Your partner in bringing products to market with strong science and regulatory confidence – from concept to claim

About Nutrasource

Nutrasource is the leading Nutraceutical and Pharmaceutical Life Sciences company that brings together the strategy, expertise and services required to help clients commercialize health and wellness products with strong science and regulatory confidence globally.

Our unique offering of clinical trial management, strategic and regulatory support services along with a state-of-the-art clinical trial site has been developed with one goal in mind – your success in the marketplace. We also offer a series of third party certification programs focused on natural health ingredients such as omega-3s (IFOS™), probiotics (IPRO™), non-GMO (IGEN™), and CBD (ICAP™).

2001

William Rowe launches omega-3 diagnostic test with Dr. Bruce J. Holub

2002

Nutrasource Diagnostics Inc. founded; Omega Score test enters U.S. and Canadian markets

2003

The company expands services to include global dietary supplement product testing

2004

IFOS certification program launched internationally; 12 full-time regulatory and corporate management staff hired

2005

New 5,000-square-foot clinical trials facility built; clinical trials team added

2006

First clinical trial published in a peer-reviewed journal

2008

The company creates divisions for Nutrition and Nutraceutical Research, Clinical Trials, and Product Analytics and doubles its staff

2010

First food health claim application submitted to Health Canada; the company takes on a new brand image, logo, and company slogan:

nutrasource diagnostics inc.

From nature to science... From science to you

Our Story

Nutrasource was established in Canada in 2002. Since then, the company has grown from a single desk in a small office unit to a global CRO and consulting firm. Headquartered in Guelph, Ontario, Nutrasource is positioned in the heart of Southwestern Ontario's agricultural, nutrition, and biotechnology research hub and currently employs over 150 staff globally.

Over the past nearly two decades, Nutrasource has expanded its services far beyond its original omega-3 blood test to include international regulatory capabilities, certification programs, clinical trials, and complete testing solutions for a vast array of consumer health products.

In recent years, regulatory firm GRAS Associates was acquired to better serve the U.S. market, providing food safety regulatory solutions for a wide range of products.

By focusing first and foremost on the needs of its customers, we are proud to have helped hundreds of health product companies develop, launch and market safe, effective, high-quality products to better people's lives through improved health and wellness.

2011

Nutrasource expands to include pharmaceutical consulting solutions; the company now has over 50 employees

2014

U.S. regulatory firm, GRAS Associates, is acquired; services expand to include full food safety and regulatory consulting services; 10th anniversary of IFOS

GRAS ASSOCIATES
Food Safety Regulatory Services, A Nutrasource Company

2016

IGEN certification program launched in North America; clinical trials group expands and divides to site and CRO

2017

The company rebrands to **Nutrasource Pharmaceutical and Nutraceutical Services** to expand leadership position in the marketplace and better showcase service offerings

nutrasource
Pharmaceutical and Nutraceutical Services

2019

Grand Reopening of Nutrasource Headquarters; Major expansion to Guelph-based clinical trials site from 3,500 to 7000 ft^2; IPRO certification program launched

2020

Additional clinical trials site expansion to > 10,000 ft^2; ICAP certification program launch

2021

Nutrasource receives Institution-Wide Cannabis Research Licence from Health Canada; staff growth to 150+ staff globally

WHY NUTRASOURCE?
Experience the Difference

Nutrasource brings the capabilities and scientific acumen of an international CRO while delivering the high-quality results you'd expect from your own team.

No other consulting firm in the dietary supplement sector brings together more expertise in nutrition, regulatory affairs, and pharmaceutical science to help our clients achieve compliance and gain market entry.

As holders of the Institution-Wide Cannabis Research Licence, Nutrasource is proud to be the first privately held and independent CRO that has been granted this type of licence for human research from Health Canada.

Working with Nutrasource, you will benefit from:

- A wide range of solutions for any stage of the product life cycle and supply chain
- Customized solutions and service packages tailored to your organization's needs
- A "pharma-lite" approach for optimum regulatory compliance
- Integrated, interdisciplinary project management terms
- Strategic consideration of regulatory, clinical, marketing, and intellectual property implications
- Global experience in a variety of markets, from functional beverages and probiotics to pharmaceutical omega-3s

INNOVATIVE STRATEGIES

IN-HOUSE EXPERTISE

"PHARMA-LITE' APPROACH

SUPERIOR QUALITY

INTEGRATED TEAMS

EXTENSIVE CATEGORY EXPERIENCE

THE NUTRASOURCE APPROACH: Starting with the End in Mind

Companies face many barriers to market entry, including budget, timelines, and pressure to be innovative. Often, the greatest challenge is figuring out what you want to say about your product—and what you *can* say—based on what it contains, how it works, and where you want to sell it.

At Nutrasource, we start with the end in mind—the desired label claim—and work backwards to develop a strategic solution to achieve your objectives.

Through our "pharma-lite" approach, we adopt key aspects from the pharmaceutical industry to provide our clients with opportunities for prolonged market access, additional claims, further regulatory classifications, and future development opportunities.

To accomplish this, we work with Sponsors from the initial idea stage through to the final project report to determine exactly what is required and how the research program should be designed to meet the client's goals. A comprehensive proposal is developed which outlines the Sponsor's objectives, budget, and our custom solution to deliver on these requirements. A project kick-off meeting is held to review scope, deliverables, and timeliness as well as key documents including the project management plan, communication plan, data management plan, statistical analysis plan, and publication plan.

With input from the client's marketing and scientific groups, we build on our vast experience to develop claims strategies based on risk, regulatory precedent, current market gaps, and competitive positioning in different jurisdictions.

By starting with the end in mind, our team has successfully completed thousands of projects for a wide range of clients by harnessing the power of Nutrasource's end-to-end capabilities, committed teams, and transparent partnership environment.

Explore our solutions to learn how we help companies gain market access – from concept to claim.

Through our concept to claim approach, we will help you:

MARKETS WE SERVE

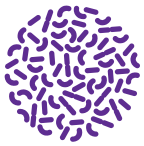
We have in-depth experience in a broad range of health product markets – from foods to pharmaceuticals and everything in between.

Our experienced team will guide you on the pathway to market by assessing and resolving gaps in your strategy to ensure your product is supported by robust scientific evidence.

WE OFFER SERVICES FOR:

DIETARY SUPPLEMENTS AND NATURAL HEALTH PRODUCTS

PHARMACEUTICALS

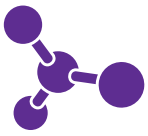


PROBIOTICS

OMEGA-3S

CANNABIS AND CBD

HERBS AND BOTANICALS



VITAMINS AND MINERALS

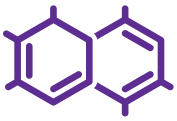
FATS AND OILS

ENZYMES

RAW MATERIALS AND INGREDIENTS

FOODS AND BEVERAGES

MEDICAL FOODS



BIOLOGICS

MEDICAL DEVICES

COSMETICS AND COSMECEUTICALS

AGRICULTURAL PRODUCTS

PET FOODS AND SUPPLEMENTS

COMBINATION PRODUCTS

SOLUTIONS WE PROVIDE

Nutrasource provides full regulatory, clinical, and testing services for all types of health products at any stage of the R&D process, product life cycle, or supply chain globally.

Through our customized project management approach, our experts will work collaboratively with your team to find a solution customized to your business goals, timelines, and budget.

Our top priority is to ensure you have confidence in your product's safety, efficacy, and quality so that you can sell more in an increasingly competitive marketplace.

Research & Development

- Project management teams focused on your unique products and objectives
- End-to-end solutions for all consumer types and markets

Clinical Trials

- Pharmaceutical-level trials for optimum quality and results, scalable to meet your goals
- Seamless regulatory integration

Claims & Certifications

- Global marketing tools that showcase transparency
- Label claims supported by real science
- Third-party certification programs

Regulatory Strategy

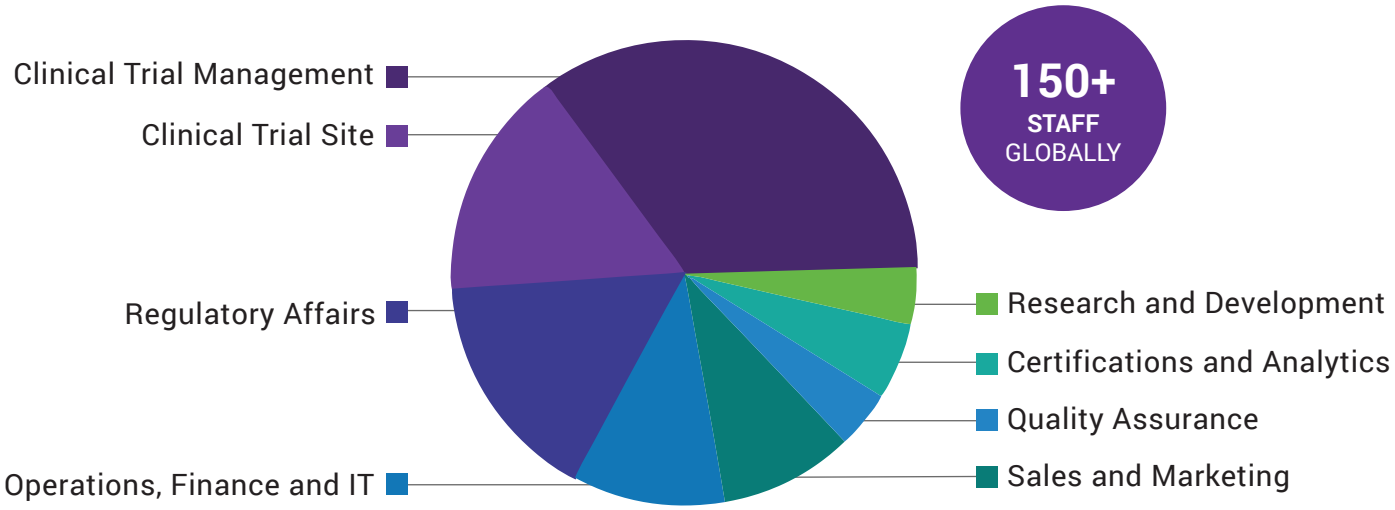
- Forward thinking solutions that maximize market potential

Testing Solutions

- The latest technologies and equipment for characterization, identification, and standardization

STAY NUTRASTRONG™ WITH NUTRASTAFF

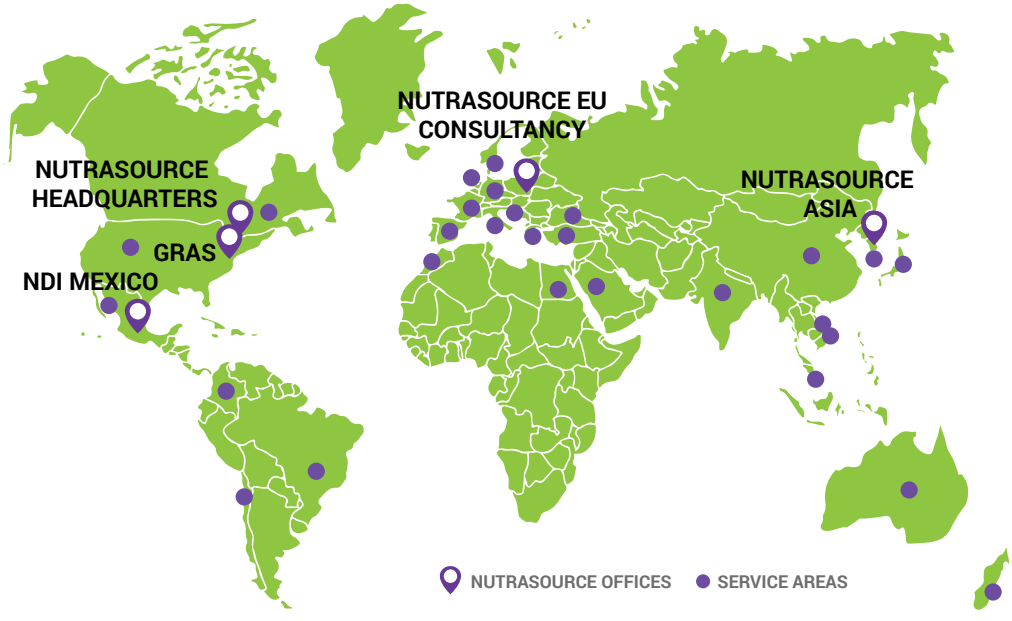
You can count on our team of scientists, experts & industry leaders from food to pharmaceuticals and everything in between.



No other consulting firm in the dietary supplement sector brings together more experience in nutrition, regulatory affairs, and pharmaceutical science to help our clients achieve compliance and gain market entry in the U.S., Canada, the E.U., Asia Pacific, and many other countries globally.

By starting with the end in mind—the product claim—our team has successfully completed thousands of projects and over 1700 clinical trials across our team for a wide range of ingredients and product types through our end-to-end capabilities, committed staff, and transparent partnership environment.

Trade Associations and Memberships



ADAPTING TO THE PANDEMIC: COVID-19

While staff and clinical trial participant safety is our top priority, we are also sensitive to project timelines and deliverables and have implemented a series of new processes. We are proud to have strong leadership and a flexible team that continues to deliver for our clients. Each day we continue to implement procedures to mitigate risks due to the ever-changing situation.

Project Management

To ensure continuance of projects with minimal deviations, we monitored locations surrounding current sites for COVID-19 infection rates and status as well as during the site selection phase to implement contingency strategies. Protocol changes were made as per guidelines.

Data Management

Specific guidances were provided by FDA, CDISC, and MeDRA for what data needed to be captured in trials, how it was to be captured and how it was to be coded. We implemented these across all ongoing and future studies.

Trial Monitoring

Due to travel restrictions and border closures, most on-site trial visits were shifted to remote monitoring. This required new processes and platforms compliant with privacy laws to be implemented to facilitate oversight of sites and data integrity.

Study Types

Prior to the pandemic most studies were on-site, with decentralized trials being a more novel concept. However, during the pandemic some trials remained on-site while others moved to a hybrid model and we saw an increase in interest in decentralized trials. Depending on the protocol, we can see a future of hybrid models.

GCP Compliance

Our team actively monitored regulatory guidance from global regulatory agencies to keep up to date of provisions for trial conduct. We monitored guidelines, Q&As and attended regulatory and ethics sessions to learn and apply requirements to ongoing and future clinical trials.

Efficacy Endpoints

Depending on the study design it may be of interest to exclude subjects who have had COVID-19, especially with potential residual effects confounding product efficacy. In other cases, including only vaccinated participants may reduce potential SAEs. It truly depends on the research question and study product.

COVID-19 Infection

In the event of a study subject testing positive, it would be treated like any other adverse event. If hospitalization occurs, we would follow SAE procedures and reporting. Depending on the protocol, the subject may be withdrawn from the study.

Options for Sponsors

We offer customizable solutions based on project risk and Sponsor risk tolerance. For example one of our Sponsors has chosen to do rapid testing on trial participants if symptoms occur during the study or every two weeks otherwise.

Multiple Trials

With numerous ongoing trials and many in start up, we quickly assessed projects and risks which allowed us to respond rapidly and continue our trials. To prevent delays and deviations, we focused on delivery of study product and materials to sites as border closures were a major concern.

PRODUCT DEVELOPMENT STRATEGY: Unlock Your Product's Potential

At Nutrasource, we take a project management approach to build strategic, focused product development plans that include an assessment of the risks and benefits of potential regulatory routes, scientific literature reviews, non-clinical and analytical testing, and an analysis of potential health and marketing claims.

Our product development services include:

- Project Management
- Theoretical Product Review
- Clinical Development Strategy
- Pre-Clinical Program Management
- Dietary Supplement to Drug Strategy

REGULATORY CONSULTING: Gain Global Market Access

The regulatory requirements for health products are constantly evolving. Knowing how your product might be affected by the latest changes—whether it's on the market now or still under development—can be a challenging task for any company.

Our knowledgeable team will guide you through the complex regulatory framework so you can gain market access quickly and efficiently.

Global Regulatory Solutions

- Compliance Consulting
- Health Claims Substantiation
- Scientific Literature Reviews
- Product Classification
- Nutrition Facts Panel Review
- Technical Label Review
- New Drug Submissions (NDS) and New Drug Applications (NDA)
- Abbreviated New Drug Submissions (ANDS) and Abbreviated New Drug Applications (ANDA)
- Biologic License Applications (BLA)

Canadian Regulatory Solutions

- Natural Health Product (NHP) Licensing
- Temporary Marketing Authorization (TMA) Applications
- Master File Submissions
- Natural Health Product (NHP) Site Licensing
- Drug Establishment Licensing

U.S. Regulatory Solutions

- Generally Recognized as Safe (GRAS)
- New Dietary Ingredient Notifications (NDIN)
- Medical Food Applications
- Dietary Supplement Facts Panel Review
- Novel Food Notifications
- Food Colouring and Additive Petitions

3,000+ projects successfully completed

2,000+ clients represented

98.75% success rate of FDA filings

20K+ supported product launches

CLINICAL TRIALS:
Support Claims With Robust Science

Your product has potential to improve human health globally. Bring your innovations to life and access the lucrative health products market through clinical research.

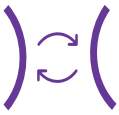
At Nutrasource, we bridge the gap between pharmaceutical CROs and the nutrition research industry to provide you with the clinical trials solutions you need in the most cost-effective manner possible.

With an experienced team and access to more than 250 clinical trial sites across North America, we have completed over 1700 clinical trials to help our clients achieve their market launch objectives.

OUR CLINICAL TRIAL EXPERIENCE INCLUDES THE FOLLOWING HEALTH INDICATIONS:

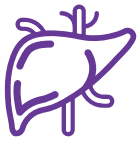
Gastrointestinal

- Gastroesophageal Reflux Disease (GERD)
- Bowel function/laxation
- Irritable Bowel Syndrome (IBS)
- Crohn's disease
- Leaky Gut



Metabolism

- Pharmacokinetics and bioavailability
- Lipid metabolism
- Glucose metabolism
- Weight loss and weight management
- Metabolic syndrome



Hepatic Function

- Non-Alcoholic Fatty Liver Disease (NAFLD)

Cardiovascular

- Cholesterol
- Hypertension
- Metabolic syndrome

250+ clinical sites across North America

7000+ contacts in patient database

1700+ clinical trials completed across our team

40+ health indications our team has experience in

100+ clinical trial applications filed

Immunity

- Immune Health
- Immune Function
- Respiratory Health
- Anti-aging

Cognitive Function

- Sleep
- E-gaming
- Memory
- Stress and anxiety
- Alertness and mental energy

Bone and Joint Health

- Osteoarthritis
- Bone Mineral Density

Respiratory/Immunity

- Cold and flu
- Allergy

Women's Health

- Menopause
- Vaginitis
- Memory
- Urinary Tract Infections (UTIs)
- Hair growth
- Breastmilk

Men's Health

- Testosterone
- Erectile dysfunction (ED)
- Hair growth

Pediatric Health

- Infant nutrition
- Cold and flu
- Growth and development

AS YOUR CLINICAL TRIAL PARTNER, NUTRASOURCE WILL HELP YOU:

Strategically Design Your Trial

- Clinical Project Management
- Clinical Trial Design
- Feasibility Studies

Achieve Regulatory Authorizations

- Clinical Regulatory Affairs

Optimize Your Trial Execution

- Early Clinical Development
- Phase I Through IV Clinical Trials
- Seamless Phase Studies
- Adaptive Trial Designs
- Rescue Studies
- Site Selection and Management

Analyze & Report Your Results

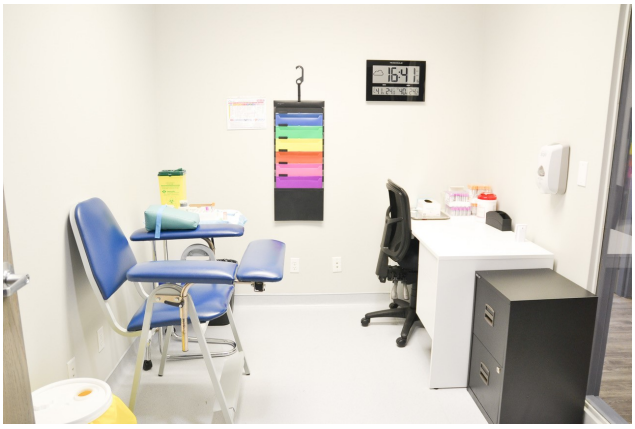
- Bioanalytics
- Medical Affairs and Pharmacovigilance
- Biostatistics

Maximize Clinical Service Solutions

- Full-Service Solutions
- Functional Services
- Pharmacy
- Medical Writing Services
- On-Site Clinical Trial Services
- Monitoring
- Data Management
- Archiving

DISCOVER:
Clinical Trial Site, Guelph

Clinic Reception and Lobby



Phlebotomy Station (1 of 3)

Examination Room (1 of 4)

Pharmacokinetic (PK) Study Area 1

Participant Kitchen

NEW
Additional
3,000 ft^2

Pharmacokinetic (PK) Study Area 2

Processing Laboratory (1 of 2)

NEW
Lab
Extension

Processing Laboratory (1 of 2)

ANALYTICAL & BIOANALYTICAL TESTING: Gain a Competitive Advantage

Ensuring your ingredients and products comply with safety and quality standards is critical to any market launch strategy. Evidence supporting your product's high quality—whether through a marketing claim, certification mark, or QA/QC documentation—helps set you apart from competitors.

We provide high-standard analytical and bioanalytical testing services in compliance with global regulatory authorities including the U.S. FDA and Health Canada for all categories and dosage forms.

Confirm Potency & Characterization

- Active Ingredient Testing
- Nutrition Analysis
- Physical Property Testing
- Species Identification

Verify Purity & Stability

- Stability Testing
- Microbial Contaminant Testing
- Heavy Metals Testing
- Herbicides and Pesticides Testing
- Radiation Testing
- Oxidation Testing
- Allergen Testing
- Stability Studies

Support Your Pharmaceutical Development

- In Vitro Release Testing (IVRT)
- Analytical Method Development
- Quality Control Release Testing
- Formulation Validation Support Testing

Substantiate Your Unique Product Claim

- Assay Method Development, Validation, and Transfers
- Preclinical and Clinical Bioanalysis
- Large Molecule Analysis
- Metabolite Identification

LABORATORY NETWORK CAPABILITIES LIST:

- RT-PCR, Digital-PCR
- HPTLC
- HPLC-UV, HPLC-RI, HPLC-ELSD
- LC-MS, LC-MS/MS
- GC-FID, GC-MS
- ICP-MS
- HRMS
- UPLC/MS/MS
- GFC
- UPLC-UV, FI, ECD
- Capillary Electrophoresis (CE)
- ELISA (Immunochemistry)
- Gel Image Analysis System
- Stability Chambers – fully validated Rees Scientific Centron Monitoring System®

ICH STABILITY STORAGE CONDITIONS

- Customized conditions
- Photostability (UV and daylight)
- Available space for expansion to meet any stability requirements
- 25°C/60% RH
- 30°C/65% RH
- 40°C/75% RH
- 5°C, -20°C, -80°C

CERTIFICATION PROGRAMS: Stand Out On The Shelf

For clients looking to target the end consumer—the retail customer—label certifications are an effective marketing tool.

Nutrasource offers testing-based certifications supported by quality science to help brands showcase the safety, efficacy, and quality of their products.

Product categories include omega-3 fatty acids, probiotics, and foods and dietary supplements that may contain genetically modified organisms (GMOs).

Nutrasource is the creator and exclusive provider of the following certifications:

- International Fish Oil Standards Program (IFOS™)
- International Genetically Modified Organism (GMO) Evaluation and Notification Program (IGEN™)
- International Probiotics Testing Program (IPRO™)
- International Cannabinoid Analysis Program (ICAP™)

150+ brands certified

50+ countries with certified products

20K+ product lots tested

Certifications by nutrasource
Pharmaceutical and Nutraceutical Services

International Fish Oil Standards (IFOS™)

IFOS™ allows marine oil companies to test and certify their products based on the highest quality, safety, and purity standards in the world. No other certification program tests fish oils by individual lot number, making it easy for shoppers to find what they are looking for.

International GMO Evaluation and Notification Program (IGEN™)

IGEN™ offers a testing-based solution for dietary supplement companies to certify products based their non-GMO status. This provides consumers with transparency in making informed GMO choices based on real scientific data.

International Probiotic Standards (IPRO™)

IPRO™ gives probiotic manufacturers and brands the opportunity to certify their products based on third-party verified testing results. Having this certification increases consumer confidence and improves decision-making in the probiotic market.

International Cannabinoid Analysis Program (ICAP™)

ICAP™ is a compliance program for CBD and other cannabinoid products. It ensures that products and ingredients meet label claims related to the concentration of THC, CBD, and other minor cannabinoids. ICAP™ also ensures product testing for contaminants such as heavy metals, pesticides, residual solvents, mycotoxins, and microbes.

Why Certifications Can Better Serve Your Brand

Shoppers are more concerned about what's in the products they consume than ever before. Consumers want to see everything from a complete ingredient breakdown to sourcing information. If a brand doesn't provide them with this information, consumers will look elsewhere for it.

This puts brands in a vulnerable position. It means being open and honest about how products are made, what ingredients they contain, and what measures were taken to guarantee quality.

By having your products certified by IFOS™, IGEN™, IPRO™ or ICAP™, it's a signal of commitment to transparency through science. Certifications by Nutrasource fosters a relationship of trust - the cornerstone of transparency - between companies and people.

For more information visit **www.certifications.nutrasource.ca**.

Ready to commercialize your innovations?

CONTACT OUR TEAM TODAY TO DISCOVER YOUR PATHWAY TO MARKET.

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