BEYOND COMPLIANCE

Regulatory, medical and scientific affairs for nutrition and consumer health products

2022

RNI

BEYOND COMPLIANCE

With a team of 17 full time consultants across France, the UK, and the USA, RNI specializes in international regulations and compliance, alongside medical and toxicological affairs. We pride ourselves on our dual regulatory and scientific competencies for global handling of your projects.

Our philosophy: we go beyond compliance to assist our clients in the development of products with proven health benefits, in accordance with regulatory requirements and current health trends.

Violaine Chaumont
CEO

Anne-Claire Thiboult
Business Manager - France

Keval Bhoola
Business Manager - UK

Sébastien Aoudia
Business Manager - USA

THE RNI APPROACH

UNDERSTAND
Understand the requirements of each regulatory framework and the differences between product categories

QUALIFY
Advise the most appropriate regulatory pathway to adopt, considering your business, regulatory, and scientific constraints

STRATEGIZE
Strategize the submission of registration dossiers in Europe, the USA, and abroad

CONSOLIDATE
Consolidate the positioning of your products with RNI regulatory, scientific, or toxicological experts

COMMUNICATE
Communicate transparently with you, and advocate with authorities on your behalf

SUPERVISE
Supervise development projects from start to finish, with your team and third party entities

Our work method is based on solid regulatory and scientific competencies alongside strong relationships with authorities. This enables us to understand, determine, and negotiate opportunities in order to support your efforts.

15+ YEARS OF EXPERIENCE

WITH YOU, ALL AROUND THE WORLD

RNI can support your regulatory and scientific needs all around the world. With 3 offices, located in France, the UK , and the USA, our company covers most markets of the world. Thanks to many years of experience, RNI will be by your side during your international expansion, giving you the best opportunity to succeed in new markets.

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2, rue de Bel Air
49000 Angers

UNITED STATES
Office
822 North A1A Highway, Suite 310
Ponte Vedra Beach, FL 32082

UNITED KINGDOM
Office
1 St Katharine's Way
London E1W 1UN

RNI IN NUMBERS

17+
The number of full time consultants at RNI

2006
The year RNI was founded in France

500
The number of unique clients

120
The number of active clients

WHAT DOES RNI OFFER?

OUR SERVICES

NOVEL FOOD **MEDICAL DEVICES** **CLAIMS**
FOOD & BEVERAGES **MEDICAL FOOD** **BORDERLINE PRODUCTS**
COSMETICS **PHARMACEUTICALS** **NEW DIETARY INGREDIENTS**
GRAS DOSSIERS **COMMON & ENRICHED FOOD**
BIOCIDES **FOOD SUPPLEMENTS**

OUR EXPERTISE

REGULATORY STRATEGY

- **Advising** the most appropriate regulatory status to adopt taking into consideration your objectives
- **Ensuring** ingredient and product compliance: food, medical devices, cosmetics, biocides, and other statuses
- **Outlining regulatory differences** between product categories around the world
- **Providing strategy** for submissions and registrations

SCIENTIFIC, MEDICAL, TOXICOLOGICAL EXPERTISE

- **Finding active and alternative** ingredients
- **Consolidation** of the regulatory strategy with scientific and clinical data
- **Authoring** of various scientific and clinical dossiers
- **Analysis of the protocols** and reports of clinical and toxicological studies

INTERNATIONAL EXPERTISE

- **Integration of an international marketing extension strategy** from the beginning of product development all the way through to market delivery
- Consideration of **new marketing opportunities** in a global context

DUE DILIGENCE

- **Compliance assessment** of regulatory, medical, scientific and human resources
- **Compliance audit** with international regulations
- **Audit** of scientific and regulatory expenditures
- **Assessment of the company** or brand in light of target country's healthcare policy

QUALITY AUDITS

- **Quality audit of factories** and CAPA plans
- **Implementation** of Quality Management Systems

TRAINING

- Tailor-made **training courses** covering all aspects of product development, regulatory assessment and product communications

SUPPLEMENTS

NAVIGATING THE REGULATORY SPECIFICITIES...

Supplements generally consist of concentrated sources of nutrients and other substances which may or may not include botanical preparations. Rules concerning the composition and labelling of supplements **differ from one country to another**. Furthermore, specific product statuses may be **defined differently across the world.**

RNI, FROM FORMULA TO LAUNCH

Navigating this complex regulatory framework can be challenging. Our consultants have **expertise in international markets** and are able to guide you through the necessary steps to market your products.

From formula review to product registration,
RNI will support you from A to Z.

REGULATORY ANALYSIS

- **Formula review** & Novel Food / GRAS / NDIN risk assessment
- **Label review**
- **Claims:** health, structure function, nutrient, consumer
- **Product registration / notification**

QUALITY CONFORMITY

- **Ingredients**, doses, and galenic form
- Ingredient **sourcing**
- **Conditions of use**
- **Targeted population**

SAFETY REVIEW

- **Risk assessment** and review of **toxicological** and **clinical safety** data
- Defining **at risk populations**, interactions, and **precautions** of **use**

SCIENTIFIC DOSSIER

- **Justification** and **substantiation** of **claims**
- **Safety dossier**
- **Regulatory** and **technical** dossier

REGULATORY AND SCIENTIFIC COMMUNICATION

- Review of **advertising** and **marketing materials**
- **Defining** and reviewing **potential claims**
- **Nutrivigilance: post-marketing** surveillance and analysis

NOVEL FOODS & GRAS

HOW TO KEEP UP THE PACE OF THE INDUSTRY?

Global food innovation is developing at a rapid pace. New food ingredients improving consumers' health and offering more sustainable alternatives are on the rise. To succeed, **manufacturers must deal with complex and costly food regulations**. **A full marketing authorization** may be required with the aim of demonstrating the safety of the food under the proposed conditions of use.

OUR EXPERTS WILL LEAD YOUR INNOVATIONS

Our team is here to support you at all stages of your project. **We will guide you through the entire Novel food and GRAS process**, considering commercial, regulatory and scientific aspects in order to get your new ingredient to market efficiently, quickly, strategically and in full compliance.

Did you know? RNI is in contact with local authorities to support your new ingredients applications.

NOVEL FOODS (EU & UK)

- **Determination** of novel food status
- **Evaluation** of the nutritional value
- **Toxicological** and **safety** review
- **Gap analysis** - inspecting necessary data for the development of the novel food dossier
- **Coordinating scientific** and **clinical** studies
- **Writing all sections** of the novel food dossier
- **Submission of your novel food dossier** to authorities
- **Actively managing** follow up questions

GRAS & NDI (USA)

- **Reviewing specific ingredients** to determine if GRAS or NDI notification is needed
- **Providing an appropriate regulatory framework** for GRAS and NDIN pathways
- **Strategic assessment of unique ingredients** to determine the best approach for compliance
- **Analysis of safety data** to identify potential gaps
- **Full GRAS dossier** for a notified (submitted to FDA) or an independent (self-affirmed) GRAS.

MEDICAL DEVICES

A WORKFLOW TO MASTER...

The medical device landscape continues to attract manufacturers looking to develop new products or reclassify an existing product. The feasibility, classification, clinical evaluation, risk assessments, and registration requirements of your devices may be **difficult steps to meet without an in-depth understanding** of the regulatory, clinical, and quality framework.

FOLLOW RNI'S PROCESS

As such, **RNI has grown into a dedicated and reliable partner** with a proven track record in helping companies achieve medical device marking (i.e. CE and UKCA) for all classifications. By partnering with RNI, you will **get access** to our regulatory, quality, clinical and toxicological experts covering the full scope of product development.

FEASIBILITY ASSESSMENTS

Assessing how to position your product as a medical device

PRODUCT CLASSIFICATION

Working with the latest guidelines and opinions to justify medical device classification

CE/UKCA MARK STRATEGY

Gap analysis and reverse planning to meet your commercial deadlines

QUALITY MANAGEMENT SYSTEMS AND RISK ASSESSMENTS

Implementation and auditing (i.e., ISO 13485)

CLINICAL EVALUATION REPORTS

Full service to write and update reports and planning new clinical studies

BIOCOMPATIBILITY REPORTS

Full service toxicological risk assessments, reporting and planning biocompatibility studies

USABILITY/HUMAN FACTORS

Formative and summative test guidance, protocols, risk assessment and reports

FULL TECHNICAL FILE CREATION

Organization of data and writing the full technical file for all classes of medical devices

MARKETING VALIDATION

Validating communication and post marketing content as well as handling PMS, PMCF plans, and materiovigilance

COMMON & ENRICHED FOOD

DO YOU KNOW THE REQUIREMENTS?

Common and enriched foods **need to comply** with local regulations, **even in cases where registration is not required**. For example, in Europe, the addition of vitamins, minerals and other active substances is regulated at a European level whereas the maximum fortification limits are not harmonized with variations existing across Member States. For the USA, FDA has established a specific policy for fortification of foods that can impact the formulation of different food categories.

FOOD WILL NO LONGER BE A SECRET

RNI can support you in understanding the applicable regulations, determining the regulatory status of your ingredients, ensuring the ingredient's specifications meet quality standards, and intended use levels abide with local regulations.

RNI has created dozens of fully compliant and commercially successful compositions.

PRODUCT DEVELOPMENT

- **Identify active ingredients** that meet your health and marketing objectives
- **Quality** and **safety** assessment
- **Determination** of the **best regulatory status**
- **Compliance** of the composition
- **Determination** of possible **claims**
- **Quality audit** in compliance with HACCP standards

LABELLING & COMMUNICATION

- **Creation** and **review** of product **labeling**
- **Assessment** of **voluntary statements** (nutritional and health claims, environmental claims, certifications, Organic Agriculture, etc.)
- **Assessment** of all **promotional content** (labeling, website, advertisements, brochures)
- **Justification** of **health claims and substantiation** for structure function claims

MARKETING

- **Drafting of authorization request files** in accordance with the regulations in force (ingredients, final products, health claims)
- **Negotiating** with competent authorities

MEDICAL FOODS

FOODS WITH MEDICAL PURPOSES

Medical Foods, also referred to as "Foods for Special Medical Purposes" (FSMPs) in the EU, are **foods that are specially processed or formulated and intended for the dietary management of patients to be used under medical supervision**. Medical foods vary from general foodstuff in that they are not meant for a healthy population.

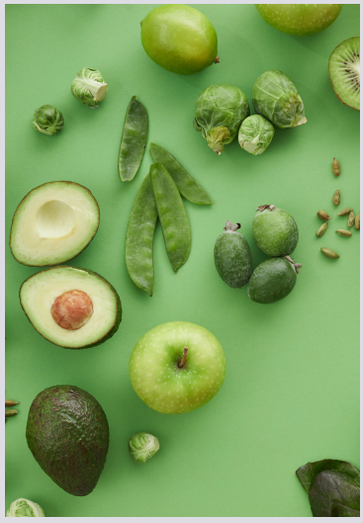
- FSMPs are integrated into food regulation dedicated to specific groups/populations.
- In the US, Medical Foods and Foods for Special Dietary Use (FSDU) are regulated as foods, but as distinct categories separate from conventional food.

In both cases, **Medical Foods require robust scientific support** for the safety and efficacy of such foods.

RNI'S EXPERTS WILL SUPPORT YOU

RNI will walk you through the regulatory landscape and help achieve your Medical Food development and launch goals. As well as Medical foods, RNI can also help you with other Foods for Specific Groups, such as Foods intended for infants and young children, and Total diet replacement for weight control.

Did you know? RNI can assist you with your Medical Food products worldwide.



FOCUS ON FSMPs (EU / UK)

- **Assessing the regulatory compliance** of your formula and label
- **Consultation** with competent authorities
- Drafting of **applications for reimbursement programs** in Europe and the UK
- Drafting **mandatory scientific supporting files**
- **Notification** before market placement
- Assessing compliance of your product **advertisement**

FOCUS IN THE US AND WORLDWIDE

- Providing a **regulatory framework** for specific product classification categories
- **Review** for potential to meet requirements
- **Strategic support** for product positioning
- Analysis of the **regulatory compliance**
- Analysis of **supporting data**
- **Consultation** with competent authorities

COSMETICS

QUALITY, SAFETY, CLAIMS... WHERE TO START?

Compliance of cosmetic products encompasses a few challenges, such as creating technical dossiers, compliance of raw ingredients, safety assessments, communication and notifying the authorities. From the development of cosmetics to the placing on the market, **the entire cosmetic regulatory process may be difficult to navigate**.

RNI HAS YOU COVERED FOR YOUR COSMETICS

Whether you are developing a new cosmetic product or reformulating an existing one, **RNI will act as your dedicated regulatory and scientific partner** that will accompany you through all the steps involved with placing cosmetic products on the market.

RNI will provide you support from the development of your cosmetics to launch on international markets.

AUDIT & DUE DILIGENCE

- **Qualification / follow up audits** of suppliers and manufacturers
- Assistance to adopt **relevant quality standards**
- **On-site GMP Audits** in Europe
- Regulatory and scientific **audits of cosmetic technical dossiers** and communication for M&A

NEW PRODUCTS

- **Investigation** into the **quality and conformance** of raw materials
- **Compliance of formulation**
- **Determination** of most suitable **regulatory status**
- **Reverse planning** of product notifications

COMMUNICATION

- **Scientific validation** and proof of cosmetic product **claims**
- **Creation of label** and packaging content
- **Validation of all forms of communication including** those present on packaging, website, advertisements, leaflets etc.

PLACING ON THE MARKET

- **Creation** of the **Product Information File** (PIF)
- Authoring of the **Cosmetic Product Safety Report** (CPSR)
- **Preparation of notification applications**, such as CPNP for the EU market, submission to FDA's Voluntary Cosmetic Registration Program in the USA

PHARMACEUTICALS

EVER-CHANGING REGULATORY CONDITIONS

Healthcare is a demanding industry worldwide, with **ever-changing regulatory conditions**. For example, the EU Commission have set regulatory obligations and processes which must be met by manufacturers, marketing authorization holders and distributors of medicinal products.

SCIENTIFIC SERVICES FOR COMPLIANCE

RNI is here to **support you bring your human and/or veterinary products to market**. Our scientific experts and medical consultants can support you with submissions management for product authorization, post-marketing procedures and meeting requirements for the risk – benefit profile of medicinal products.

In these ever-changing regulatory conditions, RNI will provide you with medicinal and pharmacovigilence services.

MEDICINAL SERVICES

- **Support on common technical dossier compilation**, Modules 2-5 of e-CTD
- **Analysis** of the specific EU requirements
- **Support in post-authorization status**
- **Toxicological support for APIs**, residuals impurities, extractables and leachables
- **Calculating the Permissible Daily Exposure** (PDE) or the Health Based Exposure Limit (HBEL) in manufacturing sites for human and veterinary medicinal products according to cGMP Guidelines

PHARMACOVIGILENCE SERVICES

Marketing authorization holders are required to monitor the risk-benefit profile of their medicinal products in post-authorization period of its lifecycle.
Our RNI team can provide your company with the below services:

- **QPPV** 24h support
- **Eudravigilance MAHs** registration
- **XEVMPD** registration
- **ICSRs** management and submission
- **Medical Literature Monitoring**
- **Periodic Safety Update Report (PSUR)** authoring and submission
- **Training**

BORDERLINE PRODUCTS

IS IT A SUPPLEMENT? MEDECINE? SOMETHING ELSE?

The different regulations applicable to nutritional and health products **often present problems when deciding what legal status** is most appropriate for your product. The blurred lines between common enriched foods, food supplements, medicines, and cosmetics may have companies wondering **what regulatory classification is best suited to your product**, as this will influence the entire regulatory and marketing approach you must apply.

LET'S OUR EXPERTS HELP YOU CHOOSE

Our regulatory and medical expertise in various product categories enables us to provide you with guidance to **choose the most appropriate regulatory status for your borderline products**.

MONITORING

Precise monitoring of the changes in current regulations for the different categories of nutritional and health products

EXPERTISE

Each RNI consultant is **specialized in specific regulatory statuses** to ensure the expertise and multi-disciplinary approach

METHOD

A **methodological approach** grounded in comparative law and jurisprudence

PARTNERS

INDUSTRY ASSOCIATIONS

Being a part of the regulatory industry and scientific world is important. Being an **active member, leader**, and **taking part in the direction the industry is heading** is even better. RNI is a **proud member** of the following industry associations:

STRATEGIC PARTNER

INNOVEOCARE

InnoveoCare offers personalized support for your nutrition and health projects, with a special focus on borderline products between food and pharma, **from their design to their first industrial production**. To give the best chance of success to your projects, InnoveoCare sustains every single step through global and multi expertise vision.

CHARITIES

SOUTH PACIFIC ISLANDER ORGANIZATION

Founded by four Indigenous and Pacific Islander Stanford alumni, the association enables access to higher education and economic opportunities in Polynesia, Micronesia and Melanesia.
www.southpacificislander.org

CLUB HOUSE FRANCE - L'ESPOIR EN TÊTE

Clubhouse France focuses its efforts on helping fight the challenges anybody can face in its lifetime. From mild depression to disabling psychiatric illness, all those involved in the development of Clubhouse France are concerned either directly or by one or more of their relatives.
www.clubhousefrance.org

OUR MODELS

A WIDE SELECTION TO MATCH ALL YOUR NEEDS

For more than 15 years, RNI has been providing regulatory and scientific support to companies in the health and wellness industry throughout the world. Through all these years, we have developed **different models to help you navigate through your domestic and international projects**. RNI can assist you in three different ways:

INDIVIDUAL QUOTES

Your company is going through a specific project, such as a label review or an ingredient review.

SUBSCRIPTIONS

You are looking for on-going support throughout the year, RNI supports you on a monthly basis.

DEDICATED CONSULTANT

RNI provides you with a dedicated consultant entirely embedded within your team.

RNI adapts its models to the objectives and the needs of its clients, tailoring its services to every project.

FOCUS – RNI DEDICATED CONSULANT

So often your regulatory and development team may have a project that requires an additional resource for a few weeks or months. However, it is a hassle to go through a recruiting agency, verifying competence and expertise, and onboarding time of the new resource. For this reason, RNI proposes the **Dedicated Consultant: a dedicated regulatory and scientific support, providing you access to all local and international RNI resources, for a fixed period of time**.

Violaine Chaumont
CEO of RNI

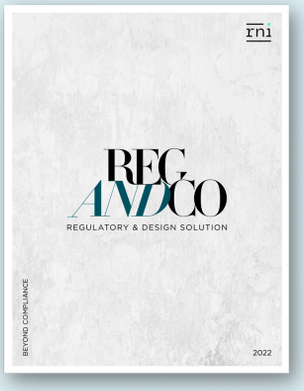
> Unlike consultants recruited through standard recruitment firms, the RNI Dedicated Consultant is part of an established regulatory firm with global expertise on many regulatory statuses. This allows your company to have a resource working directly with your Regulatory Affairs, Marketing and Business Development teams.

INNOVATIVE SERVICES

REG & CO, REGULATORY AND DESIGN SOLUTION

Your product developments and expansions can be painful experiences because of time constraints, lack of coordination, misaligned budgets... End the hassle of going global now! **Discover our new service, Reg&Co: an all-in-one regulatory and design solution**.
With Reg&Co, let RNI's experts check all the boxes for you:

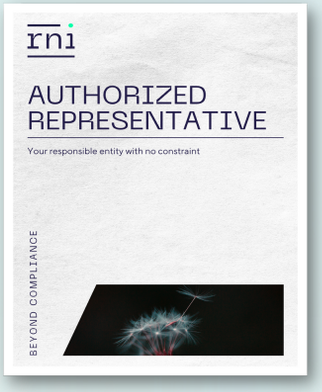
- **Create labels and packaging** that are both aesthetically pleasing and compliant
- **Save time and be cost effective** throughout the entire process
- **Adapt all your labels** when expanding internationally
- **Project management** between the departments of your company
- **Be confident** in the compliance of your labels in each country



With innovative services, RNI can support your business initiatives in unique ways, going beyond compliance.

AUTHORIZED REPRESENTATIVE

Expending from domestic to international markets can often be stressful, with tons of administrative burdens to take into consideration. One of them is the creation of a new legal entity abroad, and the responsibility of selling products that goes with it... **Discover our new service: RNI becomes your responsible entity, with no constraints!** Let RNI take the burden off of your shoulders:



- **RNI, your responsible person** on your behalf
- **Multi-statuses**, such as supplements, food, and cosmetics
- **Traceability** of customers complaints as well as nutri / cosmetovigilence
- **RNI audits your products** from a regulatory, quality, and safety standpoints
- **International**, available in several countries

Are you ready?

RNI's experts understands the daily challenges your company faces when launching new products, expanding domestically or worldwide, scaling up, or simply making sure your company reaches full compliance.

With offices in France, UK, and USA, **RNI provides regulatory and scientific consulting services in multiple international markets, including North and South America, Europe, Africa and Middle East, Asia and Pacific countries**. Among the team, each of our regulatory and scientific experts deals with complex issues with an extensive knowledge of the health, wellness and beauty industries.

Contact us today to learn more about all our services.

www.rni-consulting.com/en

Follow us on social media with #RNINews

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