

SELLING DIETARY SUPPLEMENTS IN U.S.A.

All you need to know to gain market access
and assure the regulatory compliance, safety,
and quality of your products.



Table of Contents

More rigorous quality control since 2015	3
Unique positioning and regulatory scrutiny	5
Globalized supply chain challenges	7
Essential regulatory requirements and industry driven standards	8
Technical knowledge for seamless compliance	10
Additional quality assurance measures	11
Conclusions	12
About Eurofins	13

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MORE RIGOROUS QUALITY CONTROL

SINCE 2015

The dietary supplement industry is experiencing a boom primarily driven by the increasing trend in digital sales, and has become a crucial segment for retailers, pharmaceutical companies, and food giants aiming to diversify their portfolios and capture a burgeoning market. The global dietary supplements market was valued at approximately 177.5 billion USD in 2023 and is projected to grow at a CAGR of 9.1% from 2024 to 2030, illustrating the lucrative potential of this market (Nutraceuticals World).

This trend is driven by several factors, including an aging planet, growing consumer awareness of health and wellness, advancements in nutritional science, and a global shift towards preventive healthcare. This is in turn driving growth with specialized retailers and brands, but also increasing the global export market. These trends drive increased risks as supply chains are globalized.

For traditional retailers, dietary supplements provide an avenue to enhance their health and wellness sections, attracting health-conscious consumers. Supermarkets and drugstores have increasingly dedicated more shelf space to vitamins, minerals, and other supplements, responding to the consumer demand for convenient access to these products.

Specialized retailers and nutrition-focused businesses have also reaped significant benefits from the growth of the dietary supplements market by providing high-quality supplements and personalized nutrition advice, catering to consumers looking for tailored health solutions. These retailers often offer in-store consultations with nutritionists and health experts, further differentiating themselves from general retailers.

In the midst of this rapid growth, the market has been hit by numerous allegations of quality concerns and legal challenges. The United States represents the single largest dietary supplement market hitting 64.4 billion USD in 2023 (Nutrition Business Journal). A seismic shift towards increasing requirements upon dietary supplement brands to prove the quality and compliance of their products arguably began in 2015, following the unprecedented action on the part of the New York State Attorney General ordering several major retailers to immediately cease selling supplements alleged to be adulterated and to not contain the ingredients listed on the product labels. The DNA analysis methods upon which the case rested was ultimately debunked, but the effect was to firmly establish the legal and reputational risk to retailers from the products on their shelves and to call the attention of consumers to these products.

While the total number of dietary supplement product recalls is still small compared to conventional foods, they have doubled from prior years in 2022 and 2023 (www.fda.gov/safety/recalls-market-withdrawals-safety-alerts) due in large part of increased Food and Drug Administration (FDA) testing of products sold online. FDA enforcement via Warning Letters has also shifted from solely targeting the product brands and mentioning the retailer, to issuing letters to retailers (FDA.gov).

Ensuring regulatory compliance, product safety and quality for this segment is thus an increasing necessity for manufacturers, brands and retailers, to meet consumer expectations and manage risk.

64.4 BILLION USD IN 2023

**The United States represents the single
largest dietary supplement market**





UNIQUE POSITIONING AND REGULATORY SCRUTINY

Dietary supplements occupy a unique position in the market, often straddling the line between food, pharmaceuticals, over-the-counter (OTC) medications, and even cosmetics. This positioning has led to heightened regulatory scrutiny as these products must meet stringent safety and quality standards.

The global regulatory landscape for dietary supplements varies by regions but generally includes rigorous testing and certification processes to ensure product safety and quality. In the United States, the FDA enforces regulations such as 21 CFR 111 and more recently 21 CFR 117 which outline current Good Manufacturing Practices (cGMPs) for dietary supplements. 21 CFR 101.36 regulations and the US Federal Trade Commission (FTC) both regulate product labeling and the types of claims made on product labels. These regulations ensure that supplements are produced consistently and meet quality standards. Additionally, industry-driven standards like the Global Retailer and Manufacturer Alliance (GRMA) and the Supplement Safety & Compliance Initiative (SSCI) help harmonize quality and safety standards across the industry.

Retailers and brands are now pushing downstream these requirements and certification standards through their supply chain, a sizeable part of which are coming from China and India.

China is the largest foreign supplier of dietary supplements ingredients to the US market. This dominance is driven by China's extensive manufacturing capabilities and the availability of raw materials required for supplement production. The US dietary supplement market continues to grow at rates estimated as ranging between 5-8% CAGR (Nutrition Business Journal, Market Research Future), influenced by trends such as increasing interest in nutrition as medicine, the popularity of organic and plant-based products, and the rising demand for multifunctional supplements that cater to multiple health needs simultaneously.



GLOBALIZED SUPPLY CHAIN CHALLENGES

The globalized supply chain of dietary supplements presents additional challenges. Ingredients sourced from various countries must comply with different regulatory standards, making quality control and traceability critical issues. Companies must implement robust supply chain management practices to mitigate risks such as contamination, adulteration, and mislabeling, and also ensure manufacturing conditions adhere strictly to Good Manufacturing Practices as required in their final markets.

Strong quality assurance and documentation control needs to be in place to ensure regulatory compliance locally and globally to manage an increasingly complex supply chain.



We see a growing demand to mitigate these risks in China and India particularly. While some manufacturing facilities already meet GMP expectations due to their existence in the pharmaceutical sector, suppliers emerging recently to take advantage of the growth in the market do not have any track record, or existing pharmaceutical experience at all, creating concerns in products' safety and quality.

ESSENTIAL REGULATORY REQUIREMENTS AND INDUSTRY DRIVEN STANDARDS

Many retailers, large brands and manufacturers now require a third party audit or certification to verify GMP is in place at their manufacturing sites and for all contracted co-manufacturers in their supply chain. While most retailer and brands will accept a number of third-party certifications as evidence of compliance, there are core elements of widely accepted certification programs.



INDUSTRY STANDARDS FOR DIETARY SUPPLEMENTS

21 CFR 111 (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements)

Administered by the FDA, this regulation involves the practices and documentation that are required to be in place for manufacturing dietary supplements, to support consistent quality of finished products. Any nonadherence to this regulation renders a dietary supplement adulterated in the US, and all dietary supplement programs must have this included within their scope for products sold in the US.



GLOBAL RETAILER AND MANUFACTURER ALLIANCE (GRMA)

GRMA is a joint force among retailers and manufacturers to coordinate high quality and safety standards to minimise the need for multiple supplier audits and certifications, as all members of the GRMA, and even some non-members, accept this certification. The GRMA dietary supplement certification is the only supplement certification in existence that combines all US dietary supplements regulations with best practices, GFSI benchmarking and ANAB accreditation. GRMA certification is available for dietary supplements, cosmetics & personal care items and OTC drugs.

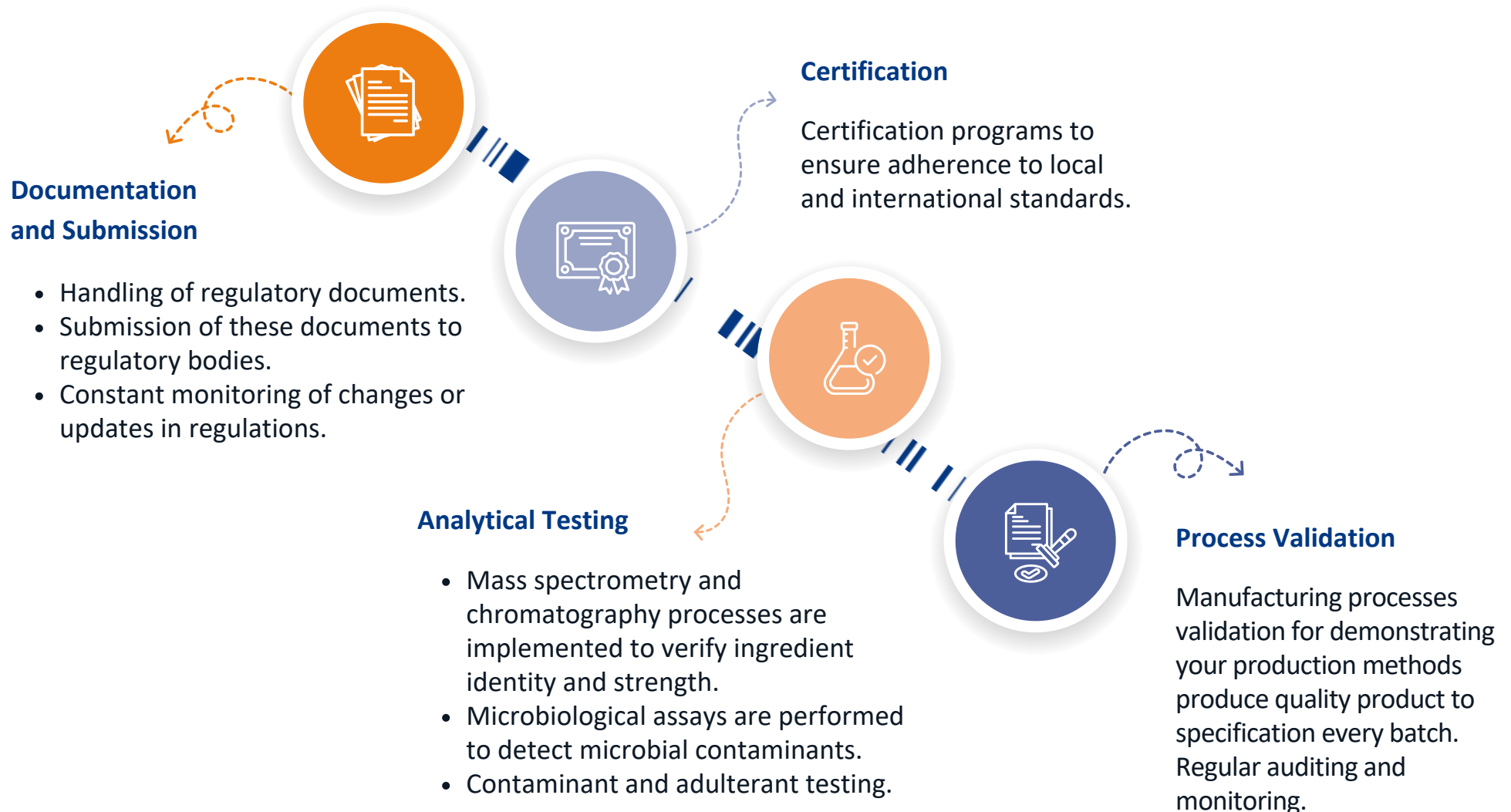


SUPPLEMENT SAFETY & COMPLIANCE INITIATIVE (SSCI)

SSCI is another industry-driven initiative that focuses on improving the safety, quality, and regulatory compliance of dietary supplement products. It provides a systematic mechanism for continuous improvement in both safety and quality, differentiating SSCI certified companies from their competitors, building brand equity and effectively managing risk.

TECHNICAL KNOWLEDGE FOR SEAMLESS COMPLIANCE

As many suppliers are new to the dietary supplements industry, they may lack in-depth understanding of regulatory and certification requirements. These suppliers come to us for technical support on a wide array of subjects:



BATCH TESTING

Official and periodical testing is performed on batches of a product at regular intervals. Maintenance of the test records in the process of established, validated methods without any loss of information should be well documented.

STABILITY TESTING

- Long-term stability testing to guarantee the effectiveness of the product over some time.
- Accelerated stability testing for quicker results.

PACKAGING AND LABELING COMPLIANCE

It is important to verify if the packaging materials are of required quality and specifications, and labels contain accurate information about the product that meets legal requirements of the country of sale. The U.S.A. has specific requirements for dietary supplements that need to be planned for during design and product development stages.

ADDITIONAL QUALITY ASSURANCE MEASURES

Employing robust quality assurance systems forms the backbone of compliance as quality cannot be improved or achieved overnight. Often we recommend dietary supplements suppliers to implement these extra steps for higher assurance.



RISK MANAGEMENT STRATEGIES

Implementing a frequent supplier audit program that involves supplier GMP certification and manufacturing practices review is an effective way to ensure strict adherence to your quality assurance and control program.

QUALITY CONTROL MEASURES

Strict quality control measures such as clear in-process specifications. Extensive monitoring and testing of raw materials and end-products.

TRACEABILITY SYSTEMS

- Traceability across the entire supply chain from raw material origin through finished product distribution, tested by regular traceability exercises.
- Clear procedures able to deliver swift action to quarantine or recall product with quality problems, proven by successful mock recalls.

CONCLUSION

While the dietary supplement requirements illustrated are primarily for the U.S.A., with dietary supplements markets booming worldwide, and with increasing scrutiny by consumers, regulators, retailers and brand owners all seeking pure, quality products, it is inevitable that similar regulations targeting this product type will emerge in other markets. The demand driven by online dietary supplement sales in a globalized supply chain environment underscores the need for transparency and safety throughout the supply chain. Whether you are planning to enter the market or are experienced in supplement product manufacturing, observing these regulatory requirements is fundamental and the need for continuous improvement to remain competitive in this changing compliance landscape is vital.



ABOUT EUROFINS ASSURANCE

Eurofins Assurance network of companies helps customers identify and mitigate risks along their supply chain with operations, processes, systems, people or capabilities across various industries.

We can deliver SSCI, GRMA and 21 CFR 111 certification worldwide, supporting compliance with our audit expertise and certification capabilities. Find out more on our dietary supplement certification at www.eurofins.com/assurance/.

Visit Eurofins Food & Feed Testing if you are looking for testing and analytical support www.eurofins.com/food-and-feed-testing/.

References

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