NUTRASOURCE

CLINICAL AND REGULATORY EXPERIENCE & HIGHLIGHTS

nutrasource

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CLINICAL & REGULATORY EXPERIENCE AND HIGHLIGHTS

Nutrasource has an extensive resume of successful clinical trials conducted both at the on-site clinical theatre in Guelph and at satellite research centres across North America.

Nutraceutical Clinical Trial Experience:

NHP Product Types:

Botanicals and botanical extracts, enzymes, essential fatty acids, isolates, homeopathics, minerals, synthetic duplicates, isolates, prebiotics, probiotics, and combinations thereof.

Study indications:

Allergies, antibiotic associated diarrhoea and smoking cessation studies, anxiety and mood, bioavailability/ pharmacokinetics, blood pressure, bone health, breast health endocrinology, cholesterol, cognitive functioning, device validation, digestibility, gastroesophageal reflux, gastrointestinal health including microbiome analysis, glucose management, glycaemic index, joint pain, laxation, lipemic index, metabolism, method formulation and application to high-fat foods, nutrient absorption, osteoarthritis, oxidative stress, satiety, weight loss.

Pharmaceutical Clinical Experience:

Actinic keratosis, brain, cardiology; acute coronary syndromes, chronic/stable angina, dental caries diabetes, dyslipidemia, gastrointestinal, hypertension, lung, melanoma, neurology, oncology; solid tumours, ophthalmology, osteoarthritis, rheumatoid arthritis

Regulatory Capabilities and Historical Success:

New Drug Submissions/Applications (over 15 submissions in combined experience). Investigational New Drug submissions/Clinical Trial Applications (over 100 submissions combined experience), Product License Applications (over 300 submissions), Site License Applications (over 25 submissions), GRAS and self-affirmed GRAS (over 15 submissions), Orphan Drug Designations (over 5 submissions), Natural Health Product Master Files (over 25), non-Traditional Health Claims (over 15).

CLINICAL AND REGULATORY MANAGEMENT TEAM

Nutrasource has a unique, cross generational, all encompassing Management Team. Our combined experience in both the Nutraceutical and Pharmaceutical Clinical and Research Development space spans over three decades.

Your Nutrasource team is organized to ensure that all products you develop receive the benefit of our multi-faceted expertise. Whether you require our services on an à la carte basis or for a full clinical development plan, we can effectively achieve your goal.

William J. Rowe, BA, President and Chief Executive Officer

- Globally commercialized the novel diagnostic Omega Score™
- Creator of the IFOS program, the only third party certification program for the marine oil industry
- Instrumental in designing and implementing clinical trial development and marketing strategies for sponsor products to comply with domestic and international regulatory requirements
- Over 15 years of experience in providing expertise for successful launches of new consumer health products and re-launches of existing projects with new claims
- Secured research and development funding for start-up companies
- Expanded the capabilities and resources of Nutrasource to meet the ever increasing needs of the client across as wide breadth and depth of scientific and regulatory services
- Oversees and manages a team of 5 Directors in the clinical, regulatory and management divisions
- Ernst and Young Entrepreneur of the Year Nominee 2012, 2013
- Current Member of Council for responsible Nutrition International Markets Committee
- Former Board member of Guelph Partnership for Innovation
- Has lead Nutrasource to place on Profit 500 list of Canada's fastest growing companies 4 of the last 6 years

Rodney Butt, M.Sc., MBA, Vice President, Programs

- Over 25 years of experience in Clinical Operations, Quality Assurance and Project Management in both Pharmaceutical and Contract Research Organizations
- Domestic and global clinical development for unique compounds, devices and biologics
- Project infrastructure for clinical trials with enrollment from 30 to 700 subjects
- Logistical support for international trials managing up to 150 operating clinical sites simultaneously
- Budget, organization, staffing of new medicines
- Comprehensive network of qualified investigators internationally and discipline specific
- Lecturer and presenter at DIA, BIO and Partnering meetings across North America

Maggie Laidlaw, Ph.D., Director, Scientific Affairs

- Over 10 years of experience as a Director of Scientific Affairs
- Adept at writing protocols, case report forms, informed consent and REB applications
- Lead author or co-author of over 20 publications in American and Canadian Journals
- Final clinical report and statistical analysis composition
- Knowledge base in clinical trials in all disciplines in the NHP and Functional Food/beverage sectors
- Guest lecturer and presenter at Women's Health Conference, International Pharmacy Academy, Experimental Biology Conference and Pharmalink International

Jennifer Ellis, B.Sc., Director Clinical and Regulatory Operations

- Over 25 years of pharmaceutical regulatory and clinical experience
- IND, CTA, NDA, NDS submissions in oncology, dermatology, cardiology, endocrinology, biologics, ophthalmology and devices
- Proficient at medical writing including protocols, CRFS, informed consent and final clinical reports
- Experience in identifying the preclinical and clinical requirements to take a product from concept to final approval in the fastest and most economical fashion
- Established relationships with FDA and TPD
- Foreign submission to countries including India, England, France, Serbia, South Africa and Japan
- Quality Assurance encompassing GCP and GMP
- Member of CAPRA, RAPS

Joshua Baisley, Hon. B.Sc., Associate Director, Clinical Development

- Over 12 years of clinical and regulatory natural health product experience and an additional 4 years of antibody research with primary focus on diabetes
- Compiled over 50 Health Canada clinical trial applications for natural health products, drugs, and veterinary products, representing over 10% of all applications received by Health Canada's Natural Products Directorate
- Expert in regulatory requirements for clinical trials including probiotics, prebiotics, herbs, extracts, vitamins, minerals, enzymes, homeopathics and combination products
- Over 15 years of medical writing experience including Investigator Brochures, protocol design and writing, informed consent preparation, CRF preparation and review, quality assurance, monitoring and auditing
- Established relationships with key Health Canada directorates (NNHPD and TPD)
- Member of Society for Clinical Trials and past member of Health Canada's Canada Vigilance Expert Working Group

"The team was constantly combing through scientific literature and clinical trials data to help support our claims and to get our Natural Product Numbers, which definitely would not have been possible without the brain power from Nutrasource."

-Shawna Page, CEO, femMED

Vic Dumbleton, B.A, B.Sc., RT, Sr. Project Manager

- 5 years of experience in the Critical Care clinical trials division at the Hospital for Sick Children and animal lab environments
- Over a decade of clinical CRO experience developing, executing and managing over 40 clinical trials for domestic and international pharmaceutical companies
- Organizes and delivers presentations on protocol, IRB and study procedures at international investigator meetings
- Active in protocol development and international redevelopment committees in the pharmaceutical industry
- Experienced in all facets of clinical study management including study monitor, coordinator and site initiation roles

Katie Keene, B.Sc., Regulatory Specialist

- Expert in collecting and critically evaluating literature from database to best assess product safety and efficacy requirements
- Part of the team that has secured over 17 Product License and Site Applications to the NHPD
- Participates in the peer review process of clinical literature reviews
- Assists in the design and implementation of the internal SOPs as they apply to NHPD

Tania John, M.Sc., Associate Director, Regulatory Affairs

- Expert in collecting and critically evaluating literature from database to best assess product safety and efficacy requirements
- Part of the team that has secured over 25 Product License and Site Applications to the NHPD
- Participates in the peer review process of clinical literature reviews
- Designed and established the internal referencing system at Nutrasource
- Assists in the design and implementation of the internal SOPs as they apply to NHPD
- Completed 3 Site License Application to the NHPD without a single deficiency

> **“We have a success story here. The payback has been immeasurable.**
>
> -Shawna Page, CEO, femMED

Rachel Rebry, M.Sc., Associate Director, Regulatory Affairs

- Project Manager on over 25 Product License and Site Applications to the NHPD
- Lead on jurisdictional investigations to determine the pathway of optimal positioning in market place for new supplements and combinations
- Extensive knowledge of product labeling requirements to ensure compliance with regulatory bodies
- Efficient and accurate literature review parameter determination as applied to food, NHPs and new listing ingredients
- Open collaboration with over 75 Sponsors determining need, requirement and comprehension of best possible regulatory pathway
- Member of the Canadian Health Food Association's Regulatory Affairs Advisory Council
- Peer reviewed publication Postprandial response in Type 2 Diabetes
- Soy protein and cholesterol lowering health claim

Katherine Welsh, B.Sc., Manager, Data Management

- Experienced in Medrio data collection systems
- Manager of the Data Management System at Nutrasource for both on-site and off-site clinical trials
- Interface with the analytical division of Nutrasource to ensure transition between data capture and sample analysis
- Quality Assurance in clinical trial and regulatory data gathering and processing to agency compliance
- Author and major contributor to nutritional science blogs and conference presentations
- Strong background in literature searches, Product License and Site Applications

GRAS ASSOCIATES

Richard Kraska, B.S. Chemistry, Ph.D, Chief Scientific Officer & Executive Vice President

- 34 years' experience in toxicology and regulatory affairs for industry and government in broad aspects of the food and chemical industries including food additives, foods, food contact materials, cosmetics, lubricants and fuels, coatings, defoamers, anti-microbial pesticides and pharmaceuticals.
- Serve as Lead Scientist and Panel Chair for GRAS determinations.
- Lead consultant for food contact regulations and preparation of Food Contact Notifications.
- Coordinate drafting and report review by chemists, toxicologists and scientists of other disciplines as needed.
- Ingredients reviewed include stevia-derived sweeteners, natural antioxidants, novel sources of dietary fiber, fats and oils and extracts from vegetables, fruit and herbs.
- Speaker at several scientific sessions relating to GRAS determinations, safety of stevia-derived sweeteners and food contact compliance.
- Served as expert panel chairman for on over 30 GRAS notifications

Robert McQuate, Senior VP, Sales & Business Development

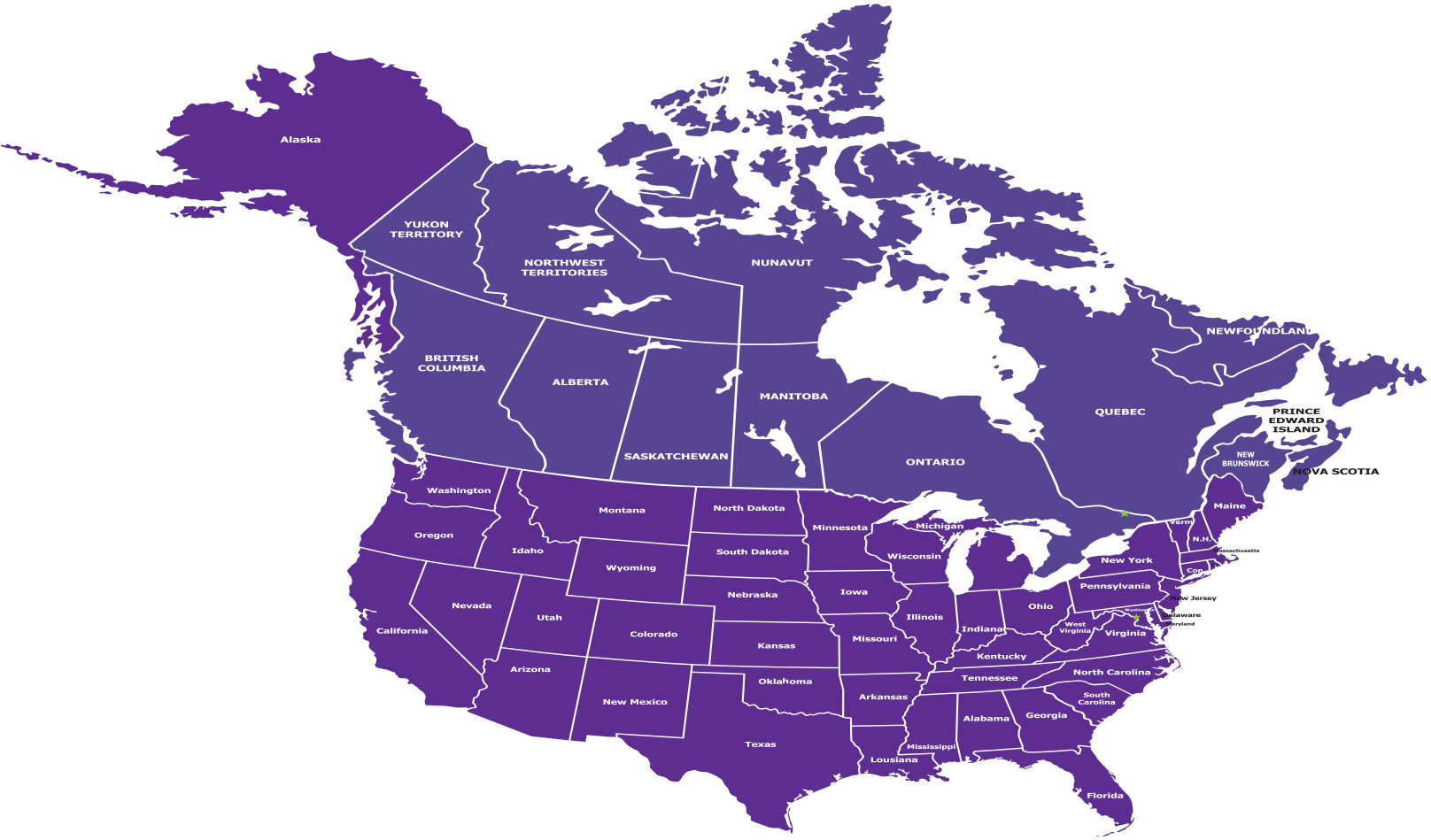
- Generate regulatory strategies to achieve food ingredient marketplace acceptance for clients.
- Interpret FDA's Red Book on food additive & GRAS safety evaluations in designing food ingredient testing regimens.
- Provide food ingredient safety evaluations, focusing on independent GRAS evaluations, food & color additive petitions, new dietary ingredient compilations, and associated FDA submissions.
- Serve on Expert Panels with particular orientation toward chemical composition and food ingredient specifications.
- Utilize quantitative risk assessment tools to ascertain likely food ingredient risks.
- Assess compositional information on ingredients---including complex natural products---to determine safety influences by various constituents and contaminants.
- Extract present day and historical consumer exposure information on foods to support clients' projected ingredient usage.
- Extensive writing & editing of technical papers and reports---including authoring food additive petitions, GRAS notifications and ingredient safety dossiers---to support client marketing initiatives.
- Interpret labeling regulations for foods and supplements and assess scientific documentation to support client labeling, product claims, and advertising representations for foods and dietary supplements.
- Serve as liaison with FDA scientific/regulatory staff in pursuing clarification of technical regulatory topics of concern to clients.
- Utilize negotiation skills to achieve mutually acceptable problem resolution.
- Develop proactive regulatory positions to avoid adverse regulatory compliance conditions by drafting client-specific Product Recall Procedures and FDA Inspection Procedures.

Cheryl Dicks, MS, RAC, Director, Operations & Regulatory Affairs Project Manager

- Over 14 years of experience in FDA regulatory in supplement/nutraceutical/pharmaceutical and device development
- Thirty years experience in business management and product quality management
- Successful submission of all phases of clinical development Phase I through IV to the FDA
- Established relationships with federal representatives at the FDA and represented a diverse sponsor base in Orphan Drug designations, Type A, B and C meetings, fast track designation and medical devices
- Lecturer for Biomedical and regulatory Affairs at Hood College
- Industry expert on Quality Management Systems connecting GCP and GLP for RAPS webcast
- Researcher and clinical trial project leader with the US Army Medical Research and Medical Command

CLINICAL TRIAL SITE LOCATIONS

Nutrasource has a vast network of Clinical Site Locations with expert physicians in a variety of clinical experience. Our clinical trial site located are situated in strategic geographical areas in North America.



PUBLISHED LITERATURE

Contributors to over 75 published research papers – entire list available on request.

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