

SUPPLEMENTS

With the differing pre-market requirements and ever-changing regulatory landscape, developing a well thought-out strategy is key to identifying the most efficient route to market and becoming an industry leader.



Whether they are referred to as dietary or food supplements, natural health products, or complementary medicines, one thing is clear: with the increasing availability of such products, regulatory authorities are demanding greater standards of evidence to ensure that the public has access to products that are safe, effective, and of high quality.

Your Challenge

The regulation of supplement products differs around the world, with some jurisdictions considering these products as foods, and others as drugs. The types of health claims and accompanying standards of evidence differ, with structure-function claims permitted in certain countries, and treatment and disease risk reduction claims allowed in others.

In addition, some regulatory frameworks have a review process for supplement ingredients, while others only consider the licensing of finished products. Standards for good manufacturing practice to ensure quality also differ, with some countries requiring the inspection and licensing of facilities involved in the manufacture of finished products. You need a clear understanding of the global regulatory landscape surrounding supplements, and a trusted partner who can effectively guide your ingredient or product to market.

Our Solutions

Intertek Assuris offers expert advice in the area of supplements and natural health products.

Our services include:

- Conducting feasibility assessments and providing recommendations to meet regulatory requirements for safety, efficacy, and quality;
- Compiling technical and scientific submissions to regulatory authorities, including new dietary ingredient notifications, product license applications, ingredient master files, and complementary medicines applications;
- Providing product development support;
- Assisting in the design, placement, monitoring, and management of clinical trial protocols for claim substantiation;
- Preparing expert opinion letters;
- Acting as a liaison with regulatory authorities during the submission review process; and
- Administering programs to meet post-market requirements, including adverse event reporting, regulatory monitoring, and surveillance programs.

The Intertek Advantage

Intertek's scientific & regulatory consultants have been successfully delivering expert advice for more than 30 years. Our dedicated team of scientists have a thorough knowledge of the scientific and regulatory requirements for supplements and natural health products in several jurisdictions, such as Australia/New Zealand, Canada, the European Union, and the United States. Our expertise in multiple jurisdictions makes us uniquely well-positioned to help you develop the most efficient and cost-effective strategy for bringing your products to market.

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

Total Quality. Assured.

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