kgkscience.com

The Science Behind Success

KGK Science | Premium Clinical Research & Regulatory Expertise

A PREMIUM CRO

Mission:

KGK Science is a leading CRO in the nutritional and cannabinoid industries, providing scientific and regulatory services to generate profit for our clients.

Vision:

To be the premier and most trusted CRO for nutritional and cannabinoid scientific research by revolutionizing the way people think about evidence-based nutrition.

Supporting Your Business with High-Quality Expertise

KGK Science is a premium contract research organization (CRO) offering high-quality clinical research trials and expert regulatory support for the nutraceutical, cannabis and hemp industries.

Over 23 years, KGK has successfully helped hundreds of companies with custom designed clinical trials and claim substantiation strategies that move products efficiently into global markets. Equipped with state-of-the-art technologies, novel research techniques, and a seasoned team of industry experts, KGK Science remains at the forefront of our industry, consolidating scientific, clinical, commercial, and regulatory expertise with innovation and agility to serve the expanding needs of global business and consumers.

Premium Clinical Research

- Pre-Clinical Services
- Clinical Trial Design & Execution
- Clinical Research Consulting Services
- Pharmaceutical Trial Services

Expert Regulatory Services

- Claim Substantiation & Review
- Safety & Risk Assessments
- Product Licensing
- Regulatory Consulting
- Serious Adverse Event Reporting

> *As part of our multi-million-dollar research program, KGK has played an important role in helping us confirm the health benefits of our products, especially VitaFiber™IMO. Their clinical trial research has contributed to our submission and product acceptance by the world's top health regulatory agencies. They are a thoroughly professional organization with a strong understanding of businesses' requirements.*

Vinti Goel
Vice President, BioNeutra North America Inc.

23
Years in Business

350
Clinical Trials
conducted across **42** indications

10M
Datapoints Collected

85
Full-time Employees

150+
Publications

25,000+
Participant Database

Substantiating Success in the Natural Health Product Industry

Since 1997, KGK Science has played a key role in the natural health product industry by providing our clients with high-quality clinical research and regulatory expertise to bring safe and effective products to global markets. As a full-service premium CRO supporting the nutraceutical, cannabis and hemp industries, KGK is one of the most reliable resources for brands looking for an experienced, trustworthy team of scientific researchers, consultants, and regulatory specialists to develop customized claim substantiation and path-to-market strategies.

From clinical study design to impactful product marketing, KGK has client success down to a science. At our state-of-the-art clinical research facilities, clinical staff, researchers, and regulatory experts quickly turn requests into results. We've guided hundreds of companies in taking their initial product concepts on to clinically proven claims and beyond, working to differentiate ideas and offer unique pathways through complex regulatory bodies including Health Canada, FDA, and FTC.

Recognized globally as thought-leaders in cannabinoid science and regulation for the natural health product industry, KGK Science is proudly the first CRO in Canada to possess a Cannabis Research License, extending our 23 years of industry experience to include cannabis and hemp-derived products.

As the leading CRO in the cannabis industry, KGK is focused on expertly conducting clinical trials and providing regulatory support to help bring innovative new health products to market, continuing to further global research and unlock the true value of the cannabis industry for clients and consumers.

Cross-Industry Collaboration

Nutraceutical

For over 23 years, KGK Science has been the leading CRO supporting the nutraceutical industry, providing clients across the globe with high-quality clinical trial research and regulatory services to successfully bring safe and effective natural health products to market. With a vast offering of pre-clinical, clinical, and regulatory services, KGK's specialized experience includes dietary supplements, branded ingredients, and functional foods and beverages.

Cannabis & Hemp

As one of the first contract research organizations in Canada to receive a research license to administer cannabis for the purposes of clinical trials, KGK Science is the industry-leader in helping advance new cannabis and hemp-derived health and wellness products through scientific research and regulatory support. Backed by a vast network of scientific, legal, and regulatory professionals, KGK is dedicated to unlocking the true value of the cannabis industry for our clients and consumers.

Pharmaceutical

KGK Science is a valued partner for the pharmaceutical industry, providing clinical trial and recruitment services that meet the highest level of standards. With a state-of-the-art, fully staffed onsite clinic and teams of quality and data management professionals, KGK provides seamless integration into multicenter pharmaceutical trials, aiding in participant recruitment, study execution, data collection and monitoring.

Relationships Matter

KGK Science has long-standing relationships with thought-leaders and important decision makers at government, industry, and regulatory agencies, allowing us to stay up-to-date with the latest trends, findings, and developments.

Leading With Expertise

Najla Guthrie, President & CEO

An internationally-recognized scientist and accomplished businesswoman, Najla Guthrie has left an indelible mark on the nutraceutical industry. At KGK Science, Najla has acted as a founding shareholder and an innovative leader. She successfully transitioned from a nutraceutical medicines researcher to President and CEO, bringing her wealth of scientific knowledge to her position as a director. Under her leadership, KGK's integrated research and product development team has gained a reputation for world-class nutraceutical science, with emerging expertise in cannabis research.

Mal Evans, DVM PhD, Chief Scientific Officer

Recognized at the international level for her work in chronobiology and nutraceutical science, Dr. Mal Evans is a leading scientist in the health and wellness sector and a field expert in developing protocols which translate study sponsor ideas into journal manuscripts with the highest impact rating. Throughout her career, she has spearheaded unique and innovative research initiatives, creating an entirely new model for the measurement of nutrients, continuously challenging traditional thought as to what constitutes competent and reliable scientific evidence to substantiate claims in the nutrition industry.

Corey Hilmas, MD PhD, Chief Regulatory Officer

Dr. Corey Hilmas is a respected scientist, medical doctor, and former U.S. federal food regulator. After having completed his medical degree and doctorate in toxicology, working as a principal investigator for many years, and serving on behalf of the U.S. government at FDA, Dr. Hilmas combines his unique science skillset with extensive U.S. regulatory training. He served as an NDI notification reviewer and as a branch chief within the Division of Dietary Supplement Programs at the FDA. As a recognized regulatory expert with intimate knowledge of the dietary supplement industry, Dr. Hilmas has made significant contributions to building and shaping the regulatory landscape.

Bibiane Zakaria, Director of Sales & Client Services

As the Director of Sales and Client Services, Bibiane Zakaria is responsible for driving sales and business development for KGK Science, with a concentration on growing client relationships, business development in new markets and regulatory sales. Since joining KGK in 2012, Bibiane has successfully grown and led the sales and business development team, tripling growth and fostering new and existing relationships with clients. With a strong understanding of clinical trial processes and regulatory requirements, Bibiane brings unique skills in helping clients build a strategy around their objectives and vision.

Andrew Charrette, M.Sc., Director of Regulatory Affairs

Leading the regulatory affairs division of KGK Science, Andrew Charrette brings extensive experience in regulatory processes for clinical trial research and an in-depth knowledge of the cannabis regulations in North America. Since joining KGK in 2013, Andrew has led over 50 submissions to Health Canada, and consulted on numerous product claims, NDI notifications and GRAS submissions to the U.S. FDA. Andrew received his undergraduate degree in Pharmacology and Physiology from the University of Western Ontario and later obtained a Master's degree in Neuroscience from the University of Ottawa.

> *"We started this adventure with very little experience as a sponsor of clinical trials. Our first study with a University Research Program was frustrating with delays, poor communication, continuous change of research partners, and lack of ownership over content. We are so grateful to have been introduced to the professional team at KGK Science. They were patient with our inexperience, assisted us in building a reputable program, created education opportunities with top notch experts in the field of Dietary Supplements and FDA regulations and guided our models to create truly imaginative studies that will contribute to the scientific body of knowledge in an honorable way."*
>
> **Jamie Langston BSN, RN, CCRP**
> Chief Research Officer, LifeSeasons Inc.

PREMIUM CLINICAL RESEARCH

As a premium full-service contract research organization, KGK Science is dedicated to providing clinical trial research that meets the highest quality standards. Led by a team of scientific research and regulatory experts, KGK combines cutting-edge clinical science with industry expertise to design clinical trial and claim substantiation strategies customized to meet the needs of our clients.

Clinical Research Expertise

Pre-Clinical Services:

- Toxicology & Safety Studies
- Efficacy Studies
- Mechanism of Action Studies
- Animal Protocol Development

Clinical Trials:

- Protocol Development & Study Design
- Regulatory Submissions & Consulting
- Marketing & Participant Recruitment
- Clinical Trial Management & Oversight
- Data Management & Analysis
- Comprehensive Final Report

Clinical Research Services:

- Protocol Development
- Protocol Templates
- Case Report Form Development
- Data Collection
- Data Analysis
- Clinical Study Reports & Summaries
- Knowledge Transfer Materials Development
- Scientific/Medical Writing
- Recruitment Support
- Pharmaceutical Trial Services

Areas of Specialization:

- Antioxidants & Vitamins
- Bioavailability
- Botanicals
- Cannabis & Hemp
- Cardiovascular Health
- Digestive Health (Prebiotics, Probiotics & Synbiotics)
- Immunology
- Inflammation
- Joint Health
- Memory & Cognition
- Men's & Women's Health
- Metabolism
- Musculoskeletal
- Sports Nutrition
- Weight Management

Pre-Clinical Services

Toxicology/Safety Studies

Whether you are bringing a new dietary ingredient to market or establishing safety for human clinical trials, pre-clinical toxicity and tolerability studies are a requirement that cannot be overlooked. A well-designed suite of toxicology studies will inform product development and aid in determining the amount of ingredient that can be safely consumed in the market.

The expert toxicologists at KGK Science provide guidance and oversight over the conduct of pre-clinical studies while always maintaining the end goal of your regulatory submission or clinical research in mind.

Efficacy Studies

Pre-clinical efficacy studies can often serve as a quick and cost-effective method to inform the decision of whether to invest in a human clinical trial. Depending on the ingredient and format of delivery, these studies may be a critical step in product development.

The experts at KGK Science will consult on the most appropriate situation and design for conducting pre-clinical efficacy studies to optimize the chances of success in downstream product development stages.

Mechanism of Action Studies

In order to truly understand your product and maximize the depth of label claims that can be made, a fundamental understanding of how the ingredient works is required. Structure/function claims often describe the mechanism of action in the body. Pre-clinical research is usually required to delineate these mechanisms before they can be substantiated in human clinical studies.

KGK Science will leverage our years of experience in the nutraceutical industry to help you expand the claims you can make on your product, starting from the ground up. Our experts will work with you to design the studies that will provide a basis for structure/function claims and inform future research.

Animal Protocol Development

Efficacy and claim substantiation are as important within the pet food and dietary supplement industry as they are in products produced for human consumption. This level of importance is recognized by regulatory bodies such as Health Canada and the FDA who have mandated regulatory compliance for ingredient content, product claims, and risk to animal health.

As a full-service CRO, KGK Science offers pre-clinical services for pet products, focusing on ensuring safety and achieving positive regulatory outcomes.

CLINICAL TRIAL EXPERTISE

At KGK Science, we believe that evidence-based research will help strengthen confidence in alternative approaches to people's overall health and wellness and we've made it our mission to partner with businesses who share this belief.

A Proven Success

Backed by a vast network of scientific research, legal, and medical professionals, KGK's team of experts will manage every step of designing and executing the perfect trial to substantiate the efficacy and safety of your product, from protocol development, regulatory approvals, recruiting and seeing participants, managing the data, to compiling results into a comprehensive final report. We put our expertise to work for you, providing a professionally managed project from end-to-end that meets the highest quality standards.

End-to-End Project Management

Whether it's your first clinical trial or your hundredth, KGK Science's professional project management team provides dedicated, end-to-end support to ensure client satisfaction. Either working as part of your team or independently, you will receive communication throughout each stage of the clinical trial process, tracking results towards successful outcomes.

KGK Clinical Trial Process:

Designing Your Trial

A good study design and an experienced research partner are the keys to providing sound results and achieving the maximum return on investment. KGK's team of scientists and researchers combine over 20 years of study design experience with a critical evaluation of up-to-date evidence-based literature to customize a trial that meets the specific needs of your business.

Customized Strategy

The strategy starts with your business – the desired outcomes you're trying to reach, your product and the market in which it will be sold. Based on your requirements, our team will develop a customized plan to ensure successful and timely results.

Strategic Analysis

- Desired outcomes
- Market assessment
- Regulatory requirements
- Literature review

Study Type

- Parallel
- Crossover
- Augmented
- Pharmacokinetic
- Pharmacodynamic

Parameters Required for Significance

- Duration of study
- Sample size
- Number of arms
- Number of visits

Protocol Development

Once the strategy is defined, KGK will develop a high-quality protocol based on ICH guidelines to provide the best scientific evidence to support your claims and satisfy regulatory and ethics authorities. Built upon a foundation of evidence-based literature and over two decades of clinical trial experience, your protocol will be well-defined, practical, and operationally sound.

Regulatory Submissions

As a full-service CRO, KGK Science has an entire team of regulatory professionals to handle all the necessary regulatory submissions for clinical trials and product approvals. Ensuring a seamless end-to-end process, we will work directly with your team to develop the required materials, submit to Health Canada, FDA, EFSA and other regulatory boards on your behalf, and handle all correspondence until approvals are received.

Our team of regulatory experts, led by a former federal regulator with the FDA, is available to provide consulting throughout the clinical trial process. With a full offering of regulatory services, KGK can also be contracted to submit to a regulatory board on your behalf for a clinical trial being run at an outside site or to obtain product approvals.

Clinical Research Sites

KGK's state-of-the-art clinical trial center is equipped to handle the most innovative of studies while offering our participants a comfortable and safe environment.

- Dedicated GCP-trained clinical research staff
- On-site Clinical Research Associates to perform monitoring and quality assurance
- Electronic Data Capture (EDC) utilizing OpenClinica® to allow point of visit data entry
- Adverse event (AE) reporting using MedDRA Coding
- Secured file and medication storage facilities with 24-hour accessibility & limited access
- 12 Lead ECG
- DEXA scanner
- Body impedance analyzer
- EndoPat endothelial function analyzer
- Multiple exam rooms and private meeting rooms

In addition to our onsite clinic, KGK has a network of partner sites across North America and Europe, certified by KGK to deliver high quality results.

Participant Recruitment

Recruitment can be a large obstacle to successfully completing a clinical trial. KGK's specialized marketing and recruitment team develops customized strategies for reaching our database of 25,000+ participants and beyond to connect with the right population to meet the needs of your study.

Working alongside our research team, dedicated project managers, and clinic staff, we develop a targeted marketing plan designed to meet trial outcomes and deliver positive clinical trial experiences for our participants. Services provided by our team include:

- Strategic marketing plan development
- Advertising content development and regulatory review
- Digital and traditional marketing and advertising execution
- Dedicated recruitment communication center professionally staffed for telephone screening, clinic appointment booking, and customer service
- Ongoing recruitment monitoring and reporting

Right on Time

It's not just about reaching the right audience. Being able to accurately plan the time it will take to fill a study is essential for effectively bringing a project to close. Using a statistical feasibility model, we will develop a custom timeline, assessing the time required for recruitment and providing you with options for achieving the fastest and most cost-effective turnaround.

COMPREHENSIVE FINAL REPORT

Upon completion of a clinical trial, all KGK Science clients receive a Comprehensive Final Report written in accordance with ICH guidelines with complete interpretation of the analyzed data. Your final report will provide you with a high-level review of the study as well as results and conclusions, compiled in a format that can be submitted to any regulatory agency, as is.

More Than Just Stats

Each Comprehensive Final Report includes:

- Introduction & rationale for the study
- Complete methodologies
- Statistical methods including FDA approved sensitivity analysis to maintain power of the clinical study
- Subgroup and responder analysis as appropriate
- Interpretation of results
- Discussion of the complete literature search on the formulation and/or ingredients to position the study results relative to similar products, benchmarking against pharmaceutical products when appropriate
- Recommendations for future studies based on the results of the current studies and available literature

Clinical Research Services

In addition to conducting end-to-end clinical trials, KGK Science provides a wide range of individual services to help support clients through the various stages of the research process.

Our professional services include:

Protocol Development

A customized clinical trial protocol optimized to detect significant effects of the study intervention in the population of interest while always abiding by ICH guidelines.

Protocol Templates

Adaptable, ICH abiding clinical trial protocols that easily facilitate modifications for use in multiple studies.

Case Report Form Development

Customized forms designed to maintain GCP and data protection while providing the comprehensive capture of clinical trial data.

Data Collection

Source documents developed to collect all data specified by the protocol and designed to ensure the quality and integrity of the data being collected. All data collected are reviewed by internal monitors.

Data Analysis

Rigorous statistical analysis performed transparently to ICH standards for both initial data analysis and previously analyzed data.

Recruitment Support

In addition to recruitment strategy development, our Communication Center can be contracted to handle outbound and inbound communications (phone, email, text) screening potential participants for eligibility.

Clinical Study Reports and Summaries

In-depth, organized reports following ICH guidelines which clearly present the details of the clinical trial design, the results of study and interpretation of the ramifications of the work. These documents are prepared in a format suitable for submission to any regulatory agency.

Knowledge Transfer Materials Development

Professionally crafted presentation materials for the dissemination of research at the expert and layperson level for meetings and conferences.

Scientific/Medical Writing

Articles for medical and scientific journals tailored to your specifications and written by medical professionals. Articles may be commissioned for original research and/or literature reviews.

EXPERT REGULATORY SERVICES

KGK Science offers the largest breadth of regulatory support services in the nutraceutical, cannabis and hemp industries. Led by a former FDA regulator, KGK's team of seasoned regulatory experts are uniquely equipped to provide an insider's perspective into regulatory operations and the most effective way to reduce regulatory risk through verifiable evidence.

Guiding Your Product to Success

Backed by a vast network of research and legal partners, KGK's regulatory experts will develop the right strategy to guide your product successfully into the hands of your customers.

Claim Substantiation & Review

- Substantiation Files
- Letters of Support for Old Dietary Ingredient (ODI) Status
- Letters to Support Substantiation of Claims Made on Labels or in Labeling
- Letters of Toxicology Support for Dietary Ingredients Used at a Specific Serving Level
- Label and Claims Review
- Novel Foods

Product Licensing

Safety & Risk Assessments

- New Dietary Ingredient Notifications (NDI)
- GRAS Conclusions
- Toxicology Risk Assessments of Ingredients or Ingredient Constituents

Regulatory Consulting

- Citizen Petitions
- Path-to-Market Strategies

Serious Adverse Event Reporting

Claim Substantiation & Review

Substantiation Files for Ingredients/Products

Being able to prove and substantiate the efficacy of your product or ingredient is important for regulators, and your customers. A thoroughly produced substantiation file is a cost-effective way to complete your due diligence process and reduce regulatory risk, providing a foundation for successfully differentiating your product from others in the market.

Letters of Support (Pre-DSHEA)

Ingredients used in dietary supplements prior to the Dietary Supplement Health and Education Act (DSHEA) of 1994 are considered Old Dietary Ingredients (ODIs) and require documentation to verify their status as such in order to be exempt from the submission of a New Dietary Ingredient (NDI) notification to the FDA.

A letter of support verifying ODI status is a cost-effective and efficient way to validate that an ingredient is safe for consumers based on historical use, supported by product and manufacturing records.

KGK Science's regulatory experts conduct thorough investigations into the available marketing information and scientific literature supporting the sale of your product or ingredient prior to the enactment of DSHEA. Investigations and results include:

- Research via a robust library of old, grandfathered, pre-DSHEA dietary ingredients
- Independent and verifiable evidence in the form of product labels, bills of lading, ingredient supply catalog entries, and other available records
- Official letter of support summarizing findings required to substantiate ODI status
- Expert advice to minimize regulatory risk

Letters of Toxicology Support

If you have an Old Dietary Ingredient (ODI), you may need a letter of support from a toxicologist to validate that changes in serving levels will not present a risk to safety.

KGK Science's regulatory team, led by the author of the Draft New Dietary Ingredient Guidance and former Branch Chief at the FDA, is uniquely equipped to provide the supporting documentation required to validate the safety of your product or ingredient, including:

- A synthesis of pre-toxicology safety evidence
- A letter from an expert toxicologist summarizing the available toxicological data with conclusions and recommended conditions of use for the product/ingredient.

Creating a Substantiation File

In addition to regulatory bodies, consumers are increasingly performing their own research into the validity of claims found on nutraceuticals. Being able to thoroughly support your claims for regulators and your downstream customers is essential for establishing market distinction and protecting your business against regulatory non-compliance and predatory lawsuits. KGK will help with substantiation by creating a comprehensive substantiation file, which documents the level of evidence for each claim made on an ingredient in a product.

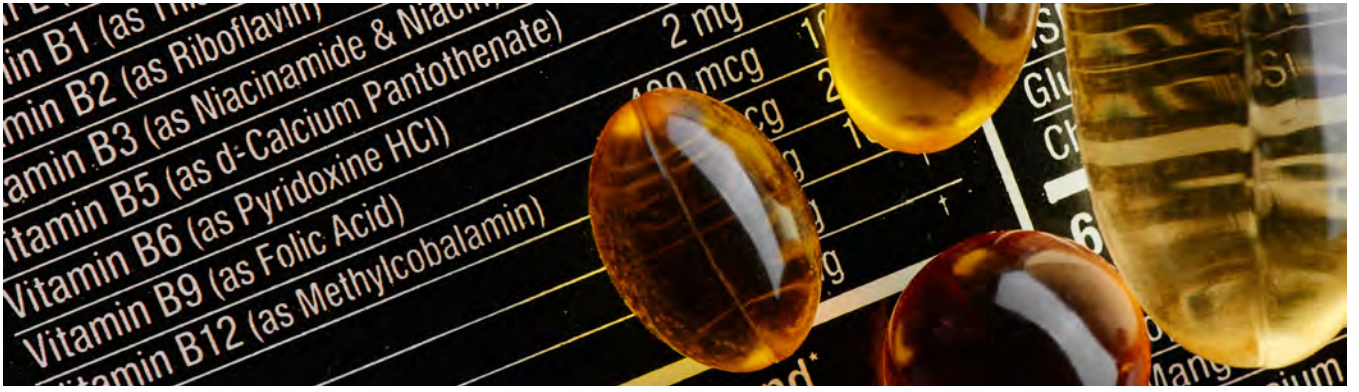
Claim Substantiation & Review - Continued

Label and Claims Reviews

Depending on the market you're selling into, failure to comply with labeling and claim requirements can result in misbranded labels or products considered unapproved foods or unapproved new drugs. Misbranded labels and/or ones with inappropriate claims result in embarrassing enforcement actions made public by regulatory authorities or costly import detentions. Products may even be added to a country's import bulletin or alert system, and company information subsequently shared with food authorities from foreign governments, resulting in further barriers to international trade.

Upon reviewing your label thoroughly through the lens of a regulatory expert, KGK Science will help you ensure that your product makes it to retailers and customers and not into the hands of federal regulators.

- Label review for violations of federal regulatory compliance requirements
- Thorough label reviews for misbranding (based on desired regulatory market)
- Review of all claims made on the label (and in labeling, if desired)
- Regulatory consulting for labeling best practices, developing new labels, improving compliance, and for entry into new markets



Novel Foods

Under the Food and Drugs Act and Regulations, all foods that have been produced through new processes, that do not have a history of safe use as a food, or that have been modified by genetic manipulation are considered novel foods and must be assessed by Health Canada before they can be sold in Canada.

Characterizing a product as novel or innovative can be tricky, as can be the process for completing the required federal assessment. KGK Science's Canada-based regulatory team, led by the author of the Draft New Dietary Ingredient Guidance and former Branch Chief of Toxicology at the FDA, is uniquely equipped to support your business in securing the required evidence for completing a successful novel foods application.

Our expert services include:

- Technical review and GAP analysis to ensure that evidence will meet requirements
- Planning studies to support identity and safety data requirements including protocol development, study management, and analysis of results
- Expert regulatory toxicologists writing your application and corresponding directly with Health Canada to ensure requirements are met and the process is completed

Safety & Risk Assessments

New Dietary Ingredient Notifications

Dietary ingredients for use in dietary supplements can either be old, pre-DSHEA, grandfathered dietary ingredients (ODI) or New Dietary Ingredients depending on whether they were marketed and sold in interstate commerce prior to October 15, 1994. KGK's regulatory team will determine whether your dietary ingredient is old or new.

NDI requirements are highly detailed, requiring an expert in NDI identity (chemistry) and safety (toxicology). Our team of regulatory experts, led by co-author of FDA's NDI Draft Guidance for New Dietary Ingredient Notification and former FDA Branch Chief for Dietary Supplement Regulation Implementation, will provide you with a customized, all-in-one solution for successfully meeting NDI compliance, including:

- Strategy for filing an NDI notification
- Technical review of identity specifications and GAP analysis of toxicology data
- Recommendation for any pre-clinical safety studies (animal toxicology)
- Direct correspondence with FDA throughout the process and facilitation of a Pre-Notification meeting to ensure a successful submission
- Writing a comprehensive NDI Notification to meet federal regulatory requirements
    - Organization of all identity and safety information
    - Organization of raw data
    - Full copies of all cited references
    - Drafting of written narratives

GRAS Conclusions

The Federal Food, Drug and Cosmetic Act places high levels of scrutiny on compliance with safety regulations for food ingredients, as do internet savvy consumers looking for FDA awareness and approval. GRAS conclusions are safety reviews conducted by experts qualified by scientific training and experience. Your GRAS conclusion will be drafted by our experts and either independently reviewed (self-GRAS), reviewed and submitted to FDA (submitted GRAS notice), or formally petitioned to FDA (food additive petition).

KGK will provide an all-in-one customized solution for ensuring your ingredient meets statutory and regulatory GRAS requirements, including:

- Technical review and GAP analysis to ensure that evidence will meet requirements
- Plan and conduct studies to support identity and safety data requirements including protocol development, study management, and analysis of results
- In-house expertise in statistics and food toxicology to assemble data and literature into a comprehensive dossier to support the GRAS conclusion
- A panel of independent expert food scientists to review the GRAS conclusion and provide final sign-off letters

Regulatory Consulting

Citizen Petitions

When bringing your product or ingredient to market, it may be necessary, advisable, or strategic from a marketing perspective to make a formal citizen petition to the Food and Drug Administration (FDA), requesting them to take (or refrain from taking) an action. Citizen petitions provide opportunities to validate the standard of quality and efficacy of your product, increase consumer confidence, and increase profitability.

Citizen Petition - Dietary Fiber

Petitioning the FDA that a non-digestible carbohydrate ingredient is a dietary fiber through the demonstration of a beneficial physiological effect in a human via clinical trials.

Citizen Petition - Exemption from 100% Identity Testing

Petitioning the FDA to do less than 100% identity testing, showing that such a sampling model of less than 100% testing does not result in a reduction in product quality.

Citizen Petition - Health Claims and Qualified Health Claims

Petitioning the FDA to make an authorized disease claim can provide market distinction from competitor products in the marketplace.

Submitting a citizen petition can be complex. KGK Science's team of regulatory experts is uniquely equipped to facilitate a customized solution to meet your regulatory needs, including:

- Expert regulatory toxicologists providing an insider perspective on the quality, safety, and efficacy of your food product or ingredient
- Technical review and GAP analysis to ensure that evidence will meet FDA requirements
- Plan studies or analyses to support the data requirements if required including protocol development, study management, and analysis of results
- Thorough assembling of data and literature into a comprehensive petition dossier
- Direct, ongoing correspondence with FDA and the submission of the citizen petition on your behalf

Path-to-Market Strategies

The path to launching a new product or ingredient into the global market can be long and winding, with many regulatory hurdles along the way. With over 20 years in the nutraceutical industry, KGK Science is fully equipped to identify the optimum pathway for your business, supporting you through each step of the process.

All path-to-market services include:

- Technical review of the product or ingredient information and all desired claims
- GAP analysis to identify applicable regulatory requirements, potential regulatory risks and custom-tailored solutions
- Expert advice on the quality, safety, and efficacy of your product or ingredient and how to maximize market opportunities

Product Licensing

The Natural and Non-Prescription Health Products Directorate (NNHPD) is the Canadian regulating authority for natural health products, ensuring that Canadians have ready access to a wide range of products for which safety, efficacy, and quality standards are in place. In addition to being a requirement for selling a natural health product in Canada, securing product licensing through the NNHPD will also allow your business to maximize the value of the efficacy claims used in the marketing of your products.

KGK Science's Canada-based regulatory team, led by an experienced Federal Regulator, will support your business in securing the evidence and assessments required for securing product licensing in Canada. Our expert services include:

- Technical review and GAP analysis of quality specifications, and safety and efficacy evidence with a summary of the claims supported and regulatory requirements for obtaining product licensing
- Completion and submission of the Product License Application including all correspondence with Health Canada

Pharmcovigilance Team for Serious Adverse Event Reporting

Triaging product complaints for serious adverse event reporting (SAER), reporting to federal health agencies, and patient follow-ups are mandatory requirements and require heavy investment in full-time staff dedicated to those duties. This mandatory requirement may be especially burdensome to nutraceutical or cannabis start-ups.

KGK Science is a one-stop-shop for managing all your SAER needs. With a high-quality Communications Center based in London, Ontario Canada, KGK representatives will handle the intake of all reported events from the U.S. and Canada; facilitating triage of each product complaint/adverse event call with qualified healthcare practitioners who will assess whether it is serious or not, according to regulations.

Serious Adverse Event Reporting services include:

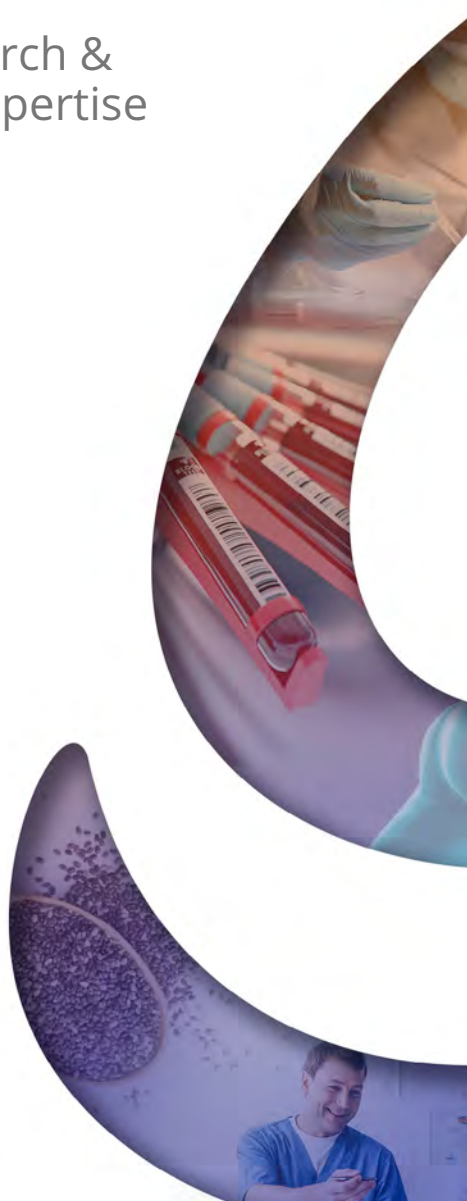
- Canada-based communication center to receive all incoming reports from Canada and the United States
- Triage services to assess the severity of reports and complaints
- Active pharmacovigilance monitoring of sentinel safety signals from product complaints
- Management of post-marketing safety reporting requirements for ensuring compliance
- Proper handling and secure storage of patient-sensitive data
- Statistical analysis of received reports and risk assessment to mine data for safety signals
- Reporting to FDA MedWatch to comply with US FDA SAE reporting requirements
- Confidential database for compiling data and record keeping
- Follow-ups with patients as per regulatory requirements
- Reporting events and reactions to the U.S. FDA, Health Canada and other health authorities
- Quarterly reports on all events, statistically analyzing the post-market data and assessing the need to take regulatory action

KGK Science | Premium Clinical Research & Regulatory Expertise

Stake your claim.

Contact KGK Science today for all your clinical trial and regulatory needs.

www.kgkscience.com



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