

Global Digital Biomanufacturing Market Size Study and Forecast by Offering (Software & Platforms, Hardware & Connected Equipment, Services), By Type (Manufacturing Execution & Electronic Batch Records, Automation & Process Control, Process Analytical Technology & Real-time Monitoring, Digital Twins, Others), By Application , By End User , and Regional Forecasts 2026–2036

<https://marketpublishers.com/r/GEA993A6169BEN.html>

Date: August 2026

Pages: 285

Price: US\$ 3,750.00 (Single User License)

ID: GEA993A6169BEN

Abstracts

The Global Digital Biomanufacturing Market, valued at USD 22.50 Billion in 2025, is projected to reach USD 84.58 Billion by 2036, expanding at a CAGR of 12.8% during the forecast period. The market consists of digital technologies, software platforms, automation systems, connected equipment and advanced analytics solutions to optimise the design, monitoring, control and management of biopharmaceutical manufacturing processes. The market is segmented into Software & Platforms, Hardware & Connected Equipment and Services. The report includes technologies such as Manufacturing Execution Systems (MES) & Electronic Batch Records (EBR), Automation & Process Control, Process Analytical Technology (PAT) & Real-time Monitoring, Digital Twins, Modelling & Simulation, Artificial Intelligence (AI), Machine Learning & Advanced Analytics, Bioprocess Data Management & Integration, Quality & Laboratory Informatics, Other digital solutions. These technologies support applications such as Process Development & Scale-up, Commercial GMP Manufacturing Execution, Real-time Process Monitoring & Control, Quality Management & Batch Release, Technology Transfer & Facility Digitalisation for Pharmaceutical & Biotechnology Companies, Academic & Research Institutes, CMOs & CDMOs and Other end users.

Rising production of biologics and expansion of cell and gene therapy manufacturing, increasing adoption of Industry 4.0 technologies, and growing demand for data-driven manufacturing optimization are driving high growth in the market. As AI-powered analytics, digital twins, cloud-based manufacturing execution systems, advanced process analytical technologies, and automated quality management platforms become more prevalent, biopharmaceutical manufacturers are seeking ways to boost production efficiency, maintain regulatory compliance and speed up product commercialization. Ongoing advances in industrial IoT, predictive maintenance, real-time process monitoring, laboratory digitalization and integrated bioprocess data management are enhancing manufacturing flexibility and reducing operational costs. Furthermore, rising investments in smart biomanufacturing facilities, continuous bioprocessing, cloud-native digital platforms and AI-enabled process optimization are creating huge opportunities for technology providers and biopharmaceutical manufacturers. The global digital biomanufacturing market is expected to grow at a significant rate over the forecast period due to the ongoing digital transformation initiatives and the increasing regulatory acceptance of advanced manufacturing technologies in the long run.

Global Digital Biomanufacturing Market: Key Highlights

The Global Digital Biomanufacturing Market size was valued at USD 22.50 Billion in 2025, owing to increasing production of biologics, increasing pace of Industry 4.0 adoption, increasing production of cell and gene therapy and increasing demand for digital transformation across biopharmaceutical facilities.

The market is anticipated to grow at a CAGR of 12.8% from 2026 to 2036 and reach USD 84.58 Billion by 2036. The increasing adoption of AI-powered manufacturing platforms, digital twins, process automation, cloud-based manufacturing execution systems (MES), and real-time bioprocess analytics are driving growth.

North America had the largest share of the global market, estimated at 40.3% in 2025. The region boasts a robust biopharmaceutical industry, high R&D investment, advanced manufacturing infrastructure, and broad acceptance of smart manufacturing technologies.

The Asia Pacific region is anticipated to witness the highest CAGR of 13.9% during the forecast period (2026–2036) due to the growing biologics manufacturing capacity, increasing pharmaceutical investments, rapid industrial

digitalization, and rising adoption of advanced manufacturing technologies in China, India, South Korea, Japan, and Singapore.

Offering segment dominated the software & platforms and is estimated to hold 45.7% of the market in 2025. The segment leadership is attributed to the rising deployment of manufacturing execution systems (MES), electronic batch records (EBR), cloud-based bioprocess management platforms, AI-enabled analytics, and digital quality management solutions.

The services segment is expected to register the highest CAGR of 13.5% over the forecast period, driven by the rising demand for system integration, digital transformation consulting, validation services, software implementation, cybersecurity and lifecycle support.

Automation & Process Control is projected to hold the type segment with a share of 24.9% in 2025, due to the increasing adoption of automated bioprocessing equipment, industrial IoT, robotics, and intelligent control systems to improve manufacturing efficiency and regulatory compliance.

AI, Machine Learning & Advanced Analytics is projected to witness the highest CAGR of 15.1% during 2026–2036, owing to the increasing adoption of predictive analytics, process optimization, anomaly detection, digital quality assurance, and autonomous manufacturing technologies.

Commercial GMP Manufacturing Execution is the leading application segment and is expected to account for an estimated share of 31.8% in 2025. The growth can be attributed to the rising commercialization of biologics, vaccines, biosimilars and advanced therapies, which require digitally integrated GMP manufacturing environment

Growing investments in digital twins, cloud-native manufacturing platforms, AI-driven process optimization, laboratory informatics, and connected bioprocessing infrastructure are expected to provide significant long-term opportunities for software providers, automation companies, equipment manufacturers, CDMOs, and biopharmaceutical organizations.

Research Scope & Methodology

The report provides a strategic analysis of the Global Digital Biomanufacturing Market during the forecast period of 2026 to 2036. The report covers market size, revenue projections, competitive landscape, technology trends, regulatory developments, and investment opportunities shaping the global digital biomanufacturing market. The assessment covers the full value chain, including process development, manufacturing execution, automation, quality control, laboratory informatics, process monitoring, data integration and commercial biopharmaceutical production. The market is studied based on Offering (Software & Platforms, Hardware & Connected Equipment, Services), Type (Manufacturing Execution & Electronic Batch Records, Automation & Process Control, Process Analytical Technology & Real-time Monitoring, Digital Twins, Modelling & Simulation, AI, Machine Learning & Advanced Analytics, Bioprocess Data Management & Integration, Quality & Laboratory Informatics, Others), Application (Process Development & Scale-up, Commercial GMP Manufacturing Execution, Real-time Process Monitoring & Control, Quality Management & Batch Release, Technology Transfer & Facility Digitalisation, Others), and End User (Pharmaceuticals & Biotechnology Companies, Academic & Research Institutes, CMOs & CDMOs, Others). The regional analysis includes North America, Europe, Asia Pacific and LAMEA, by assessing biopharmaceutical manufacturing capacity, digital transformation initiatives, Industry 4.0 adoption, regulatory structures, and investments in advanced manufacturing technologies impacting the development of regional biopharmaceutical manufacturing market. The report also looks at developments in AI-driven manufacturing analytics, industrial IoT, cloud-based manufacturing execution systems (MES), digital twins, process analytical technology (PAT), electronic batch records (EBR), laboratory informatics, and integrated bioprocess data platforms which continue to redefine the competitive dynamics of the digital biomanufacturing market.

The research methodology is a blend of comprehensive primary and secondary research in an effort to deliver reliable market intelligence and robust long term forecasting. Primary research included interviews with biopharmaceutical manufacturers, biotechnology companies, CMOs, CDMOs, automation providers, software vendors, regulatory experts, laboratory specialists and industry professionals from the major global markets. Secondary research involves a search of the following secondary sources: Biotech associations, regulatory authorities, pharmaceutical organizations, annual reports, investor presentations, scientific journals, digital manufacturing studies, and verified market intelligence sources. Market estimates are developed through a systematic approach, which involves triangulation of data via top-down and bottom-up methods to ensure the accuracy and consistency of data across all market segments and regional analyses. Forecast models include historical biologics production, pharmaceutical investment, digital transformation trends, automation

adoption, regulatory developments and macroeconomic indicators. Competitive benchmarking offers detailed insights into the evolving competitive landscape in the Global Digital Biomanufacturing Market based on the analysis of technology portfolios, software capabilities, automation infrastructure, cloud integration, geographical presence, investments in research and development, strategic alliances, and innovation strategies of prominent market players.

Key Market Segments

By Offering:

Software & Platforms

Hardware & Connected Equipment

Services

By Type:

Manufacturing Execution & Electronic Batch Records

Automation & Process Control

Process Analytical Technology & Real-time Monitoring

Digital Twins, Modelling & Simulation

AI, Machine Learning & Advanced Analytics

Bioprocess Data Management & Integration

Quality & Laboratory Informatics

Others

By Application:

Process Development & Scale-up

Commercial GMP Manufacturing Execution

Real-time Process Monitoring & Control

Quality Management & Batch Release

Technology Transfer & Facility Digitalisation

Others

By End User:

Pharmaceuticals & Biotechnology Companies

Academic & Research Institutes

CMOs & CDMOs

Others

Key Market Players

Siemens

Sartorius AG

Danaher Corporation (Cytiva)

Emerson Electric Co.

K?rber AG

Aspen Technology

Benchling

TetraScience, Inc.

Schneider Electric

Other Prominent Players

Industry Trends

Artificial intelligence (AI) and machine learning are revolutionizing biomanufacturing with capabilities like predictive process optimization, anomaly detection, automated quality control, predictive maintenance, and intelligent production scheduling. These technologies enhance manufacturing efficiency and lower batch failures and operational costs.

Digital twins are seeing broad acceptance as biopharmaceutical manufacturers are increasingly utilizing virtual process models, real-time simulation platforms and predictive manufacturing environments to optimize process development, speed technology transfer, reduce scale-up risks and improve commercial production performance.

Process Analytical Technology (PAT) and real-time monitoring systems are still growing in biologics manufacturing, providing real-time monitoring of critical process parameters (CPPs) and critical quality attributes (CQAs), allowing for real-time process control and supporting quality-by-design (QbD) manufacturing strategies.

Cloud-based Manufacturing Execution Systems (MES) and Electronic Batch Records (EBR) are replacing paper-based manufacturing documentation to improve regulatory compliance, data integrity, batch traceability, operational efficiency and global manufacturing standardization.

The Industrial Internet of Things (IIoT) and connected bioprocess equipment are the primary enablers of smart manufacturing facilities that provide benefits such as equipment monitoring in real time, remote diagnostics, predictive maintenance, automated data collection, and integration across manufacturing operations.

The demand for cell and gene therapy manufacturing is for flexible, digitally-enabled production environments that can support small-batch, high-value manufacturing, with advanced automation, digital quality management and integrated data analytics.

Laboratory digitalization is progressing with increased adoption of laboratory information management systems (LIMS), electronic laboratory notebooks (ELNs), scientific data management systems (SDMS) and integrated laboratory informatics platforms to optimize data management and regulatory compliance.

There's a growing traction for continuous bioprocessing as manufacturers increasingly combine advanced automation, AI-driven process control, PAT and digital manufacturing platforms to increase production efficiency, reduce manufacturing footprints and accelerate product commercialization.

Regulatory agencies are increasingly embracing digital transformation via acceptance of electronic documentation, advanced analytics, data integrity standards and digital quality systems that enhance compliance with Good Manufacturing Practices (GMP) and quality assurance requirements.

Strategic alliances between biopharmaceutical companies, automation providers, software vendors, equipment manufacturers, CMO, CDMOs and cloud technology providers continue to foster creativity across the industry. Investments in AI-driven manufacturing, digital twins, industrial IoT, cloud-native data platforms, advanced process analytics and smart biomanufacturing facilities are anticipated to drive the long-term growth of the global digital biomanufacturing market through 2036.

Market Determinants

Growing Biologics and Advanced Therapy Manufacturing: Increasing production of biologics, biosimilars, vaccines, cell therapies, and gene therapies is a major driver of the digital biomanufacturing market. These complex therapies require highly automated, data-driven manufacturing environments capable of ensuring product quality, process consistency, and regulatory compliance.

Rising Adoption of Industry 4.0 and Smart Manufacturing Technologies: Biopharmaceutical manufacturers are increasingly implementing artificial

intelligence (AI), industrial Internet of Things (IIoT), cloud computing, robotics, digital twins, and advanced analytics to improve operational efficiency, reduce manufacturing costs, and optimize production performance across the biomanufacturing lifecycle.

Advancements in Digital Process Monitoring and Manufacturing Automation: Continuous innovation in manufacturing execution systems (MES), electronic batch records (EBR), process analytical technology (PAT), real-time monitoring, and predictive analytics is improving process visibility, enabling automated decision-making, and supporting quality-by-design (QbD) manufacturing approaches.

Increasing Regulatory Focus on Data Integrity and Digital Compliance: Regulatory agencies are encouraging adoption of digital manufacturing systems that improve electronic documentation, traceability, audit readiness, data integrity, and compliance with Good Manufacturing Practices (GMP). This is accelerating investments in integrated digital quality management and laboratory informatics platforms.

High Capital Investment and Complex System Integration: Deployment of digital biomanufacturing solutions requires substantial investments in software platforms, connected equipment, automation infrastructure, cybersecurity, workforce training, and system validation. Integration with legacy manufacturing systems can further increase implementation complexity and costs.

Cybersecurity Risks and Data Management Challenges: Increasing reliance on cloud platforms, connected manufacturing equipment, and digital data ecosystems raises concerns regarding cybersecurity, data privacy, intellectual property protection, and compliance with evolving data governance regulations. These challenges may affect adoption, particularly among organizations with limited digital infrastructure.

Opportunity Mapping Based on Market Trends

Expansion of AI-Driven Smart Biomanufacturing Platforms: Increasing adoption of artificial intelligence, machine learning, and advanced analytics is creating significant opportunities for technology providers to develop intelligent manufacturing platforms capable of predictive process optimization, automated

quality control, anomaly detection, digital batch release, and autonomous manufacturing. AI-enabled decision support is expected to become a key differentiator across modern biopharmaceutical facilities.

Growing Adoption of Digital Twins and Continuous Bioprocessing: Rising implementation of digital twins, virtual process simulation, and continuous manufacturing technologies is creating substantial opportunities for software developers, automation companies, and equipment manufacturers. These technologies enable faster process development, reduced scale-up risks, improved production efficiency, and accelerated commercialization of biologics and advanced therapies.

Expansion of Cloud-Based Manufacturing and Connected Laboratory Ecosystems: Growing demand for cloud-native Manufacturing Execution Systems (MES), Electronic Batch Records (EBR), Laboratory Information Management Systems (LIMS), Electronic Laboratory Notebooks (ELNs), and integrated bioprocess data platforms is creating opportunities for digital solution providers to improve data interoperability, regulatory compliance, and enterprise-wide manufacturing visibility.

Expansion Across Emerging Biopharmaceutical Manufacturing Hubs: Increasing investments in biologics manufacturing, vaccine production, contract manufacturing, and digital infrastructure across Asia Pacific, the Middle East, and Latin America are creating substantial long-term opportunities. Companies investing in AI-powered automation, industrial IoT, digital quality management, cloud-based manufacturing platforms, and strategic partnerships with pharmaceutical manufacturers, CMOs, and CDMOs will be well positioned to capitalize on accelerating global demand for digital biomanufacturing solutions through 2036.

Value-Creating Segments and Growth Pockets

Software & Platforms Dominate the Market While Services Register the Fastest Growth

The Software & Platforms segment accounted for the largest market share of an estimated 45.7% in 2025, driven by the increasing adoption of Manufacturing Execution Systems (MES), Electronic Batch Records (EBR), cloud-based bioprocess management platforms, AI-powered analytics, digital quality management systems, and enterprise-

wide manufacturing integration solutions. Biopharmaceutical manufacturers are increasingly investing in digital platforms to improve production visibility, streamline regulatory compliance, optimize process performance, and enhance data integrity across manufacturing operations. Growing implementation of Industry 4.0 technologies, cloud computing, and connected manufacturing environments continues to strengthen the demand for integrated software platforms that support efficient and compliant biologics production.

The Services segment is projected to register the highest CAGR of 13.5% during 2026–2036, supported by increasing demand for digital transformation consulting, software implementation, validation services, cybersecurity, cloud migration, lifecycle support, and end-to-end system integration across modern biopharmaceutical manufacturing facilities.

Automation & Process Control Leads the Market While AI, Machine Learning & Advanced Analytics Witness the Fastest Expansion

The Automation & Process Control segment held the largest market share of approximately 24.9% in 2025, driven by increasing deployment of Industrial Internet of Things (IIoT), robotics, automated bioprocess equipment, intelligent control systems, and closed-loop manufacturing technologies across biologics production facilities. These solutions enable real-time process optimization, improve manufacturing consistency, reduce operational variability, and strengthen regulatory compliance. Growing investments in smart factories and automated manufacturing environments continue to reinforce the segment's leadership across the global biopharmaceutical industry.

The AI, Machine Learning & Advanced Analytics segment is projected to register the highest CAGR of 15.1% during 2026–2036, supported by increasing adoption of predictive analytics, intelligent quality assurance, anomaly detection, predictive maintenance, autonomous process optimization, and AI-powered decision support systems that improve manufacturing efficiency and product quality.

Commercial GMP Manufacturing Execution Generates the Highest Value While Technology Transfer & Facility Digitalisation Shows the Fastest Growth

The Commercial GMP Manufacturing Execution segment accounted for the largest market share in 2025, driven by the growing commercialization of biologics, biosimilars, vaccines, cell therapies, and gene therapies that require highly digitized, scalable, and

regulatory-compliant manufacturing environments. Manufacturers are increasingly implementing advanced digital manufacturing platforms to improve production efficiency, ensure batch consistency, maintain regulatory compliance, and support real-time manufacturing execution across commercial production facilities. Increasing regulatory scrutiny and growing global biologics demand continue to strengthen the segment's leadership.

The Technology Transfer & Facility Digitalisation segment is expected to register the highest CAGR of 14.3% during 2026–2036, supported by expanding investments in smart manufacturing facilities, biologics production capacity expansion, digital plant modernization, and seamless technology transfer between research, development, and commercial manufacturing sites.

Pharmaceutical & Biotechnology Companies Dominate While CMOs & CDMOs Experience the Fastest Growth

The Pharmaceutical & Biotechnology Companies segment represented the largest market share of approximately 52.6% in 2025, driven by increasing biologics manufacturing, substantial investments in digital manufacturing transformation, rising adoption of AI-enabled process optimization, and deployment of advanced Manufacturing Execution Systems (MES), automation platforms, and digital quality management solutions. Growing research and development activities, expanding biologics pipelines, and increasing regulatory compliance requirements continue to accelerate digital biomanufacturing investments among leading pharmaceutical and biotechnology companies worldwide.

The CMOs & CDMOs segment is projected to register the highest CAGR of 14.0% during 2026–2036, supported by increasing outsourcing of biologics manufacturing, growing demand for flexible production capacity, rising adoption of digital manufacturing technologies, and expanding investments in automated, connected, and data-driven bioprocessing infrastructure to support global biopharmaceutical production.

Regional Market Assessment

North America

North America is expected to dominate the global digital biomanufacturing market with an estimated share of 40.3% by 2025. A thriving biopharmaceutical industry, sizeable investments in biologics and advanced therapies, broad acceptance of Industry 4.0

technologies, and a cluster of top-tier software providers, automation companies and bioprocess equipment manufacturers are the key drivers of the region's leadership. The United States and Canada continue to be big spenders on AI-enabled manufacturing, digital twins, cloud-based manufacturing execution systems (MES) and smart bio-manufacturing plants.

Asia Pacific

Asia Pacific is expected to record the fastest CAGR of 13.9% over 2026–2036, driven by increasing biologics manufacturing capacity, rising pharmaceutical investments, rapid industrial digitalization, and rising adoption of advanced manufacturing technologies across China, India, Japan, South Korea, Singapore, and Australia. Furthermore, the growth of the regional market is being driven by government support for biotechnology innovation and expansion of contract manufacturing capabilities.

Europe

Europe is one of the major markets for digital biomanufacturing due to its advanced pharmaceutical manufacturing infrastructure, robust biotechnology research, stringent regulatory policies, and growing investments in smart manufacturing. Automation, AI integration, and laboratory digitalization initiatives continue to be used to develop digital bioprocessing capabilities in Germany, Switzerland, the United Kingdom, France and Ireland.

LAMEA

The LAMEA is anticipated to be a lucrative market due to the increase in investments in pharmaceutical manufacturing, biotechnology research, digital healthcare infrastructure, and industrial automation. There are longer-term opportunities for digital biomanufacturing technology providers in countries such as Brazil, Saudi Arabia, the United Arab Emirates, South Africa and Mexico, which are expanding biologics production capacity and upgrading manufacturing facilities.

Recent Developments

May 2025: Sartorius AG expanded its digital bioprocessing portfolio by introducing advanced AI-enabled bioprocess analytics and integrated data management solutions to optimize biologics manufacturing and improve process efficiency.

March 2025: Danaher Corporation (Cytiva) enhanced its digital manufacturing ecosystem through new automation, real-time process monitoring, and cloud-connected bioprocess solutions designed to accelerate biologics production and technology transfer.

October 2024: Siemens strengthened its pharmaceutical manufacturing portfolio by expanding digital twin, manufacturing execution system (MES), and industrial automation capabilities for smart biomanufacturing facilities.

August 2024: TetraScience, Inc. expanded its cloud-native scientific data platform with enhanced AI-driven analytics, laboratory data integration, and bioprocess intelligence capabilities to support digital transformation across biopharmaceutical manufacturing.

Critical Business Questions Addressed

How will the Global Digital Biomanufacturing Market evolve through 2036?

The report evaluates long-term market growth driven by increasing biologics production, AI-powered manufacturing, Industry 4.0 adoption, digital twins, process automation, and cloud-based manufacturing platforms.

Which offering, type, application, and end-user segments will generate the greatest commercial opportunities?

The study identifies the dominant and fastest-growing market segments, enabling software providers, automation companies, equipment manufacturers, CDMOs, pharmaceutical companies, and investors to prioritize strategic investments.

What are the primary factors driving market expansion?

The report analyzes the influence of biologics manufacturing, digital transformation, AI-powered analytics, industrial IoT, laboratory informatics, process analytical technology (PAT), and regulatory digitization on future market development.

Which regional markets present the strongest long-term investment potential?

The assessment compares biopharmaceutical manufacturing capacity, automation adoption, biotechnology investments, digital infrastructure, and regulatory environments across major regions to identify the most attractive growth opportunities.

How can digital biomanufacturing solution providers strengthen their competitive position in the evolving industry?

The report examines strategic priorities including AI-enabled manufacturing platforms, digital twins, cloud-based MES, industrial IoT integration, laboratory informatics, advanced analytics, and strategic partnerships to support long-term competitive advantage.

Beyond the Forecast

The digital biomanufacturing market will continue to evolve through advancements in artificial intelligence, digital twins, industrial IoT, cloud-native manufacturing platforms, autonomous process control, laboratory informatics, and predictive analytics, enabling more efficient, flexible, and compliant biologics manufacturing.

Rising investments in biologics, biosimilars, vaccines, cell and gene therapies, continuous bioprocessing, smart factories, and integrated digital ecosystems will continue creating substantial opportunities for software developers, automation providers, equipment manufacturers, CDMOs, biotechnology companies, and pharmaceutical organizations worldwide.

As biopharmaceutical manufacturing increasingly prioritizes operational efficiency, regulatory compliance, product quality, and data-driven decision-making, organizations investing in intelligent manufacturing platforms, AI-powered analytics, connected bioprocess infrastructure, and end-to-end digital transformation solutions will be well positioned to capitalize on long-term growth opportunities in the global digital biomanufacturing market through 2036.

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 - 11.2.5. Product/Services Port

- 11.2.6. Recent Development
- 11.2.7. Market Strategies
- 11.2.8. SWOT Analysis
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- 11.4. Danaher Corporation (Cytiva)
- 11.5. Emerson Electric Co.
- 11.6. K?rber AG.
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