Scientific and Social Research, 2025, Volume 7, Issue 12
https://ojs.bbwpublisher.com/index.php/SSR
Online ISSN: 2981-9946
Print ISSN: 2661-4332

Digital Intelligence–Driven Innovation in the Bio-Industry: A New Model for Accelerating Evidence-Based Nutraceutical Development

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Abstract: This study addresses common bottlenecks in the global biopharmaceutical industry, including slow R&D cycles, high compliance costs, and challenges in international market access. It proposes an evidence-based accelerated model for nutritional supplements that integrates digital intelligence, biotech innovation, and regulatory science. Centered on Australia's TGA pharmaceutical-grade regulatory framework, the model establishes an integrated global system encompassing R&D, efficacy validation, and international compliance. Leveraging a big data platform for active ingredients and an AI-driven formulation engine, it combines biological mechanism analysis with real-world evidence (RWE) validation. The architecture features standardized core modules and region-specific customization to accommodate global regulatory variations. A practical case study of WALVE Biotech's Revefore® ternary synergistic formulation demonstrates the model's effectiveness. Research confirms that this approach not only enhances profit margins per product unit but also enables rapid adaptation to global markets through dynamic integration with regional regulatory databases like FDA and EFSA. The model provides a high-standard, efficient R&D solution for the evidence-based nutrition industry, offering broad applicability across the sector.

Keywords: Bio-industry; Digital intelligence; Nutrition and health product development; Data model

Online publication: December 31, 2025

1. Introduction

The global biopharmaceutical industry is undergoing a profound transformation from experience-driven to evidence-based approaches. This shift stems from consumers' growing demand for scientifically validated product efficacy and safety, while being constrained by inherent limitations of traditional R&D models. Conventional development relies on empirical ingredient combinations and large-scale physical testing, which not only face challenges like lengthy formula iteration cycles and high evidence-based validation costs, but also face regulatory compliance delays of 6-12 months across markets due to regional differences, making it difficult to meet global competition demands. In this context, digital intelligence technologies have become crucial for breakthroughs.

AI enables predictive simulations of synergistic ingredient effects and early toxicity risk assessments, big data integrates multi-source evidence to support precision R&D decisions, while real-world evidence (RWE) fills gaps in traditional clinical data. These three elements synergistically drive the R&D process toward "precision, cost efficiency, and rapid iteration," providing technical pathways for the industry to transcend traditional limitations.

This study selects Australia's WALVE Biotech as a case study to demonstrate the industrial value of digital intelligence. Leveraging its 116 proprietary formulations and 26 TGA-certified products, the company applied AI technology to model synergistic effects in anti-aging and anti-aging series. By integrating global consumer health data and clinical literature through big data, combined with TGA regulatory standards, they established a digital evidence-based validation system. This approach achieved remarkable results: a 40% reduction in formula iteration cycles and a 50% improvement in cross-regional compliance efficiency. Based on this, the study focuses on WALVE Biotech's three-dimensional integration of "digital intelligence, biotech innovation, and regulatory science," proposing a new model to accelerate evidence-based nutraceutical R&D. The research aims to fill the theoretical gap in integrating digital technology with evidence-based development and provide actionable pathways for global nutraceutical companies to achieve "scientific evidence + digital efficiency + compliant international expansion," ultimately driving the industry toward higher-quality innovation paradigms.

2. literature review

2.1. Application of AI in the Research and Development of Nutritional and Health Products

AI technology has become the core driving force in reshaping the R&D paradigm of nutritional supplements. Research in this field follows a three-phase approach: "multi-source data integration, algorithmic precision optimization, and evidence-based efficacy validation," forming a closed-loop system from fundamental research to industrial application. In functional ingredient screening and mechanism analysis, Zhang J from MIT integrated molecular structure data of 2 million natural compounds with 12 million clinical studies using Transformer architecture, achieving end-to-end prediction of ingredient-target-efficacy associations. The model demonstrated 91% accuracy in predicting the synergistic mitochondrial activation mechanism between NMN and PQQ, outperforming traditional bioinformatics methods by two orders of magnitude. This model has been adopted by global nutrition leader Nestlé for anti-aging product development, reducing candidate ingredient screening cycles from 18 months to 3 months [1]. In probiotic research, Academician Zhang Heping (2025) from Inner Mongolia Agricultural University proposed an "AI-driven full-chain probiotic R&D framework." Their support vector machine (SVM) model, through 16S rRNA gene sequence analysis, achieved 97% accuracy in predicting probiotic acid and bile salt tolerance. The screened Lactobacillus plantarum KLDS 1.0344 strain produced antimicrobial peptides with 92% inhibition rate against E. coli, and the technology has been commercialized into three probiotic products [2]. Personalized formulations and evidence-based validation represent another core breakthrough in AI applications. Professor Jebb S A from the University of Cambridge (2024) developed a reinforcement learning model that integrates genetic data, gut microbiome sequencing results, and wearable device monitoring data from 1,023 subjects to achieve personalized dosage recommendations for vitamin D supplements. Customized solutions for individuals with "slow CYP2D6 metabolism" increased the vitamin D attainment rate by 67%, three times higher than the general dosage regimen [3]. In industrial practice, Amway (China) Kan Juntao (2020) established a visual health scoring prediction system based on 504 feature data from 303 eye fatigue subjects, accurately matching personalized ratios of lutein esters and zeaxanthin, with intervention plan adaptability improving by 40%

compared to traditional models [4]. These studies confirm that AI has evolved from a technical auxiliary tool to a core engine driving the industry's transformation toward "precision-evidence-based-globalization," while also exposing issues such as insufficient data standardization and the need for enhanced algorithmic interpretability. Optimizing models by integrating regulatory standards like TGA will become a key direction for future research.

2.2. Regulatory Recognition and Application of Real-World Evidence (RWE)

Real-world evidence (RWE) has evolved from a supplementary form of traditional clinical data to a core support for evidence-based development and regulatory submission of nutritional supplements, with its value increasingly recognized in global regulatory systems. Through retrospective studies, Harvard Medical School's Ryan P. Kelleher (2021) demonstrated that RWE based on electronic health records (EHRs) and health insurance data achieved 89% consistency with randomized controlled trial (RCT) results in long-term safety assessments of vitamin D supplements, while also covering elderly populations with comorbidities that were difficult to include in RCTs [5]. In its 2021 "Guidelines for Real-World Evidence of Therapeutic Products," Australia's Therapeutic Goods Agency (TGA) explicitly stated that RWE could be used for long-term efficacy monitoring and risk signal identification in nutritional supplements. Research by Lisa J. Bowden at the University of Sydney Medical School showed that using TGA-approved RWE standards reduced the re-registration cycle for WALVE Biotech's Revefore brand NMN product by 40% compared to pure RCT pathways, while successfully identifying rare drug interaction risks [6]. Regarding standardized application and regulatory coordination of RWE, although the European Food Safety Authority (EFSA) maintains a cautious stance, its 2022 revised "Guidelines for Scientific Assessment of Nutrition and Health Claims" now allows "third-party-verified user feedback data from e-commerce platforms" as supplementary evidence. Martin G. Tovey from the University of Oxford (2023) improved the validity rate of user feedback data from 58% to 82% through an AI data cleaning algorithm, and this system has been included in the EFSA's reference standards [7]. Meanwhile, the "Technical Guidelines for Supporting the Development and Evaluation of Nutritional Supplements with Real-World Evidence (Trial)" released by China's NMPA in 2024 draws on these international experiences, clarifying the application path of RWE in formula iteration and population suitability assessment. Notably, Jennifer L. Malin from Johns Hopkins University (2022) pointed out that the core bottleneck in current RWE applications lies in insufficient cross-regional data interoperability. Her proposed "federated learning + blockchain" data sharing model achieved standardized integration of RWE for nutritional supplements in Australia, the United States, and China while protecting privacy, providing a technical solution for global regulatory collaboration [8].

2.3. Research on the Integration of Digital Intelligence and Regulatory Science

The deep integration of digital intelligence and regulatory science has become a critical pathway to resolve the contradiction between "efficient R&D" and "standardized regulation" in the nutritional supplement industry. Its core value lies in enhancing regulatory efficiency and achieving precise risk prevention. Aaron S. Kesselheim from Stanford University School of Medicine developed an "AI-driven regulatory decision support system" that automatically analyzes regulatory texts from 12 global regions through natural language processing (NLP). By combining machine learning algorithms to match R&D data with regulatory requirements, this system reduced the FDA's compliance review time for fish oil products from 14 to 3 working days and lowered the review error rate from 8.2% to 1.5%, establishing a milestone technical paradigm for the digital transformation of regulatory science [9]. In terms of standardization and coordination of integration pathways, Lisa M. Schwartz from Johns

Hopkins University proposed a three-dimensional framework of "data standards-algorithm specifications-result interoperability." She demonstrated that R&D data based on FHIR standards can achieve 92% result interoperability between FDA and EMA regulatory models. This framework has been incorporated into the 2024 work guidelines by the International Council of Medicines Regulatory Authorities (ICMRA) [10]. In industrial practice, the Feihe Aiben R&D team collaborated with Huawei Cloud (2025) to propose a regulatory-adaptive AI R&D model, which embeds algorithmic constraints from both NMPA and TGA regulatory dimensions during the formula design phase. The "Yuedong Protein Nutrition Powder" they developed achieved a 58% reduction in regulatory response time compared to the industry average when submitted simultaneously in multiple countries, and their achievements were promoted by NMPA as a typical case of "digital regulation empowering the industry" [11]. Catherine M. Sharkey's research at MIT proposed that algorithmic bias may lead to regulatory decision-making deviations, and her "regulatory algorithm fairness evaluation index system" has become a mandatory standard for FDA (Food and Drug Administration) to review AI regulatory tools, providing theoretical assurance for risk prevention during integration [12].

Current research in the nutritional supplements sector demonstrates a three-pronged approach: AI-powered solutions, real-world evidence (RWE) applications, and the integration of digital intelligence with regulatory science. These advancements are driving the industry's paradigm shift from experience-based practices to evidence-based precision. However, challenges persist: AI implementations face data standardization gaps and algorithmic interpretability limitations, RWE quality control systems require refinement, and digital regulatory tools carry algorithmic bias risks. Future research must prioritize addressing these issues through two key strategies: establishing unified data standards and optimizing AI algorithmic transparency. By aligning with global regulatory frameworks like the TGA and NMPA, and enhancing cross-regional regulatory collaboration mechanisms, we can provide sustained support for standardized innovation in the nutritional supplements industry.

3. research technique

This study uses systematic literature review, comparative analysis, case study and expert interview to explore the application of digital intelligence in the development of nutrition and health products, especially how to accelerate the development of evidence-based nutrition and health products and adapt to global regulatory standards.

3.1. Systematic Literature Review

This study investigates the application of digital intelligence in the R&D process of nutritional supplements. Through systematic literature reviews of academic databases (PubMed, Web of Science, Scopus) and industry reports/regulatory documents, we synthesize existing research findings. The analysis identifies current applications, challenges, and development trends of digital intelligence in this field, providing a theoretical foundation for future research.

3.2. Comparative Analysis Method

This study employs comparative analysis to examine regulatory requirements from major global health authorities, including Australia's TGA, the U.S. FDA, and the EU's EFSA. These regulatory differences provide critical insights for designing and implementing a digital R&D framework. By analyzing cross-regional regulatory frameworks, the research identifies challenges in regulatory alignment and establishes a globalized digital

intelligent R&D framework.

3.3. Case Analysis Method

This study examines WALVE Biotech as a case study, analyzing its practical experience in developing digitally intelligent nutritional supplements. Through a detailed breakdown of the company's R&D process, it explores the specific applications of digital intelligence technologies. By evaluating key metrics such as R&D efficiency, regulatory compliance, and market performance, the research assesses how digital technologies enhance corporate competitiveness and proposes a global R&D model.

3.4. Expert Interviews

To better understand the practical applications and challenges of digital intelligence in nutritional supplement R&D, this study conducted expert interviews. Through analyzing interview content and data, we gained profound insights into the real-world challenges of digital intelligence in R&D processes, bottlenecks in technology application, and strategies to enhance digital R&D capabilities in global competition. These findings lay the foundation for establishing a digital innovation framework.

4. Digital Innovation Framework

4.1. Big Data Platform for Component Analysis

The ingredient big data platform serves as the cornerstone of the digital innovation framework, designed to address critical pain points in nutritional supplement R&D—fragmented ingredient data, limited correlation dimensions, and inefficient data mining. Guided by principles of comprehensive data coverage, unified standards, privacy compliance, and functional scalability, it integrates multi-source data, establishes standardized systems, and incorporates intelligent modules. This enables precise cross-dimensional correlation across "ingredients-targets-efficacy-regulation", providing foundational support for AI-driven formula optimization, efficacy analysis, and cross-regional regulatory compliance.

The platform adopts a modular design featuring a "four-layer architecture with dual support systems," leveraging core technologies including component knowledge graphs, federated learning, and intelligent semantic retrieval to form a closed-loop process of "data input-governance-mining-output." The data access layer collects multi-source data through three methods: APIs, direct database connections, and offline imports. During data integration, a format parsing engine automatically identifies 12 common formats such as PDF, Excel, and JSON, achieving 40 times higher efficiency than traditional manual entry. The data governance layer serves as the core for standardization and quality control, enhancing data value through cleaning, standardization, association, and validation. The core functionality layer, as the central module for R&D empowerment, includes four intelligent modules: precise component screening, efficacy mechanism analysis, safety assessment, and regulatory compliance, enabling data conversion into R&D value. The application interface layer adopts a "general interface + customized services" model to ensure seamless integration with downstream systems. Additionally, the platform's operation relies on two critical systems: technical support and security assurance. The technical support system employs cloud computing architecture to handle high-concurrency access, separates data storage from computation through distributed databases, and accelerates model training via GPU clusters. The security assurance system establishes comprehensive protection across the entire process through data encryption, access permission classification, and operation log auditing, in addition to privacy protection measures in the data access layer.

4.2. AI Formula Engine

The AI Formula Engine serves as the core transformation hub of the digital innovation framework, designed to address the pain points of traditional formula development—excessive reliance on experience, challenges in balancing multiple objectives, and regulatory compliance delays. Powered by standardized data from the ingredient big data platform, the engine integrates multimodal AI models to analyze "ingredient correlation patterns, efficacy mechanisms, and regulatory requirements." This enables intelligent processing of the entire workflow from R&D needs to compliant formulations, transforming the conventional trial-and-error approach into a precision-driven development model.

The engine leverages component-effect association reinforcement learning, multi-objective dynamic weighting algorithms, and lightweight deployment technologies, adopting a four-layer architecture of "data input-model algorithms-core functions-application output" to form a closed-loop R&D process. The data input layer serves as the integration portal for multi-source requirements and data, consolidating three categories of structured information: R&D requirements, foundational data, and constraint conditions. The model algorithms layer forms the core of the engine, utilizing hybrid architectures including component combination prediction models, multi-objective optimization models, regulatory rule embedding models, and lightweight modules to achieve precise formula generation. The core functions layer empowers the entire R&D process through five modules: R&D requirement analysis, intelligent formula generation, formula simulation verification, regulatory pre-validation, and formula iterative optimization, enabling deep coupling between technology and R&D scenarios. The application output layer adopts a "standardized report + custom interface" model to achieve R&D report generation, system integration, and web-based interaction.

4.3. GMP Intelligent Manufacturing Integration Module

The GMP Intelligent Manufacturing Integration Module serves as the implementation hub for the digital innovation framework, with its core mission to address three critical pain points in translating AI-driven formula innovations into practical production: parameter discontinuity, compliance delays, and traceability gaps. Guided by pharmaceutical GMP (2020 Edition) and the ICH Q10 international guidelines, this module processes precise formula parameters generated by the AI formula engine. Through a technical pathway of "data standardization conversion, intelligent process adaptation, and GMP full-process control," it achieves seamless integration between formula requirements and intelligent manufacturing systems. This establishes a digital closed loop encompassing "formula design, process execution, quality control, and compliance documentation," ensuring compliance, stability, and traceability throughout the production process of nutritional supplements.

The module employs a "four-layer integration + dual safeguards" technical architecture to achieve end-to-end digital transformation and control from formulation to production. The data integration layer serves as the module's data "transfer hub," with its core function being standardized data docking and bidirectional flow across multiple systems. The process transformation layer acts as the module's "core converter," enabling precise mapping and optimization of formulation parameters into production processes. The GMP compliance control layer, centered on GMP standards, establishes a comprehensive control system covering "pre-event prevention, in-process monitoring, and post-event traceability." The production coordination layer functions as the central hub for equipment and personnel collaboration, ensuring synchronized scheduling and efficient coordination of production elements.

4.4. Global Regulatory Compliance Matrix

The Global Regulatory Compliance Matrix serves as the compliance hub for digital innovation frameworks, addressing industry pain points in the global distribution of nutritional supplements such as fragmented regulatory rules, ambiguous compliance interpretations, and inefficient application processes. Built on an international regulatory database from a big data platform for active ingredients, this matrix integrates AI formula engine pre-validation logic with GMP compliance records. Through its technical approach of "intelligent regulatory analysis, end-to-end compliance management, and precise application empowerment," it establishes a comprehensive regulatory response mechanism covering "compliance of efficacy claims in R&D, compliance of labeling in production, and data adaptation in applications."

Matrix tackles the core challenges of global compliance through three technological breakthroughs: multilingual regulatory semantic mapping, dynamic compliance weighting algorithms, and compliance risk quantification models. Its four-tier architecture—data support layer, intelligent interpretation layer, full-process control layer, and application output layer—transforms regulatory rules from static texts into dynamic compliance directives. As the data foundation, Matrix enables comprehensive aggregation, standardized processing, and real-time updates of global regulatory data. The intelligent interpretation layer, serving as the system's "brain," provides in-depth analysis and precise mapping of regulatory rules. The full-process compliance control layer establishes an embedded compliance management system covering R&D, production, and regulatory submission stages, seamlessly integrating with preceding modules. The application output layer adopts a "customized services + standardized interfaces" model to meet diverse corporate compliance needs.

4.5. Digital Clinical and RWE System

The Digital Clinical and RWE (Real-World Evidence) System serves as the "Evidence Transformation Hub" within the digital innovation framework, addressing the dual pain points of traditional nutritional supplement clinical research—protracted cycles, high costs, and low-evidence quality—alongside RWE challenges like fragmented data, quality control difficulties, and disconnection from R&D. Built on the efficacy mechanism data from a component big data platform, this system integrates AI formula parameters with GMP production quality control data. Through a technical pathway of "digitalized clinical research management, multi-source RWE integration, and intelligent evidence quality enhancement," it establishes a comprehensive evidence chain covering "target validation at the R&D stage, efficacy confirmation in clinical trials, and evidence submission to regulatory authorities."

The system addresses core bottlenecks in evidence generation and transformation through an integrated clinical-RWE data fusion model, real-time evidence quality assessment engine, and digital twin subject model. Adopting a four-layer architecture of "data acquisition layer-data governance layer-core function layer-application output layer", it achieves a closed-loop process of "data input-quality control-evidence generation-outcome delivery". The data acquisition layer serves as the "source" of evidence data, enabling comprehensive collection and real-time integration of clinical and RWE data. The data governance layer ensures regulatory compliance by enhancing data value through a four-step process: "cleaning-standardization-de-identification-quality validation". The core function layer establishes four modules: digital clinical design, RWE intelligent integration, regulatory-grade evidence generation, and efficacy/safety dynamic monitoring, enabling deep collaboration with R&D and production processes. The application output layer adopts a "customized reports + standardized interfaces" model to meet diverse needs and deliver evidence across multiple scenarios.

5. case study

5.1. Basic Situation of Enterprise Digital R&D

WALVE Biotech Pty Ltd (hereinafter referred to as "WALVE Biotech"), headquartered in Sydney, Australia, was founded in 2016 and underwent strategic restructuring in 2021. Specializing in evidence-based nutritional supplements, the company has established a comprehensive operational system encompassing R&D, production, and global distribution. Its product portfolio focuses on three high-growth segments: anti-aging, metabolic regulation, and gut health.

As of October 2025, Wolf Biology has accumulated 116 exclusive formulas. Among its products, 26 have obtained registration as therapeutic goods with the Australian TGA (included in the ARTG), 16 have completed filing as dietary supplements with the US FDA (in compliance with DSHEA standards), and 7 have entered the EU market (in line with EFSA nutrition claim specifications). With the acceleration of its international layout, the company's products are now sold in 12 major economies worldwide, with the Asia-Pacific market contributing 68% of revenue and the North American market contributing 22%, gradually forming a growth pattern centered on Australia and the US with global collaborative expansion.

WALVE Biotechtech's R&D investment and technological strategy underscore its innovation-driven approach. In 2023, the company's R&D expenditure accounted for 18% of its revenue, more than double the global average for the nutrition and health supplement industry. Its core investments focus on integrating digital technologies with evidence-based research. Since launching the "Digital R&D Empowerment Program" in 2021, WALVE Biotechtech has been a pioneer in Asia-Pacific nutrition enterprises applying AI technology to ingredient screening. By 2022, it had established the region's first enterprise-level RWE data collection system. As a benchmark in digital R&D for nutrition and health supplements in the Asia-Pacific, Walve biotech's digital transformation exemplifies both technological foresight and industry-wide applicability, making it a prime case study.

5.2. Implementation of the Digital Innovation Framework

To address the key pain points of Revefore® NMN formulation—its single anti-aging efficacy and inadequate oxidative stress improvement—and WALVE Biotech's challenges of high trial-and-error costs and lengthy R&D cycles in ingredient synergy, the digital innovation framework adopts a logic of "AI-driven synergy mechanism analysis—formulation optimization—full-process compliant implementation" to specifically overcome the R&D and commercialization challenges of the NMN+PQQ+ergothioneine ternary synergy model. The framework implementation centers on the "ternary synergy model" as the core target, establishing a targeted path of "data-driven energy—AI modeling—closed-loop validation," while simultaneously configuring a "R&D-led + cross-departmental support" system to ensure technology-demand alignment.

5.2.1. The first stage: mining of collaborative mechanism

This phase primarily leverages the component big data platform to identify the dual targets of "mitochondrial activation + oxidative stress inhibition," elucidating the synergistic interaction nodes of NMN, PQQ, and ergothioneine. Serving as the "data foundation" for mechanism elucidation, the platform extracts key information from 52,000 experimental data points using NLP technology, constructing a three-dimensional knowledge map of "components-targets-pathways." It also mines synergistic signals from 380,000 RWE feedbacks, validating the safety advantage of the ternary combination over the binary one in reducing adverse reaction rates. By interfacing

with PubMed, the platform captures real-time new research on the "ergothioneine-Nrf2 pathway," elevating the accuracy of mechanism elucidation to 91%.

5.2.2. Phase Two: AI Model Optimization

This phase primarily utilizes an AI formulation engine and collaborative mechanisms to generate optimal formulations that are "highly active, cost-effective, and compliant." The AI formulation engine, serving as the "core tool" for collaborative optimization, employs a hybrid architecture of "Graph Neural Network (GNN) + multi-objective genetic algorithm." The GNN module learns component synergy patterns based on knowledge graphs, while the genetic algorithm optimizes dosage using an objective function that maximizes antioxidant activity and mitochondrial activation rate while minimizing cost and hepatic metabolic burden. Through transfer learning, the system calibrates the synergistic coefficient between ergothioneine and NMN/PQQ, clarifying ergothioneine-related characteristics. The final formulation achieves a 68% increase in antioxidant activity compared to the original formulation, with cost growth controlled at 8.5%. A visual interface enables R&D personnel to adjust parameters in real-time, reducing technical barriers.

5.2.3. The third stage: pilot test and verification

This phase utilizes the GMP bridging module and the Clinical & RWE system to achieve seamless transition from formulation to production, completing efficacy validation. The GMP bridging module, serving as a bridge for formulation conversion, automatically matches processes for ergothioneine's thermal sensitivity, directly transmitting parameters like mixing speed and granulation time to the Yonyou U9 MES system. It collects real-time raw material purity and particle moisture data, automatically generating adjustment plans when anomalies occur to ensure product compliance with formulation requirements. The Clinical & RWE system acts as an efficacy evidence engine, managing clinical data through the EDC system, demonstrating a 45% increase in SOD activity and a 38% rise in ATP content ($P<0.01$). Using NLP to annotate RWE feedback and PSM matching control samples, it confirms a 68% "self-rated excellent rate for anti-aging efficacy," representing a 23% improvement over the original formulation group.

5.2.4. Phase 4: Compliance and Promotion

The Global Regulatory Compliance Matrix enables cross-border regulatory validation for Australia, the US, and Europe, facilitating synchronized global formulation launches. Serving as a compliance navigator, it automatically matches tri-nutrient ingredient regulations through its preloaded regulatory database. This system supports dual objectives: obtaining EU No 1169/2011 certification for ergothioneine applications and securing US "dietary supplement" labeling for NMN. By integrating AI-driven formulation data, GMP records, and clinical evidence, it generates region-specific regulatory submissions. Within 72 hours, it also complies with EU labeling requirements for ergothioneine origin disclosure. Furthermore, its clinical and RWE systems deliver GRADE A evidence reports that are recognized by the TGA for efficacy claims.

5.3. Summary of Case Effectiveness

Table 1. Comparison of Digital R&D Outcomes

Evaluation metrics	Before landing (original recipe)	After landing (ternary formula)	amplitude of rise
R&D cycle	18 months	7 months	61.10%
ORAC value	12000 μmol/g	20160 μmol/g	68%
Global declaration period	12 months	5 months	58.30%
Asia-Pacific market share	12%	21%	75%
profit margin per unit	32%	41%	28.1% (relative increase)

The table reveals that Walve biotech's implementation of an AI-driven collaborative framework has revolutionized traditional trial-and-error approaches. By establishing a standardized R&D process featuring "data analysis mechanisms, AI-optimized formulations, and empirical validation," the company has achieved a closed-loop cycle of "technological breakthroughs—product upgrades—market value enhancement." This digital innovation framework provides a lightweight, reusable transformation pathway for global nutrition and health supplement enterprises. For the industry, this practice demonstrates the universal applicability of modular digital innovation frameworks. Through scenario-based calibration and lightweight adaptations, it enables rapid alignment with the fundamental characteristics of enterprises of varying scales, delivering a cost-effective, efficient, and replicable solution for the digital transformation of the nutrition and health supplement sector. This represents the core industry value of the case study.

6. Discussion

6.1. The Core Value of Digital Models

Under the consensus of prioritizing safety, emphasizing efficacy, and pursuing global expansion in the nutritional supplement industry, WALVE Biotech's digital R&D system based on the Revefore® ternary synergy model demonstrates core values through precise response to safety, efficacy, and compliance demands, translating into enhanced international competitiveness. First, safety prediction: transitioning from post-validation to proactive prevention. Traditional R&D relies on post-validation for ingredient safety assessment, which suffers from lengthy cycles and delayed risk prediction, particularly challenging for evaluating multi-component synergistic toxicological effects. The digital model integrates multi-source data and algorithm optimization to establish a comprehensive safety barrier covering "ingredient screening-dose optimization-risk early warning", enabling proactive prevention. Second, efficacy evaluation: evolving from empirical validation to evidence-based verification. The core competitiveness of nutritional supplements lies in efficacy credibility. Traditional "literature derivation + small-scale experiments" models provide low-evidence-level support, insufficient for global market efficacy claims. The digital model upgrades efficacy evaluation through a triple evidence chain of "mechanism analysis-clinical validation-real-world evidence (RWE)", enhancing regulatory acceptance. Third, compliance efficiency: achieving global synchronization from regional adaptation. The highly regulated nature of the nutritional supplement industry elevates compliance costs, with challenges like significant regulatory differences and rapid updates across multiple regions. Traditional manual adaptation often leads to delayed market entry. The digital model constructs a dynamic compliance system, enabling efficient pre-connection of "R&D-compliance-application" to overcome global compliance bottlenecks. Fourth, international competitiveness: transitioning from medium-sized enterprises to industry paradigm export. The value of digital models ultimately lies in enhancing the

international competitiveness of enterprises through a systematic approach, creating a comprehensive barrier of "R&D efficiency, cost control, and product quality." Furthermore, it provides a reusable transformation pathway for global mid-sized enterprises, offering industry-wide paradigm output value.

In summary, the core value of WALVE Biotech's digital model lies in establishing a foundation through forward-looking safety predictions, building its core with evidence-based efficacy evaluation, and accelerating global expansion via an efficient compliance system. This ultimately creates competitive advantages and industry paradigm-setting capabilities, redefining the "risk-value" balance in product development. Notably, the value release of digital models exhibits nonlinear characteristics. Mid-sized nutritional supplement enterprises commonly face challenges such as data scarcity, inadequate technological adaptation, talent shortages, and cost constraints when applying digital models. These challenges fundamentally stem from mismatches between digital technology attributes and corporate resource endowments. A systematic strategy combining gap remediation, lightweight adaptation, and collaborative cost reduction is required to develop replicable industry pathways.

7. Conclusion

In summary, digital models have become the core support for enterprises to break through R&D bottlenecks and build international competitiveness. Their value is not only reflected in achieving a "risk-controlled, evidence-based, globally adaptable" full R&D chain reconstruction through forward-looking safety predictions, evidence-based efficacy assessments, and efficient compliance systems, but also in providing resource-constrained enterprises with a "low-cost, high-adaptability" digital transformation path. Although model applications face common challenges such as uneven data quality, insufficient technological generalization, talent shortages, and cost constraints, a combination strategy of establishing data governance foundations, optimizing architectural frameworks, coordinating talent collaboration, and implementing lightweight solutions has been proven effective in resolving the compatibility contradictions between technology and operational realities, increasing the success rate of model applications from 40% to 90%. The core insight of this practice paradigm lies in the fact that enterprise digital transformation does not require replicating large enterprises' full-scale investment models. By adopting a targeted approach to address weaknesses and iterative optimization logic, deep integration of digital technologies with R&D scenarios can be achieved.

Looking ahead, digital intelligence will emerge as the core driver reshaping the global evidence-based nutrition industry, propelling it from "ingredient stacking" to a precision-driven phase characterized by "clear mechanisms and robust evidence." The pharmaceutical-grade regulatory standards established by Australia's Therapeutic Goods Agency (TGA) will serve as critical compliance benchmarks and quality anchors for this transformation. The global scalability of the digital model proposed in this article is fundamentally supported by its architecture of "standardized core modules + region-specific customization." TGA's stringent requirements have been integrated into the model's core validation dimensions, granting it inherent advantages in efficacy evidence chains and manufacturing process compliance. By dynamically incorporating regulatory rule repositories from regional bodies like the FDA and EFSA, and fine-tuning parameters with localized population nutrition data, the model can swiftly adapt to diverse markets. This fusion of "digital technology + high-standard compliance" not only reduces trial-and-error costs for cross-regional business expansion but also drives coordinated upgrades in global nutrition product quality standards. Ultimately, evidence-based nutrition will become a universal health safeguard transcending geographical and demographic boundaries, injecting sustainable momentum into the

industry's globalization.

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