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Functional Food Science in the era of artificial intelligence: The role of domain authority, structured validation, and responsible translation

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ABSTRACT

The rapid expansion of artificial intelligence (AI) in nutrition and health research offers a powerful analytical tool; however, it also raises concerns when applied without a structured scientific framework or domain authority. Functional Food Science, as established and advanced by the Functional Food Center (FFC), represents a distinct discipline focused on the development of functional food products (FFP) with validated health benefits through bioactive compounds, measurable biomarkers, mechanistic pathways, clinical confirmation, and long-term population validation.

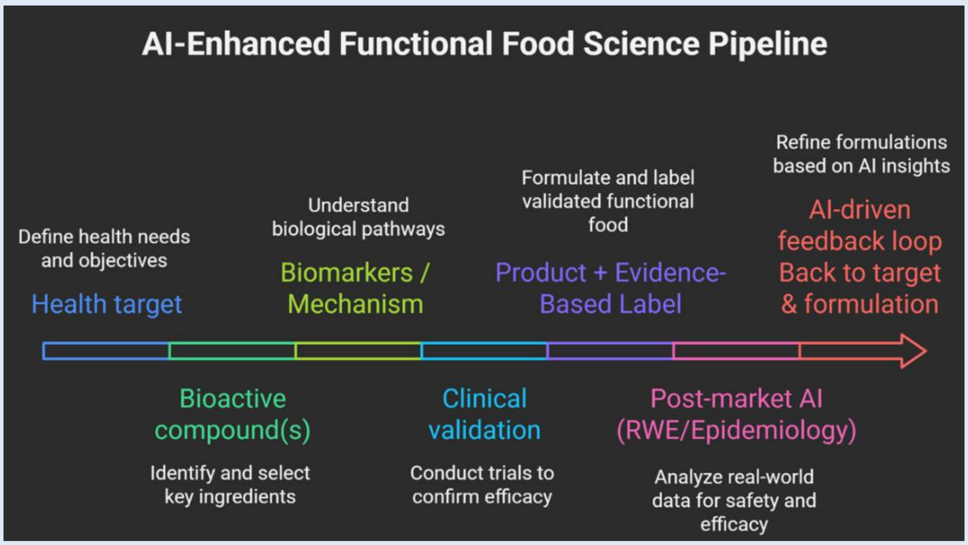
As AI's influence expands, it should be utilized as a supportive analytical tool, rather than a replacement for researchers. Here, we examine the appropriate role of AI in functional food science and propose a structured model that integrates AI as an analysis tool within the established FFC framework, ensuring that decision-making remains in the researchers' hands. This article examines the appropriate role of AI in functional food science and proposes a structured model in which AI serves as a supportive analytical tool within the established FFC framework, rather than as an independent decision-making system.

This article requires us to revisit the scientific foundations of functional food science. By contrasting the FFC development paradigm with the Japanese functional food model, which prioritizes pre-market evaluation over post-market epidemiological validation, we propose that AI's role best aligns in post-market surveillance. In this role, AI can synthesize real-world data from electronic health records, wearable technologies, and population cohorts to confirm sustained efficacy, detect safety signals, and refine functional food formulations. When integrated into a closed-loop pipeline that extends beyond market release, AI improves evidence generation while maintaining mechanistic understanding, clinical rigor, and scientific accountability.

Responsible application of AI in functional food science requires domain expertise, structured validation, and long-term population evidence. Embedded within the FFC framework, AI has the potential to strengthen scientific rigor, improve translational accuracy, and support scalable health outcomes for global populations.

Novelty of the Study: This article introduces a conceptual framework positioning AI as an enabling technology within functional food science, with particular emphasis on AI-driven post-market epidemiological validation—a step historically underdeveloped in functional food systems. By explicitly integrating AI into the FFC's structured development model, this work advances functional food science from a product-centered approach to a continuously validated health discipline.

Keywords: Functional food science; artificial intelligence; bioactive compounds; post-market surveillance; epidemiological validation; Functional Food Center; health biomarkers



Graphical Abstract: An AI-enhanced functional food science pipeline integrating target definition, bioactive compound selection, biomarker-based validation, clinical evaluation, and evidence-based labeling, followed by post-market epidemiology using real-world evidence (RWE). AI-driven feedback loops enable continuous refinement of formulation, efficacy, and safety at the population level.

INTRODUCTION

AI is rapidly reshaping how scientific knowledge is discovered, summarized, and translated into practice. In nutrition and health research, these tools allow for quicker literature synthesis, sharper pattern recognition, and more efficient hypothesis generation. However, this speed introduces a significant risk: AI can produce highly persuasive outputs that appear scientifically grounded, but lack the essential validated biomarkers, mechanistic support, dose justification, and human evidence required. Consequently, the speed of AI-driven information can outpace the scientific rigor necessary for responsible translation into health-related products and claims [1–3].

While some functional food research has historically lacked structured post-market validation, numerous recent high-quality studies have demonstrated rigorous pre-market evidence through randomized, double-blind, placebo-controlled trials with clear biomarkers and mechanisms. These provide a strong foundation that AI can extend, particularly into large-scale post-market epidemiological validation.

To ensure reproducibility and credibility, robust functional food studies eligible for AI-enhanced analysis must meet clearly defined minimum qualitative thresholds: (1) identification of a specific health target with measurable biomarkers; (2) dose-response testing; (3) mechanistic elucidation; (4) confirmation via adequately powered human clinical trials (preferably randomized, double-blind, placebo-controlled); and (5) capacity for post-market verification. Recent studies meeting these thresholds include randomized controlled trials on ursolic acid for urinary health, lutein for ocular oxidative stress, mekabu for glycemic control, peptide-enriched whey for mood and fatigue, and edible bird's nest for renal protection in metabolic models [4–8].

The FFC framework provides the necessary structure to guide this integration. Unlike general nutrition or wellness fields, functional food science requires structured validation: identifying a specific health target, linking it to bioactive compound(s), establishing measurable biomarkers, confirming mechanisms of action, and demonstrating efficacy and safety—especially in human studies. Critically, functional food science does not end at publication or market release; it requires continuous verification through post-market and population-level evaluation once products are used in real-world settings [9,13].

This research argues that the integration of AI into functional food science must reinforce, rather than replace, this evidence-based pipeline. We contend that AI's most transformative contribution lies at the current weak point of many global systems: post-market evidence generation and epidemiological validation. By aligning AI tools with the discipline's structured requirements, functional food science can accelerate discovery while preserving legitimacy, peer-reviewed rigor, and public trust [3,14–16].

Rather than a traditional editorial or methodological report, this article provides a forward-looking conceptual framework for Functional Food Science in the era of AI.

The Scientific DNA of Functional Food Science: Functional Food Science is defined not by ingredients or regulatory labels, but by the rigorous process that governs how foods are designed, validated, and translated into measurable health benefits. At the core of this discipline lies what can be described as its scientific DNA—a set of non-negotiable principles that distinguish functional food science from conventional nutrition research, dietary supplementation, or health-claim–driven product development [9,10,14]. In this context, the term "DNA" is used as a conceptual metaphor, referring not to deoxyribonucleic acid, but to the foundational scientific principles, validation steps, and structural rules that define Functional Food Science as a robust and reproducible discipline.

The FFC maintains that a product only earns the 'functional' label when developed through a rigorous scientific sequence. This begins with identifying a specific health outcome, followed by the selection of a bioactive compound capable of modulating that target. Crucially, this effect must be linked to a measurable biomarker, allowing for an objective assessment [9,10,15].

Following the identification phase, the process requires dose–response testing, elucidation of biochemical pathways and mechanisms of action, and human clinical trials to confirm efficacy and safety. Only once these steps are completed can the product be formulated, labeled transparently, and introduced to the market. However, the FFC framework does not conclude at the product's market release. Instead, it mandates a closed-loop approach: post-market confirmation through long-term observation and epidemiological assessment to verify effectiveness at the population level [9,10].

This structured framework—summarized in the FFC's multi-step functional food development model—serves as the scientific DNA of functional food science.

Due to the model's independence from specific technologies, regulatory trends, and commercial pressures, it remains valid across time, geographies, and innovations.

This scientific DNA is even more critical in the era of artificial intelligence. AI does not redefine functional food science; rather, it tests the integrity of the discipline's scientific foundations. Without a well-defined DNA, AI risks accelerating unvalidated correlations, overstated claims, and poorly controlled interpretations of large datasets. Conversely, AI has the potential to strengthen discipline by enhancing data integration, refining biomarker analysis, and—most notably—enabling large-scale post-market and epidemiological studies that were previously impractical [1,10,12,14].

Ultimately, the scientific DNA of functional food science serves as both a definition of the field and a protective framework that ensures credible translation of innovation into public health impact. AI may amplify this impact, but only when guided by domain authority, structured validation, and adherence to the foundational principles that define functional food science.

Conceptual Framework: AI-Enhanced Functional Food Science: The framework proposed by the Functional Food Center integrates artificial intelligence as a supportive analytical tool within a structured, evidence-driven pipeline. The following graphical abstract illustrates this integration, emphasizing post-market epidemiological validation and continuous evidence generation as defining components of functional food science.

Figure 1. AI-Enhanced Functional Food Science Development Pipeline

The framework proceeds through a structured sequence: starting with (1) defining a specific health target and (2) identifying relevant bioactive compounds. Next, the process moves into validation, including (3) biomarker and mechanistic elucidation, followed by (4) clinical trials to confirm efficacy. After (5) product development and (6) market release, the framework introduces a critical (7) AI-enabled post-market epidemiology phase. The seventh stage differs from traditional systems by allowing continuous analysis of real-world data to assess long-term effectiveness, safety, and population-level health outcomes. The insights generated create a feedback loop that informs health target optimization and product refinement [3,13–15].

Contrasting Functional Food Development Paradigms: FFC and Japanese Systems: Several national and regional functional food systems—most notably those developed in Japan—have contributed significantly to the formal recognition of functional foods. Frameworks such as Foods for Specified Health Uses (FOSHU) established vital precedents by requiring pre-market evaluation of safety and efficacy. These systems played a critical role in shifting functional foods beyond general nutrition and toward evidence-based claims [14].

However, while these paradigms provide robust pre-market standards and have produced high-quality evidence through rigorous clinical investigation [4–8], they typically treat regulatory approval as the primary endpoint, with less emphasis on systematic post-market or long-term population-level monitoring [9,14,15]. Consequently, real-world effectiveness and long-term safety signals are often assessed indirectly or on a limited scale.

In contrast, the Functional Food Center's framework treats market release not as an endpoint, but as a transition point into continuous scientific evaluation. Within this model, post-market observation and epidemiological studies are essential to confirm that clinical benefits persist at the population level under real-life consumption patterns. This requirement reflects a fundamental truth: functional foods, unlike pharmaceuticals, are consumed broadly, continuously, across diverse dietary and lifestyle contexts.

Historically, large-scale epidemiological studies in this field were constrained by logistical and financial limitations. Even systems that acknowledged the importance of such validation struggled to operate it consistently. The emergence of artificial intelligence removes these barriers. AI-enabled analysis of real-world data provides the tools necessary to fulfill this core FFC requirement that was previously difficult to execute [10,12,15].

In summary, the difference between FFC and Japanese systems is not one of scientific rigor, but of methodological trajectory. While the Japanese model follows a linear, unidirectional path focused on robust pre-market standards, the FFC framework integrates AI to create a closed-loop feedback system for continuous validation. AI does not redefine this model; rather, it operationalizes the previously unaddressed stage of post-market surveillance. This evolution moves functional food science beyond regulatory approval toward greater rigor and public health relevance.

Table 1. Comparison of Traditional Functional Food Development vs. AI-Augmented FFC Functional Food Science

Development Stage	Traditional Functional Food Approaches	AI-Augmented FFC Functional Food Science
Conceptual Foundation	Often nutrition- or ingredient-driven; health claims may precede mechanistic understanding	Health-target–driven science rooted in bioactive compounds, biomarkers, and validated mechanisms
Health Target Definition	Broad or descriptive (e.g., "supports health")	Precise, measurable health outcomes defined *a priori*
Bioactive Compound Identification	Based on historical use, compositional analysis, or limited screening	AI-assisted discovery using literature mining, molecular modeling, and network pharmacology

Development Stage	Traditional Functional Food Approaches	AI-Augmented FFC Functional Food Science
Biomarker Selection	Frequently absent or weakly correlated	AI-supported identification and validation of clinically relevant biomarkers
Dose Determination	Empirical or based on traditional use	AI-guided dose–response modeling integrating safety, efficacy, and inter-individual variability
Mechanism of Action	Often speculative or minimally addressed	Mechanistically defined pathways supported by AI-enabled pathway analysis and causal inference
Clinical Validation	Limited trials, surrogate outcomes, or observational evidence	Optimized clinical trial design supported by AI analytics and responder stratification
Product Formulation	Focus on feasibility and sensory acceptance	AI-assisted formulation optimizing bioavailability, stability, and functional integrity
Labeling & Claims	Marketing-oriented, loosely connected with clinical evidence	Transparent, biomarker-linked, and clinically verifiable
Regulatory Alignment	Compliance-focused, static	Dynamic compliance supported by AI-assisted claim validation and risk analysis
Market Release	Endpoint of development	A transition point to real-world validation
Post-Market Surveillance	Rare, passive, or absent	**Core scientific stage** using AI to analyze real-world data, health records, and wearable inputs
Epidemiological Validation	Generally, not performed	AI-enabled large-scale epidemiological studies confirming long-term efficacy and safety
Feedback to Research	Minimal or none	Continuous AI-driven feedback loop refining formulation, dosage, and target populations
Scientific Accountability	Fragmented and static, lacks continuous verification	Continuous, self-updating, and population-validated science
Role of AI	Minimal or absent	Enabling infrastructure that enhances—not replaces—scientific rigor
End Goal	Product commercialization	Long-term, validated improvement of population health

The FFC model uniquely incorporates post-market surveillance and epidemiological validation as essential scientific steps, enabled by artificial intelligence.

As summarized in Table 1, the FFC framework differs from traditional functional food approaches by treating post-market surveillance and epidemiological validation as core scientific requirements rather than optional or absent steps. Additionally, the framework also integrates AI as a tool throughout the pre-market states of development to enhance speed and accuracy.

Illustrative Examples of Human–AI Collaboration in Epidemiological and Post-Market Functional Food Science: Within the FFC framework, artificial intelligence is best understood as an analytical partner operating under rigorous human oversight, particularly during epidemiological and post-market phases of evaluation. During pre-market release, domain experts define core biological questions such as target health outcomes, relevant biomarkers, and confounding variables; while AI provides the computational power to analyze large-scale observational datasets, electronic health records, and longitudinal cohort data. Through multivariate analysis, AI excels at identifying trends in functional food consumption and biomarker modulation across diverse populations. However, the responsibility for interpreting these findings, assessing biological plausibility, and determining casual relevance remains with trained scientists. In this collaborative model, AI acts as a catalyst for evidence synthesis, while human expertise ensures that all findings maintain mechanistic coherence, clinical relevance, and scientific validity.

This collaborative dynamic extends to post-market surveillance, where functional foods are evaluated under real-world conditions. While human researchers establish the safety parameters and effectiveness of benchmarks based on pre-market validation, AI systems provide the infrastructure for continuous monitoring. By consolidating consumer-reported outcomes, data from wearable devices, and population-level health data, AI can detect emerging safety signals, inter-individual response variability, and changes in long-term effectiveness. These AI-generated insights inform expert-led decisions regarding formulation refinement, dosage adjustment, and labeling updates. Importantly, this feedback loop reinforces the FFC principle that market release represents a transition rather than a conclusion. In this way, AI enables scalable, long-term population validation that was previously logistically untenable, while preserving the scientific accountability and domain authority essential to the discipline. This approach builds on existing high-quality research such as the recent trials cited above [4–8].

Implications for the Scientific Community: Formalizing Functional Food Science as a structured, independent discipline provides framework for researchers, journals, industry stakeholders, and AI developers. For researchers, this formalization establishes standardized benchmarks for study design and clinical validation. Journals and reviewers gain a structured rubric for evaluating the legitimacy of functional food claims, ensuring that only evidence-backed research is published. Industry stakeholders are provided with a credible development pathway that prioritizes consumer safety and long-term effectiveness over short-term financial gains. AI developers are provided to receive domain-aligned frameworks that improve the reliability of automated evaluation [12,22]. Adopting FAIR data practices can improve interoperability across datasets and AI pipelines [17].

Scientific Innovation and Practical Implications: The responsible integration of AI into functional food science drives profound scientific innovation while delivering concrete practical benefits across the health ecosystem. Recent advancements illustrate AI's capacity to accelerate bioactive compound discovery and optimization, predict peptide bioactivity, refine extraction processes from food byproducts, and enable personalized nutrition strategies tailored to genetic and metabolic profiles [23-28]. These innovations expand the scope of functional ingredients—such as non-starch polysaccharides, peptides, and grain-derived compounds—while enhancing mechanistic understanding through predictive modeling and large-scale data integration.

Practically, AI empowers consumers through personalized recommendations that improve functional food selection and adherence, fostering better health outcomes [28]. For industry, AI streamlines research and development, reduces costs in processing and quality control, and supports sustainable sourcing, particularly in resource-limited settings [25, 27]. At the population level, AI-enabled post-market surveillance facilitates real-world evidence generation, rapid safety signal detection, and iterative product improvement—closing the feedback loop envisioned in the FFC framework [23,27]. Ultimately, these innovations strengthen public trust, enhance regulatory decision-making, and amplify the global impact of functional foods on chronic disease prevention and health promotion when guided by structured validation and human oversight. Recent reviews highlight how AI-driven personalized nutrition and AI-enabled functional food innovation can support these goals when evidence standards are maintained [26-28].

Alignment with the FFC 17-Step Functional Food Development Model: As a conceptual contribution rather than an empirical study focused on a single product, this work bridges artificial intelligence integration across the entire 17-step model, enhancing efficiency, analytical depth, and feasibility while upholding human domain authority, mechanistic understanding, and scientific accountability.

In particular, the proposed AI-augmented approach supports Steps 1–3 (health target definition, literature review, and bioactive compound selection) through accelerated literature mining and predictive modeling; Steps 5–7 (biomarker identification, dose–response determination, and mechanism elucidation) via advanced omics and pathway analysis [16]; Step 10 (clinical trial design) with optimized stratification, as exemplified in recent high-quality randomized, double-blind, placebo-controlled human trials [4-8]; and, most critically, Steps 16 and 17 (post-market surveillance and epidemiological validation), where AI operationalizes large-scale real-world evidence analysis and feedback loops that have historically been challenging to implement. By embedding AI as a supportive tool within these steps without replacing expert oversight, this research strengthens the FFC model, advancing functional food science toward continuous, population-validated outcomes and sustained public health impact.

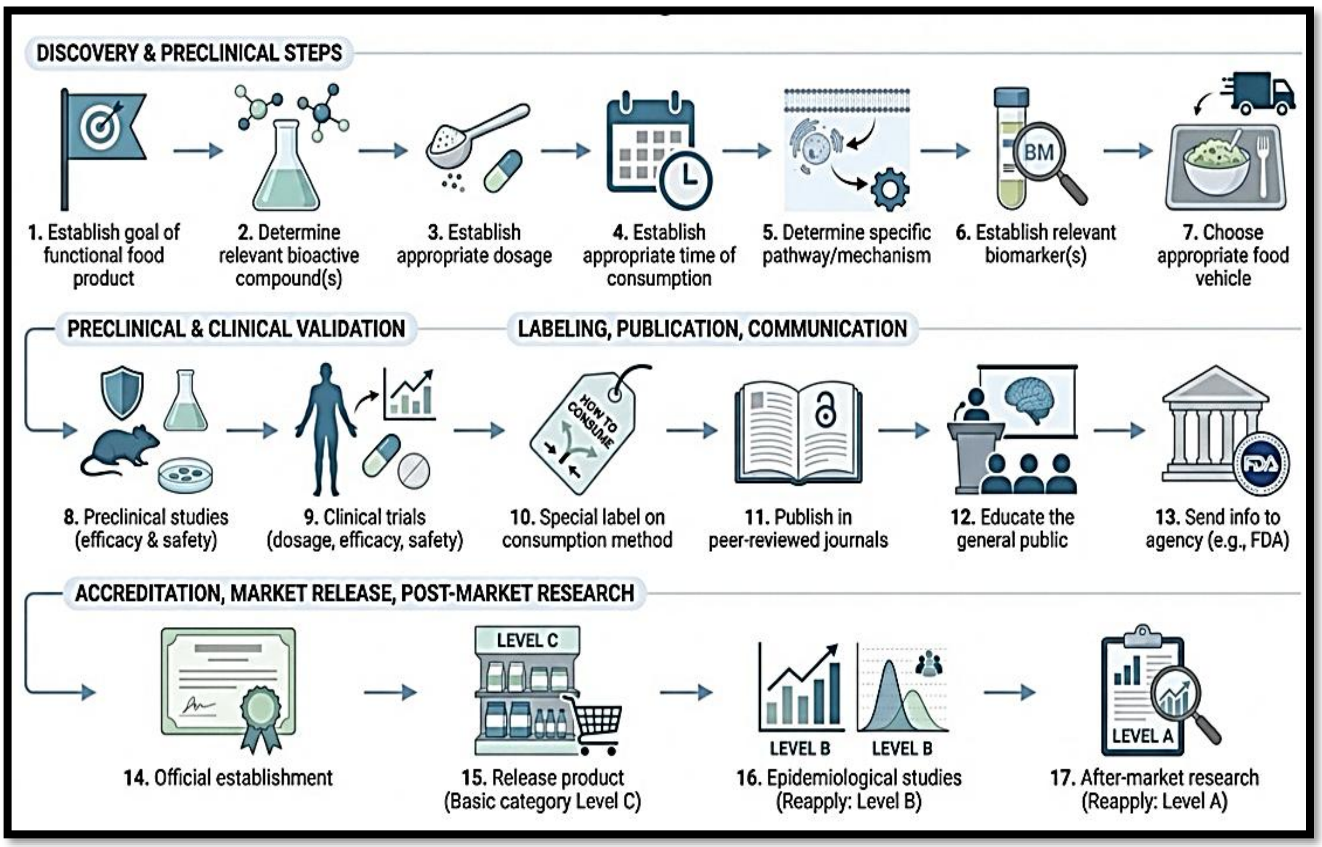


Figure 2: 17-step Functional Food Development Pipeline

Evaluating Scientific Evidence: FFC Standards for FFP in the Era of AI: The FFC has established a structured, evidence-based framework for the development of FFP, centered on the identification of specific bioactive compounds, elucidation of their mechanisms of action, determination of safe and effective daily dosages, and validation through in vitro, in vivo, human clinical, epidemiological, and post-market studies [9,11]. Within the FFC 17-step functional food development model, these activities correspond primarily to Steps 1–5, while longer-term population validation and post-market monitoring are addressed in Steps 9, 16, and 17 (see Figure 2) [11].

This framework emphasizes that bioactive compounds form the scientific backbone of FFP and that health benefits must be demonstrated using defined biomarkers and reproducible experimental and clinical evidence [11,32,34]. Functional food recognition therefore requires not only demonstrated efficacy, but also clearly established intake levels, duration of use, and safety margins supported by well-designed clinical and population-based studies [34-36].

In this context, artificial intelligence (AI) can enhance several stages of functional food development, particularly within the early and intermediate steps of the FFC model. AI-supported tools may assist in bioactive compound screening, dose–response modeling, biomarker identification, and systematic synthesis of evidence across large preclinical and clinical datasets [34-36]. When aligned with the FFC workflow illustrated in Figure 2, AI-supported analytics may facilitate more transparent and reproducible decision-making across the functional food development pipeline [34-36].

However, consistent with FFC standards, AI should be viewed strictly as a decision-support technology rather than a substitute for controlled experimental studies or human clinical trials [34-37]. Final validation of FFP must remain grounded in reproducible biological evidence, clearly defined biomarkers, and rigorously designed clinical investigations. When integrated responsibly within the FFC 17-step framework, AI offers an opportunity to improve efficiency and evidence synthesis while preserving the scientific rigor required for functional food development [34-37].

CONCLUSION

Functional Food Science has reached a stage where further advancement depends on rigorous structure, standardization, and the responsible integration of artificial intelligence. The Functional Food Center's definition of functional foods and the 17-step Functional Food Development Model (as detailed in Table 1 and Figure 2) provide the necessary roadmap to ensure scientific integrity and practical relevance. As an independent scientific discipline, Functional Food Science requires clear domain authority to guide research, evaluation, and translation. This aligns with broader scientific initiatives emphasizing rigor and transparency in biomedical research.

Integrating AI into this framework—restricted to studies meeting minimum quality thresholds—is essential to ensure that innovation remains grounded in validated science. By embracing this closed-loop model, the field can fulfill its goal of contributing to global health and wellness.

Abbreviations: FFC: Functional Food Center; FFS: Functional Food Science; AI: Artificial Intelligence; RWE: real-world evidence; FFP: Functional Food Product

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