aBR

Article

New Raw Material Product Launch Strategy in the Biopharmaceutical Market: A Case Study of Avantor's Successful Market Entry

WonHyun Hwang1,*

Received date: 10 January 2025
Revised date: 20 October 2025
Accepted date: 20 March 2026
Published date: 30 May 2026

1 Avantor Performance Materials; tkdh04@gmail.com
* Correspondence: tkdh04@gmail.com

Abstract: The global biopharmaceutical industry presents significant growth potential, with substantial investments and business expansions underway not only in global markets but also across Asia, where many governments have prioritized biopharmaceuticals as a key growth driver. (1) Background/Purpose: Despite growing demand for new raw materials driven by innovations in mRNA vaccines, viral vectors, antibody-drug conjugates (ADCs), and bispecific antibodies, Avantor recorded zero revenue in the biopharmaceutical raw materials market in the Asia, Middle East, and Africa (AMEA) region in 2022. This study analyzes how Avantor successfully overcame this challenge through the A3 Project, achieving revenues of $2,740,805.32 within ten months—a 680% excess over the initial $400,000 target—and derives strategic implications for new product launches in the biopharmaceutical supply industry. (2) Study Design/Methodology/Approach: This research applies the Kaizen/A3 lean methodology, incorporating process mapping (current and future state), problem definition, root cause analysis using the 5 Whys technique, and Fact/Opinion/Guess (F/O/G) analysis. Competitive analysis employs Porter's Five Forces model and SWOT analysis. Voice of Customer (VoC) interviews were conducted with AMEA pharmaceutical clients to identify unmet needs. (3) Findings: The root causes of zero revenue were identified as: insufficient product knowledge across all departments; lack of marketing and regulatory documentation; absence of internal training programs; limited sample availability with long lead times; inadequate competitive intelligence; and insufficient collaboration between global headquarters and regional offices. Process lead time was reduced from 741 days to 196 days through infrastructure optimization. Twenty action items were executed across four domains: internal infrastructure, marketing and branding, technical application support, and internal capability development. (4) Originality/Value: This study demonstrates that systematic project management (A3/Kaizen), customer-centric application service platforms, differentiated regulatory documentation support, and cross-functional collaboration between global and regional teams are essential success factors for new product launches in complex, highly regulated biopharmaceutical markets. The findings provide a replicable framework for suppliers entering emerging biopharmaceutical markets in Asia, the Middle East, and Africa.

Keywords: biopharmaceutical raw materials; new product launch strategy; Kaizen/A3 methodology; market entry; Avantor; CDMO; application service; regulatory documentation; process development; AMEA market

1. Introduction

The biopharmaceutical industry is rapidly advancing through innovative technology and research and development, with outstanding growth potential globally. In particular, since 2000, various regions including Asia have adopted biopharmaceuticals as a new growth driver, with active national investment in this field. Global pharmaceutical companies—including Pfizer, Novartis, Eli Lilly, and Roche—have invested enormous capital in biopharmaceuticals, resulting in the emergence of diverse innovative new drugs such as mRNA vaccines, viral vectors, antibody-drug conjugates (ADCs), and bispecific antibodies. These new drugs have brought major changes to the pharmaceutical industry and are transforming the competitive landscape.

Additionally, contract development and manufacturing organizations (CDMOs) such as Samsung Biologics, Thermo Fisher, WuXi, and Lonza are strengthening their process development and production platforms to

enhance competitiveness. Global manufacturing suppliers such as Merck, Avantor, and Cytiva are playing a critical role in improving biopharmaceutical processes and accelerating development speeds. These companies are introducing new raw materials and technologies to the market, contributing to the advancement of the biopharmaceutical industry.

Avantor is a global company providing innovative scientific solutions across various industrial fields, occupying an important role particularly in the life science and pharmaceutical industries. Avantor supports pharmaceutical bioresearch and production through high-purity chemical reagents, solvents, consumables, and equipment, and supplies specialty chemicals and industrial chemicals needed by the chemical industry. It also provides various process chemicals, single-use products, customized services, and technical support to improve efficiency and maintain quality in large-scale manufacturing processes, as well as raw materials and services for manufacturing processes in various industries including food, analytical, semiconductor, electronics, and aerospace. Through this, Avantor is strengthening its competitiveness in the biopharmaceutical market.

However, biopharmaceuticals require a great deal of time and complex regulatory approval during development, and many drug candidates fail to commercialize due to problems such as process complexity, marketability, side effects, and timing. To resolve these challenges and achieve successful market entry, Avantor needed to develop new products and market penetration strategies. In particular, since the Asia, Middle East, and Africa regions had generated zero revenue from new products, Avantor needed to analyze market environments in each region and prepare strategic approaches tailored to each country's characteristics.

This business plan analyzes the case in which Avantor overcame these challenges and successfully exceeded new product introduction and revenue targets through the A3 Project, thereby providing insights into strategic, operational, and market-centered approaches for sustainable growth in the biopharmaceutical industry.

1.1. Research Background and Purpose

Biopharmaceuticals refer to drugs created using living organisms or biotechnology, and the classification includes proteins, cell therapies, and gene therapies. In particular, protein-based pharmaceuticals have the largest market size and steady market growth is projected, expected to reach $566.8 billion by 2030.

Gene therapies are emerging as the next growth driver, expected to form a market of $52.4 billion by 2033. Currently, many pharmaceutical companies worldwide are forming task force teams (TFTs) for platform development. Cell therapies were developed to overcome intractable diseases and cancer treatment—in particular, immune cell therapies play direct and indirect roles in tumor control and have established themselves as one of the 'four major cancer treatment methods' alongside surgery, radiation therapy, and chemotherapy. Accordingly, many pharmaceutical companies are accelerating cell therapy development, with market size predicted to reach approximately $37.4 billion by 2033.

The manufacture and development of biopharmaceuticals includes multiple variables that can affect drug safety and efficacy due to their complexity and specificity. In general, the production process is divided into the upstream process (including cell culture) and the downstream process (including purification)—as shown in Figure 1—and the raw materials used in each process have variables that can affect drug safety and efficacy due to the complexity and specificity of biopharmaceutical manufacturing and development, hence there are chemically very diverse raw material products.

Raw materials used in upstream processes include, for example, cell culture media, inorganic chemicals, and organic chemicals. Representative raw materials used in downstream processes include chromatography resins, reagents for buffer solution preparation, and other solvents. By using these diverse raw materials, R&D researchers optimize new biological molecules with complex structures and processes to develop biopharmaceuticals. To define control strategy elements related to raw materials used in pharmaceutical manufacturing, it is essential to evaluate the manufacturing process, raw material characteristics, and the impact on raw material quality. In particular, when evaluating correlations between impurities in raw materials or intermediate products and the Critical Quality Attributes (CQAs) of drug substances, it is essential to review the ability of the manufacturing process to control raw material or process impurities to ensure the safety of final drug products.

As a result, many pharmaceutical companies are investing considerable time and capital to establish processes providing high productivity and safety in shorter timeframes. This is a major challenge for pharmaceutical companies that must comply with strict regulations and process optimization standards for pharmaceutical manufacturing and development. Many suppliers are launching numerous new raw material products to meet increasing market demand. In this context, this study introduces some newly launched products from Avantor (Table 1).

Table 1. Avantor New Product List.

Product Category	Description
Virus Inactivation Solution	Developed for high-efficiency virus inactivation in biopharmaceutical manufacturing processes; serves as a Triton X-100 replacement
Cell Lysis Solution	Developed to extract and recover viral particles from producing cell lines
Endonuclease	Developed to remove host cell DNA impurities and improve process efficiency
IPTG	Isopropyl β-D-1-thiogalactopyranoside; developed to induce recombinant protein expression during microbial culture for protein production
Polymer Chromatography Resin	Developed for high-efficiency purification of biopharmaceuticals
ProCHIVA™ Resin	Developed for high-efficiency purification of antibody drugs

However, Avantor faced the difficulty of recording $0 in revenue in the biopharmaceutical market in 2022. This suggested that existing business models and strategies had not sufficiently reflected the complexity and high regulatory requirements of this market, resulting in great difficulty in market penetration and customer acquisition. To improve this situation, Avantor focused on providing customer-tailored services, strengthening technical support, and increasing efficiency and resolving problems through continuous improvement and lean methodologies, such as the A3 Project.

This study evaluates the strategy for market entry and growth centered on the A3 Project from the situation of zero revenue in 2022. By analyzing this project—which exceeded revenue targets by 680% within one year—the aim is to illuminate the importance of customer-centric approaches, efficient infrastructure construction, and global collaboration, and to derive success factors in the biopharmaceutical raw materials industry.

1.1.1. Key Outcomes of the A3 Project

Table 2. Key Outcomes of the A3 Project.

Outcome	Description	Activity Result
Outcome 1	Customer-Centric Platform and Infrastructure Construction	Successfully built a platform enabling close communication with customers
Outcome 2	Strategic Communication and Collaboration	Real-time problem resolution and strategy coordination between global headquarters and Asian offices were achieved smoothly
Outcome 3	Technical and Regulatory Support Enhancement	Market environment understanding and responsiveness were high through clear document provision and regular education
Outcome 4	Customized Marketing Strategy	Drove revenue growth by improving brand awareness and trust through country-specific market environment strategies

1.1.2. Business Plan Structure

Table 3. Business Plan Structure.

Phase	Description	Activities
Phase 1	Industry Overview	Analyze global trends and regional opportunities
Phase 2	Case Study – A3 Project	Discuss Avantor's strategy, implementation process, and results
Phase 3	Challenges and Solutions	Highlight key obstacles and strategies to overcome them
Phase 4	Recommendations and Future Direction	Provide insights for leveraging sustainable growth and market opportunities

2. Environmental Analysis

2.1. Market Analysis

While many industries struggle to adapt to the COVID-19 pandemic, the biopharmaceutical industry has shown

overall growth. Biopharmaceutical R&D and manufacturing facilities are expanding worldwide and, considered an essential industry, were operating relatively smoothly. Remote work, social distancing, and worker group isolation became the new standard, with emphasis on maintaining supply chain robustness and securing appropriate internal inventory.

Many facilities that previously maintained only 6-12 months of inventory now maintain 12-18 months. In response to questions about the major long-term impacts on biopharmaceutical manufacturing processes, the most frequently mentioned responses among developers and supplier executives were: increased outsourcing, supply chain localization, and supply stability for currently scarce single-use products (Figure 2 reference).

According to BioPlan's Top 1,000 Global Biopharmaceuticals Facilities Index, approximately 1,625 biopharmaceutical and manufacturing facilities worldwide have a total production capacity of approximately 17.3 million liters. The majority of global bioprocessing capacity is occupied by a small number of large facilities, with the top 100 facilities accounting for approximately two-thirds of total capacity. The United States—focused on R&D, process development, and clinical manufacturing—has the most bioprocessing facilities, but Asian facilities are gradually narrowing the gap with the United States in terms of production capacity.

Table 4. Distribution of Global Biopharmaceutical Manufacturing Capacity.

Region	Share of Global Capacity (approx.)	Key Characteristics
United States	~50%	Largest number of facilities; R&D, process development, clinical manufacturing focus
Europe	~20%	High-quality GMP manufacturing; regulatory leadership
Asia-Pacific	~25%	Rapidly growing; China, Korea, India, Singapore key hubs; closing gap with US
Rest of World	~5%	Emerging; Middle East and Africa developing capacity

Source: BioPlan Associates, Top 1,000 Global Biopharmaceutical Facilities Index.

Many pharmaceutical companies and CDMOs are emphasizing the importance of continuous process technology in manufacturing processes, and demand is expected to increase significantly in the future due to improved process productivity and cost reduction. Mammalian cell culture plays an important role in biopharmaceutical development and manufacturing, with Chinese Hamster Ovary (CHO) cell lines being used as the primary production cell lines. Recently, other mammalian cell lines such as HEK293 are widely used not only for monoclonal antibody and recombinant protein production but also for manufacturing adeno-associated virus (AAV) and viral vectors for gene therapy. This suggests that demand for raw materials required for animal cell culture and purification processes is expected to increase significantly in the future (Figure 3 reference).

2.2. Voice of Customer (VoC) Analysis

Avantor conducted Voice of Customer (VoC) analysis to identify demand for new raw materials and unmet needs of biopharmaceutical and pharmaceutical companies. Interview results showed that customers centrally raised requirements including reference material and literature provision, technical support and education reinforcement, and regulatory approval support. Customers responded that they need case studies applicable to process application and research, and analytical methods required for quality control. Demand for hands-on training and application guides to understand new products was also high. This analysis became an important foundation for Avantor to build trust through customer-centric technical support and document provision and to strengthen market entry strategies.

Table 5. Voice of Customer Analysis – AMEA Client Requests.

Customer Request / Challenge	Number of Cases
Product and application reference literature	72
Hands-on product training	66
Quality analytical methods (residual analysis, reference samples, etc.)	65
Reference laboratory equipment for testing	58
Safety and regulatory documentation	45

Application protocols and case studies	35
Process development consultation	30

2.3. Market Environment Analysis

2.3.1. Porter's Five Forces Analysis

Porter's Five Forces model—a strategic analysis tool developed by Michael Porter—was applied to analyze the competitive structure in the pharmaceutical industry and the market environment for Avantor's new products. This model evaluates the competitive intensity within an industry and analyzes key factors determining corporate profitability. Avantor used this framework to evaluate the competitive environment facing its new products and strengths in the market. Industry changes due to the COVID-19 pandemic had various impacts on the market environment related to Avantor's new products.

(1) Rivalry Among Existing Competitors

Following the COVID-19 pandemic, as many therapeutic and vaccine projects slowed, pharmaceutical companies are returning to early development stages to develop new drugs. This has resulted in decreased demand for raw materials for large-scale production, while demand for small-scale laboratory supplies and specialty chemical products is increasing. This change presents a dual challenge for suppliers like Avantor. In the existing large-scale production raw materials market, competitive intensity is increasing due to decreased demand, potentially creating pressure for revenue decline.

However, in the high-value-added product market for products such as virus inactivation solutions, cell lysis solutions, and endonucleases, companies with stability and technical capability like Avantor hold strong competitive advantages. Since entry is difficult due to technical and cost barriers, competitive intensity in the existing market is relatively low. Avantor can maintain competitiveness and secure customer trust by strengthening leadership in this domain.

(2) Threat of New Entrants

In the pharmaceutical industry, new entrants play a limited role in competing with existing companies. Companies like Avantor form strong entry barriers in the market through long experience and technical capability, and a portfolio meeting regulatory requirements. In particular, high-end product lines related to virus purification and cell culture have high technical complexity and initial investment costs, so the threat of new entrants is not significant.

(3) Threat of Substitutes

The specialty chemical products and technical support services provided by Avantor are relatively less exposed to the threat of substitutes. In particular, products such as virus inactivation solutions require high quality and stability, and competing products that can substitute these are limited. However, if price competitiveness is low, alternative sources may appear attractive to customers. Avantor must minimize this risk through continuous technological innovation and cost efficiency.

(4) Bargaining Power of Buyers

Pharmaceutical companies can have high bargaining power in negotiations with suppliers, due to the scale of major buyers and high supply chain dependence. Price negotiation power is even higher in the case of bulk purchases. Avantor can mitigate buyer bargaining power by fulfilling customer requirements through customized service provision and technical support, and by emphasizing added value of products and services.

(5) Bargaining Power of Suppliers

Avantor secures raw materials and technology through global supply chains. However, the supply of some raw materials may become unstable due to external factors such as supply chain disruptions following COVID-19. Avantor must manage these risks through supply chain diversification and securing alternative raw materials, maintaining stable product supply.

2.3.2. Post-COVID Market Changes and Avantor's Response Strategies

Changes in the pharmaceutical industry following COVID-19 present both challenges and opportunities for suppliers like Avantor. Demand for large-scale production-centered raw materials is decreasing, while demand for small laboratory supplies and customized solutions needed in early development stages is increasing. Avantor captures these market changes and proposes the following strategies:

- Technology Leadership Enhancement: Expand R&D investment in advanced products such as virus inactivation solutions to strengthen technological differentiation.
- Customized Service Provision: Strengthen customized solutions and technical support meeting customer process development requirements to build long-term customer relationships.
- Supply Chain Stabilization: Maintain product supply stability by diversifying global supply chains and securing alternative raw materials.
- Price Competitiveness Securing: Improve cost efficiency to gain advantage in price competition with alternative sources.

Following the COVID-19 pandemic, the biopharmaceutical industry faced new challenges and changes. In the early pandemic period, resources and capabilities were concentrated as demand for vaccines and therapeutics surged, but subsequent decreases in vaccine projects and expansion of alternative sources emerged as major changes. These changes promoted strategies utilizing diverse suppliers to resolve supply chain problems, enabling the emergence of new suppliers and substitute products in the market. Pharmaceutical companies are returning from large-scale production models to early development stages, increasing demand for laboratory supplies and raw materials. In particular, new products such as Triton X-100 substitutes have important competitiveness in the market in response to regulatory environment changes.

2.3.3. SWOT Analysis

Avantor comprehensively analyzed its strengths, weaknesses, opportunities, and threats to establish strategic direction. SWOT analysis is a strategic tool systematically evaluating an organization's Strengths, Weaknesses, Opportunities, and Threats, helping companies understand internal and external environments and make strategic decisions.

Strengths:

Avantor operates 17 research and application technology support centers worldwide and has a history of providing free technical support services in the biopharmaceutical field. These services support customers in utilizing products more efficiently and include diverse support such as process development, product application, and training. Avantor holds over 200 references and a vast technical library, establishing firm brand recognition in the industry. Additionally, it operates an expanded global sales network through over 15,000 sales personnel. Avantor's product portfolio consists mostly of cGMP or multi-compendial grade high-purity chemical raw material products, meeting the strict quality standards of the pharmaceutical industry and securing reliability. This high-quality product portfolio provides potential to create new business opportunities, with additional growth expected particularly through linkage with recently launched new products.

Weaknesses:

Avantor's business operating model includes direct sales, distributor sales, and e-commerce models, but distributor-based sales showed low contribution to revenue. This is because the distributor sales network has not sufficiently expanded, acting as an obstacle to Avantor's global expansion strategy. Furthermore, average delivery delays of 1-3 months compared to competitors represent an important factor weakening competitiveness in the pharmaceutical industry. In particular, there have been frequent cases where marketing and promotional materials were not prepared at the time of new product launches, resulting in sales and technical support teams lacking sufficient understanding of products. This acts as a barrier to initial market entry of new products and customer persuasion, causing difficulties in expanding market share compared to competitors.

Opportunities:

Avantor recently launched new products such as JT Baker virus inactivation solutions, cell lysis solutions, endonucleases, and chromatography resins. Currently these products have relatively few competitors in the market, suggesting a large opportunity for rapid market entry. In particular, Triton X-100 is widely used in pharmaceutical production for virus inactivation, cell lysis, endotoxin control, and as a formulation additive. This substance has been designated as an endocrine disruptor in Europe, and its use in pharmaceuticals is being banned for drug safety reasons. Accordingly, pharmaceutical companies are actively seeking raw materials to replace Triton X-100. Avantor's new products are optimal substitute products capable of meeting these requirements and can contribute to reducing the time and costs pharmaceutical companies spend on change management and process development.

Threats:

Following the COVID-19 pandemic, demand for large-scale production raw materials is decreasing as many therapeutic and vaccine projects slow. This is one of the major factors adding to revenue decline pressure for

suppliers like Avantor. Additionally, competitive intensity is increasing with new suppliers and substitute products entering the market. In particular, strengthening price competitiveness of competitors in price-sensitive markets can be a threat to securing Avantor's market share. Finally, global supply chain disruptions and regulatory changes act as factors creating uncertainty in raw material procurement and product launch timing, which can affect Avantor's operational stability.

2.4. Strategy and Plan for New Product Launch

Based on SWOT analysis, Avantor's leadership team established a concrete business plan for future new product launches. First, trust is built and differentiation strengthened through customized services and regulatory document support meeting customer requirements. Second, the advantages of new products are effectively conveyed through training programs targeting distributors and internal sales teams. Third, innovative new products such as Triton X-100 substitutes are rapidly launched with active promotions. Fourth, market requirements are quickly responded to through lead time reduction and alternative source securing. Fifth, the position in major markets including Asia, Middle East, and Africa is strengthened by establishing detailed strategies reflecting regional market characteristics.

3. Case Analysis: Avantor's New Product Business Success Case

3.1. Introduction and Application of Kaizen/A3 Methodology

Kaizen is a management philosophy targeting 'continuous improvement,' originating from Toyota's lean production system. This concept encourages all members to achieve overall quality improvement and operational efficiency through small changes. Kaizen pursues sustainable change rather than one-time improvement, acting as an essential element for maintaining and strengthening competitiveness.

A3, Kaizen's practical tool, provides a systematic approach that clearly documents all stages from problem definition, data analysis, and implementation planning to standardization. A3 originated from Toyota's lean production system and focuses on improving business processes through scientific and organizational problem solving. This methodology systematically improves an organization's problem-solving capabilities and provides a foundation for flexibly responding to changes in the market environment.

Avantor utilized this methodology to secure competitiveness and promote sustainable business growth in the Asia, Middle East, and Africa (AMEA) market. In particular, the A3 Project played an important role in designing and implementing strategic responses reflecting the market characteristics of each region.

3.2. Problem Definition

In 2022, Avantor planned large-scale new product launches targeting revenue growth and business expansion in the biopharmaceutical raw materials market. However, contrary to expectations, initial global revenue from new products faced zero. This presented a critical challenge to the company's growth strategy, and the A3 Project was introduced to resolve it.

For analysis of new product launch process and identification of improvement directions, the current process related to product launch was analyzed in depth and improvement measures were proposed to systematize approaches for maximizing efficiency and increasing revenue generation potential in the future. Analysis was divided into current process maps and future process maps, with problems occurring at each stage defined and root causes identified to derive improvement directions.

Table 6. Current Problems and Impact Level on New Product Revenue.

Problem Category	Affected Departments	Key Issue
Lack of product knowledge and information	All departments	Teams operated sales activities without product understanding; other departments lacked infrastructure to support new product sales
Insufficient marketing materials	Marketing	Difficulty creating marketing materials due to absence of product data and information
Missing price information	Sales, Strategy	Pricing and cost information not shared at launch timing, hindering business planning and customer response
Inadequate internal training	All departments	Product and application training insufficient at

		launch; unable to properly respond to customer inquiries
Lack of competitor product information	Sales, Marketing, Strategy, Application	Difficulties in business planning and promotion strategy development; sales teams did not even know competitor product names
Insufficient reference/regulatory documents	R&D, Application, Quality, Tech Support, Sales	Many pharmaceutical companies hesitant due to regulatory, process suitability, and product stability challenges; regulatory support documents needed
Standardized samples and lead times	Sales, Logistics, Application	Sample shortages in AMEA; inventory not tracked in system; samples not delivered at appropriate timing when requested
New product market data sharing	Strategy	AMEA requires Go-to-Market strategies tailored to each country's culture and environment; pre-launch market, process, and competitor data needed
Brand awareness	Marketing	Budget insufficient for seminars, conferences, and digital marketing in AMEA
Packaging container quality	R&D, Application	Packaging cap durability weak; easily damaged upon opening; urgent change management required
Bundled product lines	Sales, Application	Bundled product offerings would promote sales and provide customers with more choices
Regular project meetings	Sales	AMEA teams receive insufficient information compared to US and European teams; regular meetings with headquarters needed
Customer networks	Sales	New products target cell and gene therapy segment; acquiring new customers in this field is critical

3.3. Process Mapping

3.3.1. Current Process Map

The current process map is divided into two main areas: business infrastructure construction and sales activities for new products, with lead times and key activities at each stage analyzed in detail. Key tasks in the initial stage for new product introduction and marketing included application guides, regulatory documents, and standard pricing information. Subsequently, the marketing and e-commerce teams collaborated on website registration and digital marketing material development, with internal training and direction-setting work also proceeding in parallel. The total lead time required for business infrastructure construction was 545 days, with a cycle time of 23.7 hours.

In the second stage of sales activities, all processes from customer meetings and seminars through application team technical support and product testing, customer feedback, and purchase order processes were mapped, with time spent by Avantor and customers separately analyzed. Avantor's total process lead time was 123 days, and customer lead time was 73 days. According to the current process map from new product business preparation to purchase order, Avantor requires a total of 668 days and customers require 73 days of lead time. The total process lead time combining both lead times is 741 days, with a cycle time of 1.7 days. This explains why products launched last year failed to generate revenue within one year.

3.3.2. Future Process Map

The future process map focuses on the completion of infrastructure for all new product businesses and optimization of processes. Avantor's total process lead time was expected to be 123 days total, including customer meetings through product testing and purchase order processes. Customer process lead time and cycle time were expected to require a total of 73 days of lead time from feedback to order process based on existing references. That is, combining Avantor's and the customer's process lead times yields 196 days, suggesting the possibility that new products can generate revenue within one year.

3.4. Root Cause Analysis

3.4.1. Fact/Opinion/Guess (F/O/G) Analysis

In the A3 Project, F (Fact), O (Opinion), G (Guess) analysis is used to accurately diagnose situations in problem resolution processes and clearly distinguish the basis for each problem to make strategic decisions. All teams classified the top 10 items by impact on revenue through team brainstorming based on content discussed in the problem definition stage.

Table 7. Fact (F), Opinion (O), Guess (G) Analysis Results.

Issue	F/O/G	Global Can Control?	AMEA Can Control?	Cannot Control?
Customer hesitation to change products	F	0%	70%	30%
Delivery delay problems	F	40%	60%	0%
Insufficient infrastructure for GMP application	O	80%	0%	20%
Price differences vs. domestic suppliers by country	O	0%	30%	70%
Customer resistance to samples	O	0%	70%	30%
Difficulty in customization	O	80%	0%	20%
Insufficient network with gene/cell therapy customers	G	0%	100%	0%
Difficulty focusing on new product-related work	F	0%	100%	0%
Global headquarters support	G	50%	50%	0%
Insufficient product quality and performance	F	20%	80%	0%

3.4.2. Five Whys Analysis

In A3, the 5 Whys technique is widely used as a tool to find the root cause of problems, greatly helping to more accurately diagnose problems and find practical solutions.

(1) Customer Hesitation to Change Products (70% AMEA control, 30% cannot control, F):

The first question is 'why do customers hesitate to change products?' The answer to the first 'Why' is 'because customers cannot see the specific benefits of our products.' The second 'Why' can be divided into two reasons: 'insufficient product information' and 'not feeling the value of process application or change management for new products.' The answer to the third 'Why'—why our new products lack information and value—is that communication with global headquarters is absent and the complexity of procedures for confirming product information is problematic. Additionally, the absence of internal product training procedures means that teams were unaware that products had been launched, making it impossible to establish business plans. The final 'Why' was that selling, promoting, and providing application support for well-known existing products is more efficient for individual performance management than focusing on work for new product launches.

(2) Delivery Delay Problems (60% AMEA control, 40% Global team control, F):

The first question is why lead times are extended. The reasons are: difficulty in demand forecasting due to lack of visibility of customer decisions in the process of changing from existing to new products; much time consumed in inter-departmental communication due to improperly established internal processes; and significant time required for delivery when customers request samples because test samples or promotional samples are not held by country. The second Why's answer involved absence of clear marketing strategy, product information with competitive capability compared to existing commercial products, process references, case studies, and problematic internal processes and communication. The root cause of these problems was that documentation and process development related to product information meeting GMP standards had not been sufficiently conducted.

(3) Insufficient Product Quality and Performance (80% AMEA control, 20% Global team control, F):

The reason why the quality and performance of new products are not sufficient to attract customer interest is that establishment and revision of promotional materials, technical support, and regulatory support documents are needed, and there is lack of rationale for pricing due to insufficient standard cost information. In the second

question, insufficient product understanding, lack of case study literature on protein and gene/cell therapy applications, customer disinterest due to pricing errors, and quality risks were identified as problems. The root cause was identified as the absence of seminar materials capable of explaining various technical data and cases when conducting customer meetings or promotional seminars.

3.5. Countermeasures and Implementation

3.5.1. Four Implementation Domains

The implementation plan was divided into four major parts for Avantor's new product business success. Each part focused on strategic infrastructure construction, marketing reinforcement, technical support and application improvement, and internal capability development for new product market entry and sales promotion.

Domain 1 – New Product Business Infrastructure Construction:

New product data development was led by global headquarters' R&D and product management departments, with progress shared through regular meetings. SAP system product registration and order management were handled by each country's sales department managers, enabling efficient order management through the system. Pricing and global communication involved rapidly sharing standard cost information with global headquarters, with market conditions continuously updated through regular meetings with AMEA regions. Product images were managed by marketing and e-commerce departments to upload product promotional materials to websites and utilize them in face-to-face and digital marketing activities.

Domain 2 – Marketing Material Development and Branding:

The core of marketing activities was new product brochure development, revised from the existing simple product descriptions to a technical note format based on scientific approaches. A digital campaign infrastructure was built, establishing foundations for effectively reaching target customers through SNS channels, webinars, and promotional videos. Website updates provided new product information in each region's language for better accessibility in AMEA markets. Asian city seminar events activated face-to-face networking and increased product understanding.

Domain 3 – Technical Support and Application:

Application support platform development reflected the importance of process testing and technical sales activities, promoting efficient collaboration and case sharing between application teams in each region. Reference and case study material development secured data from gene cell therapy processes and provided them to marketing and e-commerce departments in monthly guidebook form. Application guides and product instructions were written to improve product usability, and seminar materials targeting R&D and MSAT customers were developed to secure technical credibility. New product information updates and global communication involved sharing regulatory and technology trends between each region and global headquarters.

Domain 4 – Internal Capability Development:

Internal training was conducted through development of training materials on new product applications, enabling all department employees to enhance understanding of new products and gain deep awareness of market and product characteristics. Training was hosted by application and R&D departments and conducted company-wide.

IMPACT Program: To motivate employees toward new product activities, Avantor implemented the IMPACT program—a company-wide employee motivation initiative where points are awarded between managers and employees, which can be exchanged for products or gift certificates through an employee welfare portal. This performance-based reward system motivates employees to focus on specific tasks and achieve results, providing more immediate and concrete benefits.

3.6. Business Results

All plans and work were completed from February 2023 through December 2023, with all 20 tasks completed according to the implementation plan. As a result, total new product revenue of $2,740,805.32 was achieved within 10 months. This exceeded the initial target of $400,000 by approximately 680%. New business opportunity acquisition for new products also exceeded 180 cases total for AMEA, surpassing the initial target of 100 business opportunities by more than 55%.

Avantor also achieved results in building market trust. Customer trust was strengthened through customized technical support and regulatory documents, and market awareness and demand for new products increased significantly. These efforts played an important role in Avantor differentiating from competitors.

Significant progress was also made in process efficiency. By reducing lead time from an average of 741 days to 196 days, the speed of market entry was greatly accelerated. This contributed to strengthening competitiveness by enabling Avantor to introduce new products to the market more quickly. Such countermeasures promoted overall improvement of Avantor's new product launch and sales strategy, simultaneously strengthening customer satisfaction and market competitiveness.

3.7. Implications

Avantor's A3 Project is a successful case of exceeding targets in the new product business, demonstrating the impact of systematic approaches and execution on strengthening corporate competitiveness. In particular, customer-tailored services and technical support acted as important factors for new product market entry and success. Based on this success, Avantor plans to flexibly respond to the changing market environment and pursue sustainable growth. Avantor will continue to strengthen internal capabilities through Kaizen/A3 methodology and continuously secure competitiveness in the global market.

4. Strategic Recommendations

As a result of Avantor's careful analysis of internal infrastructure and procedural problems in the early stages of new product business, several improvements were derived. Initially, process lead time from new product business preparation to customer purchase orders averaged 741 days—an excessively long period to maintain competitiveness. Internal processes were standardized, each department followed the same procedures, and unnecessary steps were eliminated to achieve improvements. As a result of these efforts, lead time was reduced to 196 days, which became a major foundation for new products to generate revenue within one year.

4.1. Internal Infrastructure Improvement for New Product Business

Problems with insufficient clear information and training on new products were also improved. Avantor thoroughly educated employees on product characteristics and application cases through regular internal training and seminars. This enabled provision of systematic materials and information that could build trust with customers. Additionally, product applications, regulatory support documents, and brochures were systematically managed and shared to strengthen customer trust. An internal sharing system for pricing and product updates was established, communication with global headquarters was strengthened, and differentiation strategies for competitor products were also developed. Meanwhile, various incentive programs were introduced to motivate employees. These encouraged employees to engage more actively in their work and played an important role in business success.

4.2. Application Platform Construction and Utilization

Avantor developed a customer-centric application platform focusing on cell and gene therapy process development support, customized application provision, and training support. This platform was provided free of charge to customers who purchased new products, enabling Avantor's new products to quickly gain market awareness and trust from pharmaceutical customers. Additionally, this support provided Avantor with opportunities to participate in process development of diverse pharmaceutical candidates and helped secure numerous case studies.

Application services provided practical value beyond simple technical support in customers' process development processes. For example, services including virus purification, protein drug analysis, and cell culture medium customization supported customers in efficiently optimizing processes. This approach greatly contributed to improving customer productivity and differentiating Avantor's new products from competing products.

4.3. Marketing and Technical Document Development

Avantor systematically prepared regulatory support documents, case studies, and promotional brochures to support sales and marketing teams in effectively utilizing them. In particular, regulatory support documents played an important role in conveying trust to customers that Avantor's new products meet regulatory requirements and safety and quality are guaranteed. These materials minimized customers' legal risks and helped position products as customer-friendly based on transparency and reliability of product information.

Avantor used these documents to provide customers with technical trust, supporting customers in clearly understanding actual application cases and advantages of products. This acted as an essential element in successfully leading initial market entry of new products.

4.4. Growth and Future Strategy

Avantor's A3 Project is a successful case leading to over 680% excess achievement of revenue targets in the new product business, establishing an important turning point in the company's sustainable growth strategy. Based on this, Avantor proposes the following major future strategies.

1. Process Development Support Platform Expansion: Continuously expand the functions of the process development support platform and accumulate additional case studies and technical materials for various molecules. This will strengthen relationships with customers and enable securing competitive advantages by participating from the early stages of new projects.
2. Research Reinforcement on Emerging Markets: In emerging markets such as Asia, the Middle East, and Africa, it is necessary to create new business opportunities by studying growth potential in fields such as plasma products and vaccines beyond proteins, gene therapies, and cell therapies.
3. Free Service ROI Analysis: The Return on Investment (ROI) of freely provided application services should be analyzed to evaluate service provision efficiency and profitability, enabling future strategy adjustment based on this.
4. Long-term Customer Relationship Management: Long-term relationships should be built and sustainable business models prepared through customer-tailored services and technical support. Through this, Avantor will be able to maintain sustainable competitive advantages over competitors.

5. Conclusions

5.1. Summary

This business plan described the implementation process and results of the A3 Project for Avantor's new product business success. All 20 action items completed by December 25, 2023 were successfully executed, enabling Avantor to achieve total new product business revenue of $2,740,805.32. This is approximately 680% above the initial target of $400,000, clearly demonstrating project effectiveness and performance. Additionally, Avantor exceeded the target of acquiring over 100 new business opportunities related to new products, succeeding in creating 155% or more additional opportunities.

The core of the A3 Project lay in providing customized process application services and process development application services, and satisfying customer company requirements. These customized services enabled close collaboration with customers, obtaining customer trust and continuously creating new business opportunities. Additionally, through systematic preparation and distribution of technical, marketing, and regulatory documents, product promotion and customer convenience and regulatory requirement compliance were simultaneously considered. This service-centered strategy contributed to Avantor establishing itself as a trusted partner within the pharmaceutical industry and became a foundation for creating additional business opportunities.

Furthermore, regular training of sales, marketing, and application teams promoted understanding of products and markets, enabling updated latest information to be continuously received and business strategies tailored to each country's market environment to be devised. These efforts greatly improved market awareness and reliability of new products, which became an important foundation for Avantor's continuous business growth. Therefore, the A3 Project can be said to be a very successful case of Avantor exceeding targets in the new product business and strengthening competitiveness in the market through customer-tailored services and technical support.

5.2. Practical Implications

Avantor's new product business success was achieved through combination of the following key factors. First, specific and systematic A3 Project execution: the A3 Project set clear targets and continuously monitored them by executing 20 predetermined action items on schedule. Timely adjustments were made according to project progress, and this systematic approach contributed to maximizing business performance.

Second, differentiation of technical support services and product convenience: Avantor's process development and customized process application services built customer trust, generating more business opportunities. These services not only supplied products but strengthened long-term relationships with customers by resolving their problems and supporting process development. This played an important role in building a sustainable business model.

Third, regular training and information sharing: regular training of sales, marketing, and application teams

improved understanding of new products and markets and enabled strategies tailored to each country's market environment. By sharing the latest information through regular meetings, rapid response to changing market conditions was possible. Each team adjusted strategies in real time and established effective marketing and sales strategies. This collaborative approach contributed to effectively informing the market about new products, delivering trust to customers, and strengthening positions in the global market.

Avantor's A3 Project is a successful case of exceeding targets in the new product business, demonstrating the importance of systematic project execution, technical support services, and team collaboration. This success is the result of customer-tailored services, continuous market environment analysis, and strategic execution. Based on this experience, Avantor is expected to lead sustainable growth in the global market and secure even stronger competitiveness within the pharmaceutical industry.

5.3. Research Limitations and Future Research Proposals

While the strategy and execution presented centered on Avantor's new product business infrastructure construction case provided useful insights into new product success factors, there were several limitations.

1. Customer company characteristics and requirements were not sufficiently segmented. The pipeline characteristics, company scale, and technology levels of customer companies are all different, and if these factors had been analyzed and reflected in detail, more specific and effective business strategies could have been established.
2. The research evaluated performance primarily based on quantitative data such as revenue performance. However, qualitative data such as customer satisfaction, brand reliability changes, and customer psychological factors influencing new product success were not sufficiently considered.
3. Although Avantor's strategy produced positive outcomes, analysis of similar strategies or responses by competitors was insufficient. If Avantor's strategy had been evaluated by comparing it with competitor data in terms of how differentiated and effective it was, Avantor's competitiveness could have been demonstrated more clearly.

In future research, it will be necessary to deepen the analysis of the value of customer-tailored services such as 'process development application service' in the biopharmaceutical market. In particular, segmented market strategies should be derived by systematically analyzing needs by customer company, and customizing strategies meeting individual customer requirements should be strengthened. Additionally, research including qualitative data should be conducted to deeply analyze factors such as customer satisfaction, brand reliability, and customer experience. Furthermore, comparative research with competitor strategies is needed. Through this, Avantor's differentiated strengths and weaknesses can be clearly identified, and competitiveness can be further strengthened. Finally, research tracking and analyzing the long-term impact of Avantor's technical support and regular training activities on customer satisfaction and business growth is needed.

References

- Protein Therapeutics Market Size to Surpass USD 566.82 Billion by 2030 (July 7). Retrieved from https://www.biospace.com/protein-therapeutics-market-size-to-surpass-usd-566-82-billion-by-2030
- Gene Therapy Market Size Poised to Surge USD 52.40 Billion by 2033 (April 18, 2024). Retrieved from https://www.globenewswire.com
- Cell Therapy Market Size to Grow At 22.67% CAGR Till 2033 (April 22, 2024). Retrieved from https://www.globenewswire.com/news-release/2024/09/05/2941682
- Rathore, A. S., Kumar, D., & Kateja, N. (2018). Role of raw materials in biopharmaceutical manufacturing: risk analysis and fingerprinting. Current Opinion in Biotechnology, 53, 99–105.
- Meeting the process development challenges of a diverse biologic pipeline. Retrieved from https://www.cytivalifesciences.com
- Development and manufacture of drug substance (Chemical entities and biotechnological/biological entities) Q11, pp. 6–65.
- 2021’s Bioprocessing Year In Review & 7 Key Takeaways. Retrieved from https://www.bioprocessonline.com
- Post-COVID Supply-Chain Challenges Are Easing, Part 1: New Competition Is Changing Industry's Buying Behavior. Retrieved from https://www.bioprocessintl.com

- Regulations in the European Union for the Use of Triton X-100 in the Pharmaceutical Industry. Retrieved from https://www.bdo.com

Notes

Upstream Process: In the process of producing biopharmaceuticals, refers to the cell culture and biological production stages.

Downstream Process: The process of purifying and precisely processing substances generated after cell culture to create the final finished pharmaceutical product.

Critical Quality Attributes (CQA): Important characteristics determining the quality of a pharmaceutical product, characteristics that must be managed and monitored to ensure the safety, efficacy, consistency, and quality of a product.

Triton X-100: A non-ionic surfactant used to dissolve cell membranes to extract intracellular materials or dissolve other biological materials. Designated as an endocrine disruptor in Europe.

cGMP (current Good Manufacturing Practice): Regulatory standards issued by the FDA and other health authorities for manufacturing, processing, packing, or holding drugs and pharmaceutical products.

IMPACT Program: Avantor's internal employee motivation program where points are awarded between managers and employees, exchangeable for products or gift certificates through an employee welfare portal, serving as a performance-based reward system.