nutrasource

Pharmaceutical and Nutraceutical Services

Support claims.
Gain market access.

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

About Nutrasource

Nutrasource Pharmaceutical and Nutraceutical Services is a full-service contract research organization (CRO) that helps health companies bring products to market with strong science and regulatory confidence.

Through our vertically-integrated service platform, Nutrasource is your one-stop shop for international regulatory, clinical, and product testing solutions for dietary supplements, pharmaceuticals, and everything in between.

As your virtual R&D department, we will help you tackle your toughest scientific problems so you can sell safe, effective, high-quality products to improve healthcare globally.

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

The International Fish Oil Standards (IFOS) testing and 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 name: Nutrasource

Our Story

Established in 2002 as an omega-3 diagnostic test provider, Nutrasource has since grown from a single desk to a global CRO employing over 100 staff across four sites in North America.

Over the past nearly two decades, Nutrasource has invested in the latest research infrastructure and top scientific talent to meet our clients' needs as the health products industry evolves.

By focusing first and foremost on the needs of our customers, we are proud to have helped hundreds of clients develop, launch, and market health products across the globe.

2011

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

2013

Diteba, a pharmaceutical laboratory, is acquired; 35 analytical chemists and pharmaceutical scientists hired to meet demand for topical drug testing

DITEBA
Analytical & Bioanalytical Services
A Nutrasource Company

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 GMO certification program launched in North America; clinical trials team adds 6 full-time employees

2017

The company celebrates its 15th anniversary and takes on new corporate identity: Nutrasource Pharmaceutical and Nutraceutical Services.

nutrasource
Pharmaceutical and Nutraceutical Services

2018

Diteba laboratory expansion begins to double testing capacity; Nutrasource looks to a bright future helping its clients commercialize their innovations

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.

Working with Nutrasource, you will benefit from:

- A wide range of solutions for any stage of the product life cycle and supply chain
- Customizable service packages tailored to your organization's needs
- A "pharma-lite" approach for optimum regulatory compliance
- Integrated, interdisciplinary project management teams
- 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 how Nutrasource will deliver on these requirements. A project kick-off meeting is held to determine 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

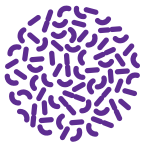
We have in-depth experience in a broad range of health product markets – from foods to pharmaceuticals and everything in between.

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

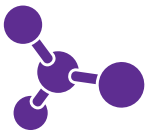


PROBIOTICS

OMEGA-3S

CANNABIS AND CBD

HERBS AND BOTANICALS



VITAMINS AND MINERALS

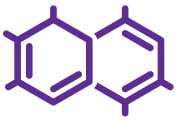
FATS AND OILS

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 team brings over 120 years of combined experience in nutritional science, clinical trials, and pharmaceutical development. 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
- Seamless regulatory integration

Claims & Certi ications

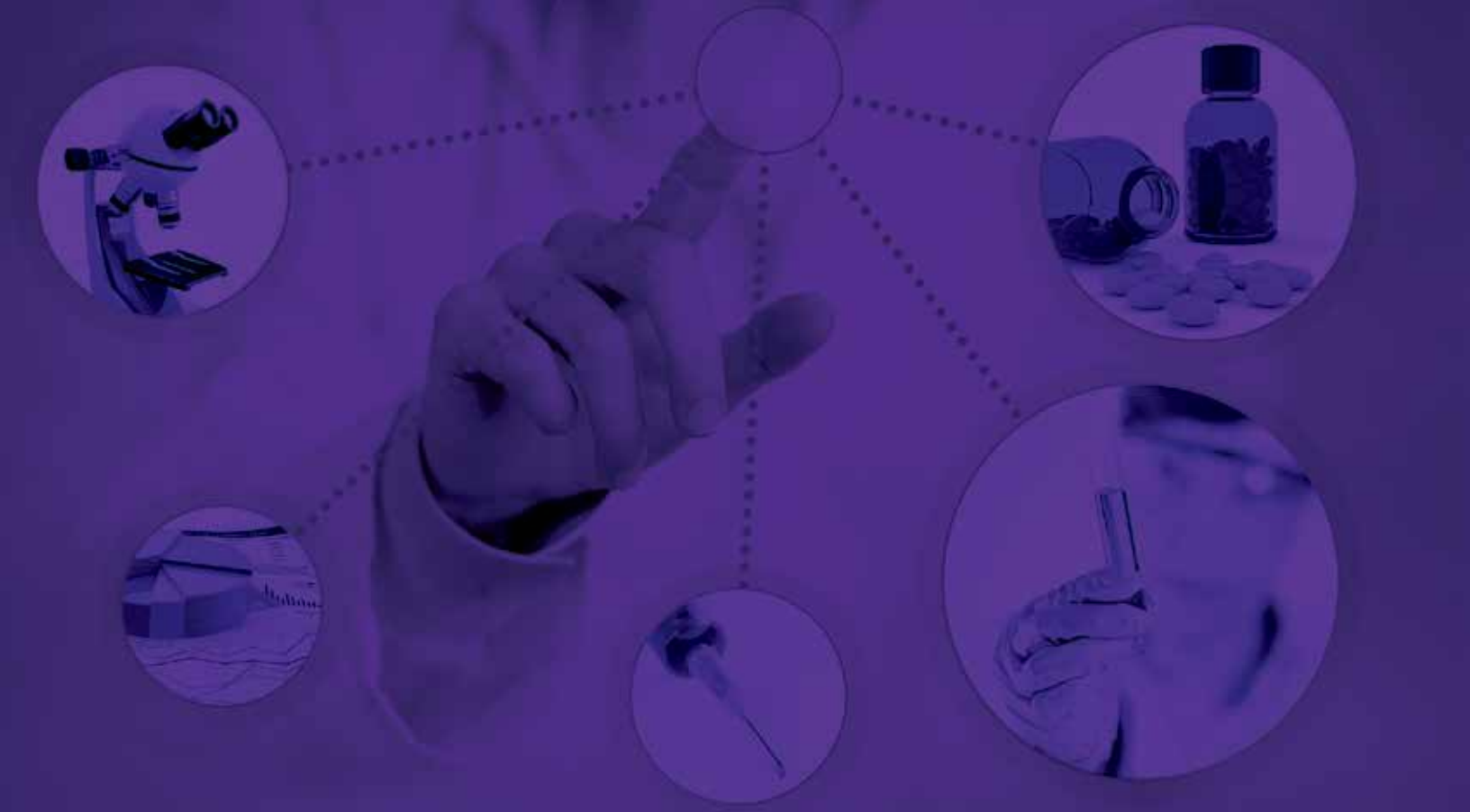
- Global marketing tools that showcase transparency
- Label claims supported by real science
- Third-party certification programs

Regulatory Strategy

- Forward thinking solutions that maximize market potential

Testing Solutions

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



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

2,000+ regulatory applications filed

97% success rate

100+ scientific & regulatory staff

250+ years combined experience

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 100 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

Cognitive function

- Alertness
- Memory
- Stress

Bone and joint health

- Osteoarthritis
- Bone Mineral Density

Women's health

- Menopause
- Vaginitis
- Urinary tract infections (UTIs)
- Hair growth

Men's health

- Testosterone
- Erectile dysfunction (ED)
- Hair growth

Respiratory

- Cold and flu
- Allergy

250+ clinical sites across North America

100+ clinical trials conducted

3,000+ subjects in patient database

75+ clinical trial applications filed

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 II/III Clinical Trials
- Phase IV Clinical Trials
- Rescue Studies
- Site Selection and Management
- Monitoring
- Data Management

Analyze & Report Your Results

- Bioanalytics
- Medical Affairs and Pharmacovigilance
- Biostatistics

Maximize Clinical Service Solutions

- Full-Service Solutions
- Functional Services
- Pharmacy
- Archiving
- On-Site Clinical Trials Services

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 EQUIPMENT 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).

- International Fish Oil Standards (IFOS) Program – fish oils
- International GMO Evaluation and Notification (IGEN) Program – non-GMO for dietary supplements
- International Probiotics Testing Program (IPRO) – probiotics

IFOS

Launched as Nutrasource's inaugural certification program in 2002, 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. www.ifosprogram.com.

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. www.igenprogram.com

IPRO

IPRO allows probiotics manufacturers and brands to certify their products based on third-party verified testing results to increase consumer confidence and improve decision-making in the probiotics market.

150+ brands certified

50+ countries with certified products

15K+ product lots tested

Ready to commercialize your innovations?

CONTACT OUR TEAM TODAY TO DISCOVER YOUR PATHWAY TO MARKET.

nutrasource
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DiTEBA
GRAS ASSOCIATES

Nutrasource
120 Research Lane, Suite 203
Guelph, Ontario, Canada N1G 0B4

info@nutrasource.ca
+1 877 557 7722
www.nutrasource.ca