



## Live long. Live healthy.

#### THE SCIENCE BEHIND ISAGENIX



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- The Research & Science Foundation of Isagenix
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## Live long. Live healthy.

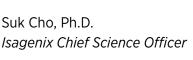
#### A word from the chief...

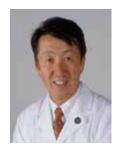
When Isagenix Founder and Product B<sup>™</sup> Formula Developer John Anderson started this company with Jim & Kathy Coover, he knew that if it was to become a world leader in health and wellness, it would take "no compromise" products.

Now, the QRTS department (QRTS stands for Quality, Regulatory, Technology, and Science) consisting of more than 30 scientists—including nutritionists, dietitians, food scientists, chemists, organic chemists, microbiologists, toxicologists, and biologists—continues that tradition by collaborating with John, the elite health professionals on the Scientific Advisory Board, and highly-respected universities to ensure that "real results" are at the heart of every product.

Together, the company creates leading-edge products that are innovative, backed by science, safe, and effective. In this newsletter, we give you a "fly on the wall" view of what it's like to be part of the QRTS department and the process involved in creating real solutions for the world.

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## From Idea to Product



Partnering with
John Anderson, our
Product Innovation &
Commercialization Teams
actively collaborate with
experts from diverse scientific
disciplines to develop unique
products and solutions that
provide Isagenix Associates
with real results.

Behind any great health and wellness company, there have to be great products. And behind those great products, there has to be an experienced yet forward-thinking team of knowledgeable and skilled experts. Isagenix is no exception to this rule. The Product Innovation & Commercialization Teams at Isagenix work tirelessly to develop product formulas based on substantial research with the safest and most effective ingredients delivering optimal benefits.

Embracing the ambitious vision of John, our product development process includes diverse layers of scientific testing and an exacting attention to detail to create our "no compromise" line of products (1, 2). This process requires constant collaboration across a number of scientific disciplines with a unified commitment to quality and a goal to provide Isagenix associates with real results.

This complex process of developing and launching new products around the world can be broken down into four phases:

- 1. Discovery: Some companies are only after creating products that will sell in the market-even if that means dismissing scientific efficacy or bypassing measures to ensure safety. At Isagenix, the discovery phase of the innovation process is more than just reviewing market trends. Before a product is formulated, hundreds of hours go into investigating the latest scientific evidence on ingredients, dosage, effectiveness, and safety. Together, the scientists in the QRTS department identify how various ingredients work synergistically in a new, innovative product to benefit various aspects of health.
- **2. Feasibility:** The feasibility of a product is determined by evaluating whether there is a sustainable supply

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chain, how a product tests with consumers, what novel delivery systems are available, and what market and cultural preferences there are relative to a product. The company formulates products to be sure they are suitable for those with specific dietary restrictions (e.g. gluten-free) and for those with cultural preferences (e.g. Kosher). In addition, the team seeks out the highest standards in packaging to support sustainability.

**3. Development:** When developing a product, Isagenix invests many of its resources in conducting multiple analytical and sensory tests on both raw materials and finished products until quality, safety, and efficacy standards are met. Additionally, Isagenix makes clinical research a priority and partners with well-known and respected universities to design and conduct

studies evaluating Isagenix products and systems. Because of this extensive testing, Isagenix can proudly stand behind quality products.

4. Commercialization: Products must comply with governmental regulations as outlined by the Food and Drug Administration (FDA). Being an international company, Isagenix products must also work with government administrations around the world including Health Canada, Therapeutic Goods Administration (TGA) of Australia, and Ministries of Health (MOH) of Hong Kong and Taiwan. This involves meeting strict requirements on product licensing, labeling, and claims. While some companies may see this as an inconvenience, Isagenix sees it as a reliable system of checks and balances to ensure production of high-quality products.

When you enjoy your Creamy French Vanilla IsaLean Shake or bite into an Oatmeal Raisin IsaLean Bar, know that it was carefully crafted by a team of highly qualified professionals after hundreds of hours of testing and research to ensure that the product is effective and supported by science. By following these phases of development, the Product Innovation and Commercialization Teams at Isagenix are setting you up for success.

#### **REFERENCES**

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## SHOW ME THE DATA: RESEARCH & SCIENCE

The Isagenix Research and Science Team is responsible for spearheading clinical research on Isagenix products, reviewing evidence-based literature to substantiate product structure-function claims, and contributing innovative ideas for product development. The team also keeps an ear to the ground for the latest developments in nutritional science and devotes time to communicating science to Isagenix Associates through presentations, podcasts, and articles found at IsagenixHealth.net.

#### COLLECT DATA

Tasked with following the latest science emerging from the nutrition and health fields, the Research and Science (R&S) Team spends their days combing through research, analyzing studies, and writing supporting documents for all existing and future products. Because that's the foundation for every product Isagenix creates: scientific research. Educating the field on the scientific research behind the products, as well as general nutrition and health topics and how Isagenix products fit into any healthy lifestyle is another important responsibility for the R&S Team.

#### REVIEW AND COLLABORATE

The Isagenix R&S team includes nutritionists and registered dietitians who oversee all health and nutrition discussions at Isagenix. They also collaborate on analyzing the latest scientific data with John Anderson and the Isagenix Scientific Advisory Board. Because of this review process, Isagenix develops products that have scientific support showing sufficient benefit to consumers and have evidence of safety.

A great example of this dedication to science is the research that was conducted in the formulation of the Isagenix Brain Boost and Renewal (1). Isagenix partnered with Michael Colgan, Ph.D., to create a new and novel product targeting brain health and healthy aging. Together, they reviewed hundreds of animal and clinical studies, identified a synergistic blend of nutrients to support brain health, and conducted a six-week trial to select the most effective formula.

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IsagenixHealth.net is your onestop platform for learning about the science behind Isagenix products. Stay abreast of the latest evidencebased updates about weight management, healthy aging, and energy and performance.

### JOINING FORCES WITH UNIVERSITY SCIENTISTS

At Isagenix, we understand the importance of evidence-based nutrition, which is a comprehensive research evaluation model taking into account the sum of all available evidence. Not only do our experts use this method when reviewing scientific research, but they also contribute to evidence-based nutrition by joining forces with several well-respected universities in conducting research including University of Illinois at Chicago (UIC), Arizona State University, University of Maryland, Skidmore College, and University of Colorado. Recently, for example, UIC conducted a clinical study using Isagenix products that was published in two peer-reviewed journals (2-3). These studies serve to measure the benefit provided by Isagenix products, ingredients, or systems, but they are also meant to add to the body of evidence-based nutrition research that advances the understanding of the human body and what can improve health.

#### **EDUCATE, EDUCATE, EDUCATE**

One of the most important roles of the Isagenix R&S Team is to educate Isagenix Associates on the health benefits of Isagenix products and systems. We understand that not everyone has extensive education in nutrition or health—and you don't have to be an expert to be an Isagenix Associate!

Scientific literature can be highly complex and difficult to understand. The R&S Team is tasked with taking this information and presenting it in an understandable and compelling manner. Be sure to subscribe to IsagenixHealth. net for regular articles, product training calls, quarterly newsletters, and other informative flyers. Not only will you learn about the science behind Isagenix, but you will feel confident sharing that information with others. It's the science that supports the products, but it's the R&S team that's here to support our Associates.



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# Isagenix Quality Assurance Doesn't Cut Corners

As it should be, your safety is our first priority at Isagenix. Having safe, effective, "no compromise" products means giving no slack when it comes to selecting and testing raw materials, following the appropriate regulatory guidelines, and verifying that the finished products meet purity and composition standards.

The Isagenix "No Compromise" Quality Policy is extensive and thorough, covering every detail from ingredient sourcing to manufacturing guidelines. By following key procedures, Isagenix can stand by their products with confidence.

#### RESEARCH AND SELECTION OF RAW MATERIALS

After a product has been proposed and approved, it's time to select the best source of the raw material to begin formulation. Quality ingredients could mean the difference between products having no effect and providing fantastic results. At Isagenix, raw materials are only sourced from suppliers with a proven track record of sustainability and quality.

One of the best examples of Isagenix's quality standards is the whey protein found in IsaLean shakes. New Zealand undenatured whey protein was carefully selected after vigorous research and testing because the quality of the protein can't be beat. It's the best of the best.

#### MEET AND EXCEED MANUFACTURING GUIDELINES

"No Compromise" quality does not stop after raw materials have been selected. When the ingredients are delivered to the manufacturing facility, there are strict guidelines with how materials are handled. These guidelines that define how manufacturing should be conducted are known as current Good Manufacturing Practices (cGMPs). Isagenix works to ensure that all products meet or exceed the highest

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WHILE IN QUARANTINE, RAW MATERIALS ARE TESTED FOR:

#### » IDENTITY

• Botanicals & Phytochemicals

#### » PURITY

- Microbial Activity
- Pesticides, Herbicides, Fungicides
- Heavy Metals
- PCBs & Dioxins

#### » STRENGTH & COMPOSITION

- Standardization & Potency
- » ORGANOLEPTIC PROPERTIES
- Taste, Color, Odor & Texture





- » Supervision of use-test performed by manufacturers.
- » Evaluation of the identity, purity, strength and composition of the final product.
- » Third-party independent claim testing to ensure the product fully meets label claim(s)
- » Stability testing to confirm that composition and strength is accurate

## WHAT ARE cGMPs?

Guidelines on how manufacturing should be conducted to guarantee raw materials and finished products are safe and free of impurities.



#### THE RESULT:

Ingredients that have been thoroughly tested and products that are safe, pure, and effective.

### EACH RAW MATERIAL IS EVALUATED.

All ingredients must meet or exceed **cGMPs** as outlined by FDA and other international regulatory boards such as Health Canada, Theraputic Goods Administration, and Ministries of Health.







standards of cGMPs for dietary supplements.

cGMPs are outlined by the FDA and other international regulatory boards such as Health Canada and the Therapeutic Goods Administration (TGA) in Australia. These guidelines include authenticity, quarantine and release procedures, potency and purity testing of raw materials and finished products, cleanliness of the facility, employee training, and documentation (1-3).

Meeting all of these guidelines can make the release of products internationally a fairly complicated, yet beneficial, process. Through this series of checks and balances, Isagenix can stand by the quality of its products with pride.

#### STANDARDIZED TESTING METHODS

Isagenix also adheres to detailed written Standard Operating Procedures (SOPs) to ensure consistency and safety in each phase of our manufacturing process. One SOP Isagenix follows requires that every raw material that arrives

in the manufacturing facilities be immediately quarantined, thoroughly inspected, and tested for:

- Identity (botanicals & phytochemicals)
- Strength & composition
- Organoleptic properties (taste, color, odor, & texture)

Any raw materials that do not meet these standardized testing methods are rejected or destroyed.

Testing to confirm safety and purity of raw materials is very extensive. Rigorous testing is performed for:

- Microbial activity: total aerobic bacterial, yeast and mold, salmonella and E. coli strains, and other bacterial strains
- Pesticides, herbicides, and fungicides
- Heavy metals: all botanicals are tested for the presence of lead, mercury, cadmium, and arsenic
- PCBs and dioxins: each batch of fish oil is third-party tested to

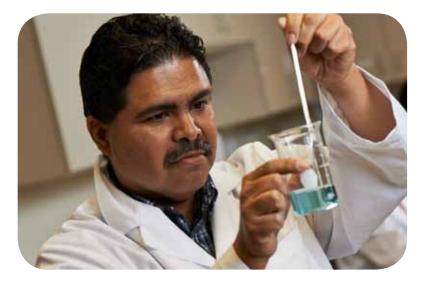
confirm undetectable levels of heavy metals, PCBs, and dioxins

#### FINISHED PRODUCT VERIFICATION

In addition to testing raw materials, Isagenix is unique in that they also thoroughly evaluate the efficacy of finished products. This includes reanalyzing the product for identity and purity. Third-party claim testing on vitamin and mineral content is also conducted to ensure the products fully meet what is said on their labels. Finally, stability testing is done to confirm that the strength and composition as indicated on the label of the product is accurate up until at least the expiration date.

#### STATISTICAL PROCESS CONTROL

Another major role of Isagenix Quality Assurance is statistical process control. This involves tracking trends to ensure product quality is continuously monitored and upheld. By putting this much care and attention towards product quality and safety, Isagenix knows it's doing right by its customer and their health.



There are few other companies that can stand by their quality assurance commitment. By putting this much care into their products, Isagenix knows they are putting the health of their customers first.

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- 1. Food & Drug Regulations. U.S. Food and Drug Administration. Retrieved July 2013, from www.fda.gov
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# SHARING ISAGENIX SOLUTIONS WITH THE WORLD



Bringing Isagenix "no compromise" products to other markets takes skill and global partnerships. John Anderson and the International Regulatory Team are prepared to bring the highest of Isagenix standards for safety and efficacy to the entire world!

When you look at the statistics, it's hard to deny that the health of the world is worsening. In 2008, the World Health Organization reported that more than 1.4 billion adults were overweight, and of those, 500 million were obese. Type 2 diabetes, a disease largely linked to obesity, is projected to become the seventh leading cause of death by 2030.

Luckily, there's a solution—Isagenix. Backed by strong evidence from the University of Illinois at Chicago's clinical study using Isagenix products, we know Isagenix products can reverse the trend of declining health by supporting better diet and lifestyle habits for healthy weight management, energy and performance, and healthy aging.

#### **GLOBAL CHALLENGES**

Positioned as a global leader in health and wellness, Isagenix can help nurse the world back to health. However, as dedicated as our company is to sharing solutions with other countries, there are several obstacles when supplying nutritional products around the globe.

For example, each country has their own unique regulations as outlined by agencies—such as the Food and Drug Administration (FDA), Australia's Therapeutic Goods Administration (TGA), and Health Canada—that specify limitations on certain ingredients, sources of ingredients, processing methods, and delivery systems (1-3). There are also rules regarding labeling of products and claims that can be made.

Another consideration is accommodating the different marketing environments in each country. This involves addressing differences in purchasing methods, product positioning, and market competitors. Isagenix must also consider cultural preferences—including taste profiles and kosher and halal certifications—when creating products for international use.

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#### REAL RESULTS AROUND THE WORLD

With the skilled professionals that make up the International Regulatory Team, Isagenix is prepared to overcome these barriers. This team is always expanding to keep pace with Isagenix's incredible international growth. They work directly with John Anderson to reformulate products to ensure they comply with regulations across international markets including Taiwan, New Zealand, Australia, Hong Kong, China, Singapore, Canada, and Mexico. Their goal is to maintain the overall integrity of the original products made for the U.S. as well as its purpose for use while staying compliant to each country's rules and regulations.

For example, while there may be a few minor differences in the vitamin and mineral contents of an IsaLean Shake found in Canada compared to one in Hong Kong, the main ingredients are still there, and it has been tested to ensure it's a safe and effective product. Another product, Cleanse for Life, has a slightly different ingredient profile from

country to country, but each has been formulated to maintain its effectiveness. With Isagenix, the integrity of a product is never compromised in order to meet international regulations.

As Isagenix expands into more countries all over the world, John and the International Regulatory Team will be there to pave the way and ensure all products uphold the highest of quality and safety standards while providing real results. Isagenix is transforming lives and fighting for a healthier world, one country at a time.

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### Where In The World Is Isagenix?

