biomanufacturing, build-out
Middle East	High-growth	Saudi Arabia, Israel, UAE — biotech investment, access
Latin America	Emerging	Brazil, Mexico — biologics access, manufacturing
Africa	Emerging	South Africa, Egypt — access, local manufacturing

KEY MARKET DRIVERS & RESTRAINTS

Drivers	Restraints
<ul style="list-style-type: none"> • Patent-cliff + payer-cost-pressure convergence • Affordability & access value • Policy support (interchangeability, biosimilar pathways) • Manufacturing-cost & commercial-reach economics • Process, formulation & analytics gains 	<ul style="list-style-type: none"> • Originator-defence & launch-sequencing pressure • Regulatory navigation & interchangeability burden • Manufacturing-cost & pricing competition • Single-use plastics & sustainability scrutiny • Uptake, substitution & reimbursement gaps

SEGMENTATION SNAPSHOT

By Biosimilar Type	mAb biosimilars · insulin & hormone · fusion-protein · filgrastim / growth-factor · interchangeable
By Regulatory Status	Approved · interchangeable · in development
By Application	Oncology · rare / genetic disease · immunology & infectious disease
By End User	Hospitals · pharma / biotech · CDMOs · academia
By Business Model	Product sales · CDMO services · licensing
By Region of Supply	Domestic · imported

TABLE OF CONTENTS — PARTS & CHAPTERS

The full report is organised into nine parts across 53 chapters, listed below. Detailed sub-headings, country tables and directories are provided in the full report.

Part I — Report Foundation, Discovery and Strategic Intelligence

- › Chapter 1. Scope, Methodology and Report Architecture
- › Chapter 2. Industry Discovery Summary — Biosimilar Drug Formulations
- › Chapter 3. Executive Intelligence and Decision Dashboard
- › Chapter 4. Strategic Findings, Materiality and Investment Verdict Preview

Part II — Market Intelligence, Sizing, Forecasting and Segmentation

- › Chapter 5. Industry Overview and Market Evolution
- › Chapter 6. Market Dynamics
- › Chapter 7. Global Market Size and Forecast, 2020–2032
- › Chapter 8. Market Segmentation Analysis
- › Chapter 9. End-User and Demand-Side Intelligence
- › Chapter 10. Pricing, Cost and Commercial Model Intelligence

Part III — Regional and Country Intelligence

- › Chapter 11. Global Regional Intelligence Framework
- › Chapter 12. North America Market Intelligence
- › Chapter 13. Europe Market Intelligence
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Part IV — Technology, Innovation and Category-Specific Intelligence

- › Chapter 19. Technology Landscape and Architecture
- › Chapter 20. Emerging and Next-Generation Technology Intelligence
- › Chapter 21. Category-Specific Intelligence Module
- › Chapter 22. Research, Innovation and Funding Landscape

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- › Chapter 25. Mergers, Acquisitions, Partnerships and Ecosystem Intelligence
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- › Chapter 40. Unit Economics, CAPEX, OPEX and Return Analysis
- › Chapter 41. Investment, Sustainable Finance and Bankability Intelligence

Part VIII — Scenario, Future Intelligence and Final Due Diligence Verdict

- › Chapter 42. Scenario Analysis and Future Intelligence
- › Chapter 43. Sustainability Due Diligence Framework and Data-Room Index
- › Chapter 44. Risk Register, RAG Rating and Anti-Greenwashing Screen
- › Chapter 45. Bottom-Line Verdict and Strategic Recommendations
- › Chapter 46. Implementation Roadmap and Stakeholder Playbooks

Part IX — Annexes, Directories and Reference Material

- › Chapter 47. Methodology Annex
- › Chapter 48. Corporate Directory and Company Intelligence Annex
- › Chapter 49. Patent Directory and Patent Intelligence Annex
- › Chapter 50. Project Intelligence Annex
- › Chapter 51. Forecast Annex
- › Chapter 52. Sustainability KPI Annex
- › Chapter 53. Reference Annexes

COMPETITIVE & INVESTMENT SNAPSHOT

The competitive field spans global biopharma majors, specialist biosimilar drug formulations makers, and emerging innovators. Deal activity — M&A, technology acquisition and platform expansion — signals a market consolidating around scalable, scaled, GMP-ready platforms.

Representative players profiled in the full report:

Sandoz Group AG · Pfizer Inc. · Amgen Inc. · Samsung Bioepis Co., Ltd. · Celltrion, Inc. · Biocon Biologics Limited · Teva Pharmaceutical Industries Ltd. · and 20+ further profiled players across specialists, CDMOs and challengers and emerging innovators.

Investment intelligence: venture, infrastructure, development, climate and blended finance, green bonds and sustainability-linked loans — culminating in a bankability assessment and a Go / No-Go / Conditional-Go investment verdict.

KEY QUESTIONS THIS REPORT ANSWERS

- ? How large is the global biosimilar drug formulations market, and how fast will it grow to 2032?
- ? Which regions, countries and segments offer the strongest risk-adjusted opportunity?
- ? How do manufacturing cost, scalability and access change value versus incumbent therapies?
- ? Who leads, and where is the competitive and patent white space?
- ? Is the investment case bankable — and under what conditions?
- ? How does the category align with the SDGs, health-equity and patient-access and disclosure regulation?

WHY ANMD — THE DIFFERENCE

Most market studies stop at units and revenue. This report is built as a sustainability due diligence instrument — fusing market sizing with ESG, SDG, climate, water and natural-capital intelligence and a decision-ready bankability verdict in a single architecture.

- **Triangulated sizing** — every market read three ways so value, volume and production-volume views reconcile rather than conflict.
- **Region-honest forecasting** — Latin America, Africa and the Middle East reported in full, never hidden inside Rest of World, every forecast resolved to the 2025 base year.
- **Integrated evidence base** — company, patent and project databases linked to the analysis, with published-filing patents and FTO treated as an indicator, not a legal conclusion.
- **No-fabrication discipline** — every estimate carries a data-confidence rating and disclosed sources; gaps are flagged for further diligence, never filled with invented numbers.
- **Anti-greenwashing rigour** — SDG-washing and greenwashing screens plus claim-substantiation checks built into the ESG and project analysis.
- **Decision-first structure** — 9 Parts and 53 Chapters culminating in stakeholder playbooks and a clear Go / No-Go / Conditional-Go investment verdict.

WHO SHOULD BUY THIS REPORT

Investors and life-sciences / PE funds, pharma and biotech companies, CDMOs and CROs, hospitals and treatment centers, tools and consumable suppliers, payers and regulators, and corporate strategy and ESG teams, plus strategic corporate planners and decision-makers.

Access the Full Report

The complete report delivers all 53 chapters in full, with every sub-heading, country table, company and patent directory, forecast model and due diligence checklist.

Purchase at www.anewmarketdynamics.com · Standard & Premium licences · Single-Site (SSL) and Global-Site (GSL) options at checkout.

Want the Complete Detailed Table of Contents?

This prospectus lists the nine parts and 53 chapters. The complete detailed table of contents — every sub-heading, country table, exhibit, company and patent directory and annex — is available on request to registered users. To receive it, register with your official company email at www.anewmarketdynamics.com. The full detailed table of contents will be sent directly to your registered company email address.