STANDARD PROCESS **PRODUCTS**

The Standard Process certified organic farm

Why Whole Food Nutrient Solutions Matter

As you know too well, many of today's patients eat what is considered the average American diet containing large amounts of refined and processed foods, some of which have limited nutritional value. Patients aren't eating enough fresh foods that are naturally high in nutrients like vitamins, minerals, and phytonutrients that help the body thrive and maintain health. Most of these patients can benefit from supplementing their diets in order to bridge this nutritional gap.

> *"The best sources of vitamins and minerals are found in whole foods."*
>
> *—Dr. Royal Lee, founder of Standard Process*

Your patients come to see you for many reasons, such as stress, fatigue, digestion issues, and hormone health, just to name a few. They may not realize it, but many of their complaints may have a nutritional component. That's where you and Standard Process come in.

Clinical nutrition and the relationship between food and a healthy body are more important than ever. Knowing how nutrients are digested, absorbed, transported, metabolized, stored, and eliminated by the body helps you communicate nutrition's significant role in many health challenges. This knowledge also helps you to explain how the complexity of whole food and other ingredients in our supplements can support your patients.*

Buckwheat field on the Standard Process certified organic farm

*These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.

The Standard Process Difference

There are a lot of supplement companies in the marketplace. What makes Standard Process supplements made with whole foods and other ingredients so unique? Here are just a few reasons.

Alfalfa

Beet

Peas

Whole Foods and the Whole Food Philosophy

Since 1929, Standard Process has been the visionary leader in whole food nutrient solutions. We are dedicated to creating quality supplements based on the whole food philosophy introduced by Standard Process founder, Dr. Royal Lee. Dr. Lee's goal was to provide nutrients as they are found in nature, where he believed their natural potency and efficacy would be realized. Our goal is to carry on his mission, creating holistic formulas by incorporating whole food ingredients along with targeted vitamins and minerals.

Starting With Whole Foods

Following this philosophy, we start with whole foods—foods you might find in the grocery store, like peas, radishes, and beets. Then, like any good cook, we prepare these ingredients in a way that safeguards their nutritional value. The resulting whole food ingredient is then added to a complex formula that may include whole food concentrates; animal tissue extracts and concentrates; botanicals; whole food isolates; and synthetic ingredients as required to meet our high formula standards.

Why are whole food nutrient complexes important?

The nutrient complexes found in whole foods are valuable and essential to good health. Standard Process founder Dr. Royal Lee referred to these complexes as "the life element," and they can be produced only through biological processes. That is why we start with the highest-quality whole food ingredients when making our supplements.

These ingredients contain complex structures that combine a variety of elements that work together to support healthy balance in the body. We add additional targeted ingredients to formulas as needed to support specific systems in the body.*

Our Focus Is on Quality, Not Quantity

When we take supplements, we often think that more is better. This common misperception can lead to megadosing, or taking vitamins that contain amounts of certain nutrients that exponentially exceed daily recommendations.

Quality is far more important than quantity when evaluating and choosing nutritional supplements. Supplements that contain only synthetic vitamins have just a fraction of the beneficial compounds that are found in foods. Those supplements may only focus on certain challenges in the body. Supplements that include whole food ingredients are more complex, as they contain a mix of constituents that can be used to address a wider range of the body's needs.*

High-Quality Ingredients

As in any recipe, the quality of ingredients affects the quality of the final product. Manufacturers who grow their own ingredients have control over them, which is why Standard Process owns a 623-acre certified organic farm. The farm, located just a mile down the road from company headquarters in Palymra, Wisconsin, harvests 6.7 million pounds of vegetables every year. More than 80 percent of the raw plant ingredients used in our products are grown on our farm.

We promptly process our farm-harvested crops to minimize the loss of phytonutrients and deliver those nutrient complexes so integral to Dr. Lee's vision.

For items we can't grow, Standard Process has an extensive, rigorous system of supplier auditing and validation. This allows us to provide patients with a product that has been controlled, vetted, tested, and verified from beginning to end.

Some types of processing can destroy enzymes and phytonutrients. Our manufacturing process is designed to minimize the loss of vital nutrients from each ingredient.

Buckwheat

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How Standard Process Defines Quality

How we define quality frames our approach to making supplements, from our whole food philosophy and our careful ingredient sourcing to our formulations and dedication to rigorous testing and safety. "Quality from seed to supplement®" is more than just a tag line to us—it's a commitment we take to heart during every step of the production process.

Brussels sprouts

Kale

Oats

A whole food supplement is a complex formula of targeted ingredients that may include:

Whole food ingredients—complete foods prepared in a way that safeguards their nutritional value

On our product labels are many ingredients that you recognize as foods. Some of these whole food ingredient sources are regularly grown locally on our certified organic farm, including alfalfa, barley grass, beets, Brussels sprouts, buckwheat, kale, kidney beans, oats, pea vine, and Spanish black radish. This allows us to control the quality of these ingredients from seed to supplement.

Whole food concentrates—processed parts of a whole food containing two or more constituents of the original whole food

These concentrates are used when a beneficial concentration of nutrients cannot be obtained using a whole food ingredient. Fish oil is a good example. Derived from whole fish, the nonconcentrated triglyceride oil that makes up our final product allows patients to take advantage of the naturally occurring DHA and EPA omega-3 fatty acids.

Whole food isolates—single components from a whole food

Sometimes foods do not contain sufficient quantities of specific nutrients to address certain health challenges. In this case, we use evidence-based food isolates to complement whole food ingredients for optimal nutritional support.

Isolates like glucosamine are used in our products because they are well-researched and have strong evidence for efficacy. Isolates derived from whole food sources are combined with other ingredients to maximize efficacy.

For 90 years, Standard Process has provided health care professionals with high-quality nutritional supplements made with whole food and other ingredients.

Specialized protein isolates and concentrates—whole food ingredients derived from bovine, ovine, and porcine sources

The use of specialized protein isolates has a long history at Standard Process. The first product based on a Protomorphogen™ brand extract was introduced in 1952 and contained bovine heart PMG™ extract. Why do we start with protein isolates and organs? They are inherently different from skeletal muscle. They have more DNA per gram than skeletal muscle, different protein profiles, and different starting concentrations of vitamins and minerals. All raw specialized protein isolates are exclusively from U.S. Department of Agriculture (USDA)-inspected facilities.

Protomorphogen™ Brand Extracts

Continuing the pioneering work of Dr. Royal Lee, certain Standard Process products contain specific Protomorphogen™ brand extracts. Protomorphogen™ brand extracts are specific materials extracted from specialized protein isolates and organs through a complex, multistep process to retain what Dr. Lee termed "cellular determinants." Current laboratory methods have confirmed that Protomorphogen™ brand extracts contain minerals, nucleotides (the components of nucleic acids like RNA and DNA), and peptides (short chains of amino acids).

Cytosol™ Brand Extracts

Cytosol™ brand extracts are derived from the cytoplasm of selected organs and glands through a process similar to the Protomorphogen™ extraction process. However, these extracts contain cellular factors such as hormone precursors and synergistic cofactors that are the biochemical building blocks essential to cellular metabolism.

Whole Desiccates

Whole desiccates are tissues that have been dried to provide the nutritional content of the organ in a concentrated form.

Botanicals—plants and plant extracts with health-supporting properties

Botanicals provide important constituents that contribute additional support to the body's systems by complementing the vitamins, minerals, and tissue concentrates found in whole food ingredients.*

Synthetic ingredients—a nutrient produced by chemical means

We know Dr. Lee included synthetics in his original formulas to meet label claims and/or enhance product effects. Historically and still today, this type of ingredient is used selectively. Where synthetics appear, they have been added to protect the complexity and synergistic design of the formula.

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To attract bees, tree lines along the Standard Process farm are kept intact, and plants are blooming from spring to fall in a native pollinator garden. The habitat is home to more than 500 plants and 35 different varieties that attract insects to the farm.

The Standard Process Certified Organic Farm

Our founder, Dr. Lee, emphasized the importance of producing high-quality supplements made with whole food ingredients. We are proud to be one of the few supplement manufacturers that can assure quality ingredients by continuing our tradition of growing many of our raw materials locally and organically.

More than 80 percent of the raw plant ingredients used in our products are grown on our 623-acre farm. We harvest 6.7 million pounds of produce per year on the farm, which is located just a mile down the road from our corporate headquarters. Standard Process has become a respected leader in the regional and national organic farming community.

Formed by glaciers, Wisconsin's Kettle Moraine region contains nutrient-rich soil for our certified organic farm. It is here that we grow strong, vital plants for use in our supplements, including:

- Alfalfa
- Barley grass
- Beets
- Broccoli
- Brussels sprouts
- Buckwheat
- Celery
- Kale
- Kidney beans
- Oats
- Parsley
- Pea vine
- Red clover flower
- Spanish black radish

Organic Farming Methods

We use organic farming practices that have been part of our culture for 90 years to ensure that the quality of our farmland is maintained for years to come. In accordance with our organic certification, we follow strict guidelines to grow our crops and keep detailed records of our farming practices. Our farmland is monitored annually by the Midwest Organic Services Association (MOSA) to ensure that only approved farming practices are used. At Standard Process, we are involved from the moment a seed is planted through shipping the finished product to your door.

> *"Whole food nutrition begins with sun, water, and fertile soil."*
>
> *—Dr. Royal Lee*

Seeds
In an organic system and on our certified organic farm, there is zero tolerance for genetic engineering. On the Standard Process farm, we use certified organic seeds whenever they are available, whether they are purchased or saved from our own farm. If after a diligent search it is determined that organic seed is not available, other untreated seed that has not been genetically engineered is only then considered an option.

Soil
We take soil samples annually to determine mineral and nutrient levels in the soil. We never use any synthetic fertilizers or pesticides in the organic growing process.

Weed Control
Like all farmers who strictly adhere to organic weed-control standards, we spend many of our days managing weeds. There is no simple approach, just a comprehensive one that includes cultivating, mowing, and hand weeding. To minimize weeds, we grow cover crops and institute crop rotation. These practices have additional benefits: Cover crops are a great source of nitrogen and organic matter, and crop rotation helps maintain the health of the soil and the plants.

Irrigation
When irrigation is necessary, water is supplied from a naturally occurring artesian flowage below the farm's surface.

Pollination
Colony collapse disorder has had a catastrophic effect on the honeybee population in the United States and threatens the pollination of our nation's fruits and vegetables. That's why our farm has planted more than 500 plants of 35 different native species in a permanent habitat for honeybees and other pollinators.

Composting
It is a goal of every organic farm to increase fertility and improve soil health. We use the biological process of composting to turn organic production waste from the farm's press room into a rich and extremely fertile humus-like substance that we spread over our fields.

Environmental Buffers
Our farm is surrounded on all sides by environmental buffers to minimize the impact of nonagricultural land and synthetic inputs from conventional farming practices.

Manufacturing: Processes That Preserve Nutrients

Preserving the whole food complex is a top priority when manufacturing our supplements. Our formulas are based on Dr. Lee's time-proven philosophies. Quality takes time. Our manufacturing process, from raw materials to finished product, takes an average of six weeks. Throughout the process, raw materials are handled in a carefully controlled environment and tested for quality.

Exclusive Certified Organic Manufacturing Processes

Our manufacturing processes are certified as organic by MOSA, ensuring that ingredients remain organic from seed to supplement. Our processes are also certified by NSF International for GMP compliance. Each process is designed to preserve nutrients in raw materials.

Juice Extraction

To capture the nutrients from raw materials such as buckwheat, alfalfa, and pea vine, the juice is pressed from the plants and separated from the pulp. The result is a concentrated product containing both fat- and water-soluble nutrients.

Separation Process

Selected animal tissues used to make our Protomorphogen™ and Cytosol™ extracts are ground to create a liquid slurry. The slurry is subjected to our proprietary multistep separation methods. All raw animal tissues are obtained exclusively from USDA-inspected facilities.

Drying

To safeguard the complexity of our raw materials, we use equipment that allows for accurate temperatures and highly reproducible processes.

- Double drum: dries extracts from both plant and animal tissues
- Forced air: a multistage forced-air belt dryer that works like a sophisticated food dehydrator

Isolated Production Processes

We use isolated production suites for the following processes. These suites enhance cleanliness and reduce the risk of cross-contamination in the manufacturing area.

Mixing

Dried materials are precisely measured and carefully mixed. Because of the variability in natural and organic ingredients, color, texture, and odor may vary from batch to batch. However, the basic formula remains constant, and is tested for quality assurance.

Standard Process is proud to be an industry leader in organic certifications. Not only do we have our own certified organic farm, our manufacturing processes are also certified as organic.

Binding and Processing Aids
After mixing, our fluid bed granulator is used to add natural binding ingredients, such as honey and arabic gum, to the product batch for tableting. Other processing aids we use include cellulose and calcium stearate. Cellulose is often used to give body to the powders. When needed, calcium stearate, derived from vegetable sources, is used to help product release from the tablet and capsule machines. We do not use artificial flavoring.

Tableting, Capsuling, Perling, and Powder Filling
Our supplements are offered in several forms of delivery. The most common are tablets, capsules, softgels/perles, and powders.

Tablets—Tablet presses used by Standard Process allow for high-volume production without sacrificing quality. All of our finished tablets are routinely analyzed for content to ensure that label claims are accurate.

Capsules—Capsule machines are continuously monitored to ensure that precise amounts of product are enclosed in gelatin and/or cellulose capsules. Capsules are packaged by weight, not volume. Therefore, the denser the product, the less you will find in the capsule. The gelatin capsules are considered pareve/parve, meaning the capsule has been processed so extensively that it can be considered to have been prepared without meat or other derivatives.

Softgels/Perles—Our soft gelatin manufacturing process consists of: gelatin preparation, encapsulation, drying and inspection. Temperature and humidity are carefully monitored during this process.

Powders—For powder formulas, we use a volumetric filler, which achieves very accurate fill amounts.

Packaging
Our products are packaged in either amber glass bottles or bisphenol A (BPA)-free bottles made of polyethylene terephthalate (PET) plastic. The color of the bottles helps protect the supplements' nutrients from damaging light, while the sealed bottle helps prevent product oxidation. Seals and neckbands protect against product tampering. The majority of the products are then packaged in eco-friendly cardboard cartons, providing easy storage, protection, and shipping.

Cleaning
In between product runs, all of the equipment used in our manufacturing process is taken apart, cleaned, and sanitized. Adenosine triphosphate (ATP) testing is used to validate the effectiveness of the equipment-cleaning process. In addition, the surrounding production suite, including the floors, walls, and vent covers, is cleaned.

Environmental Monitoring
In order to monitor the general level of manufacturing hygiene, Standard Process has implemented an environmental monitoring program for the facility. The program is twofold: It highlights the presence of any foodborne pathogen that may be in the facility and determines the source of these pathogens. Routine meetings between production and quality control personnel are held to maintain the highest level of cleanliness throughout all areas of the facility.

Quality Control: Comprehensive and Meticulous

Another way Standard Process is a leader in the supplement industry is through its quality control program. In fact, since the good manufacturing practices (GMPs) for dietary supplements were published in 2007, many companies began to look at quality in the way Standard Process has been doing for decades.

Our quality control laboratory recently earned ISO 17025:2005 accreditation for Determination of Metals, Direct Yeast & Mold, Coliforms, and E. coli. Laboratories who receive this accreditation have demonstrated that they are technically competent and able to produce precise and accurate tests and calibration data. In order to be accredited, third party auditing was conducted to ensure adherence to all requirements of the standard.

Our quality control team consists of highly trained microbiologists and chemists who work meticulously to guarantee our customers receive quality products. This department performs testing after critical stages of production to ensure our label claims are met and confirms products are free of bacterial contamination. Shelf-life studies are also conducted on each product to make certain that label claims are met throughout the life of the product.

Quality Assurance

We use high-performance thin-layer chromatography (HPTLC) to identify incoming raw materials and in-process materials and qualify them based on consistency, potency, and purity. HPTLC is used to create a unique banding pattern, or "fingerprint," by isolating key chemical constituents to aid in identification of these materials.

Quality Audits

We work very closely with our suppliers, using a questionnaire for qualification and an auditing program designed to ensure quality. Planned site visits are conducted 12-14 times per year based on risk analysis. Our purchasing department evaluates on-time delivery, customer service, invoicing, and more.

Testing

Testing of every batch is repeated in various stages throughout the manufacturing process to ensure quality and safety of our products. On average, a batch is tested six times. Every week, our scientists in our full-scale quality control laboratory run as many as 1,100 tests on raw materials, in-process product batches, and finished product. We use analytical methods approved by nationally recognized evaluative bodies, including the Association of Analytical Communities (AOAC) and United States Pharmacopeia (USP).

Gluten

We pay special attention to ensuring that the products we label as "gluten-free" are indeed gluten-free. In conjunction with the research and development team, the quality control department has internally validated a method approved by the Association of Analytical Communities for gluten testing using the RIDASCREEN® Gliadin by R-Biopharm. The testing consists of an enzyme immunoassay to quantify the prolamines that are found in wheat, barley, and rye.

In order for a product to be considered gluten-free by U.S. Food and Drug Administration standards, it needs to contain less than 20 ppm of gluten. Products listed with this GF designation are tested each time they are manufactured to ensure gluten-free compliance.

Laboratory Information Management System (LIMS)

Standard Process' quality control department has fully validated and implemented the Nexxis iLAB laboratory integrated management system (LIMS) by Labtronics. The system allows for a centralized storage location for all data analysis conducted by the laboratory.

High-Performance Liquid Chromatography (HPLC) vitamins A, E, B_6, B_{12}, C, D; niacin; folic acid
Gas Chromatography (GC) solvents
Inductively Coupled Plasma (ICP) minerals, heavy metals
High-Performance Thin-Layer Chromatography (HPTLC) botanical identification
Fourier Transform Infrared Spectroscopy (FTIR) raw material identification
LECO® protein analyzer

Chemistry

Multiple assays, or tests, are performed to guarantee that our products meet or exceed label claims and to ensure the viability of the product through its "Best Used By" date. We use the following instrumentation in testing raw materials and final product mixes: The chemistry laboratory personnel also conduct wet chemistry tests. The vast testing capability of the chemistry laboratory allows Standard Process to verify the identity, purity, and strength of our products and of the raw materials used in our products.

Microbiology

Every product batch is tested for pathogens to ensure our products are safe to continue to the next stage of production. Testing is conducted in all phases of the manufacturing process, including raw materials, mixing, milling, tableting, capsuling, and packaging. Raw materials, in-process products, and final products are only released to the next stage of production by the quality control unit upon verification that the material or product has passed all testing requirements.

Tableting and Capsuling Process

Many tests are performed after the product is tableted or capsuled, including:

- Monitoring tablets for size, weight, water activity, and hardness (Hardness testing ensures that tablets remain intact throughout the packaging and shipping process.)
- Monitoring capsules for size, weight, and water activity
- Monitoring powders for water activity
- Verification of tablet and capsule weight to guarantee that label claims are met

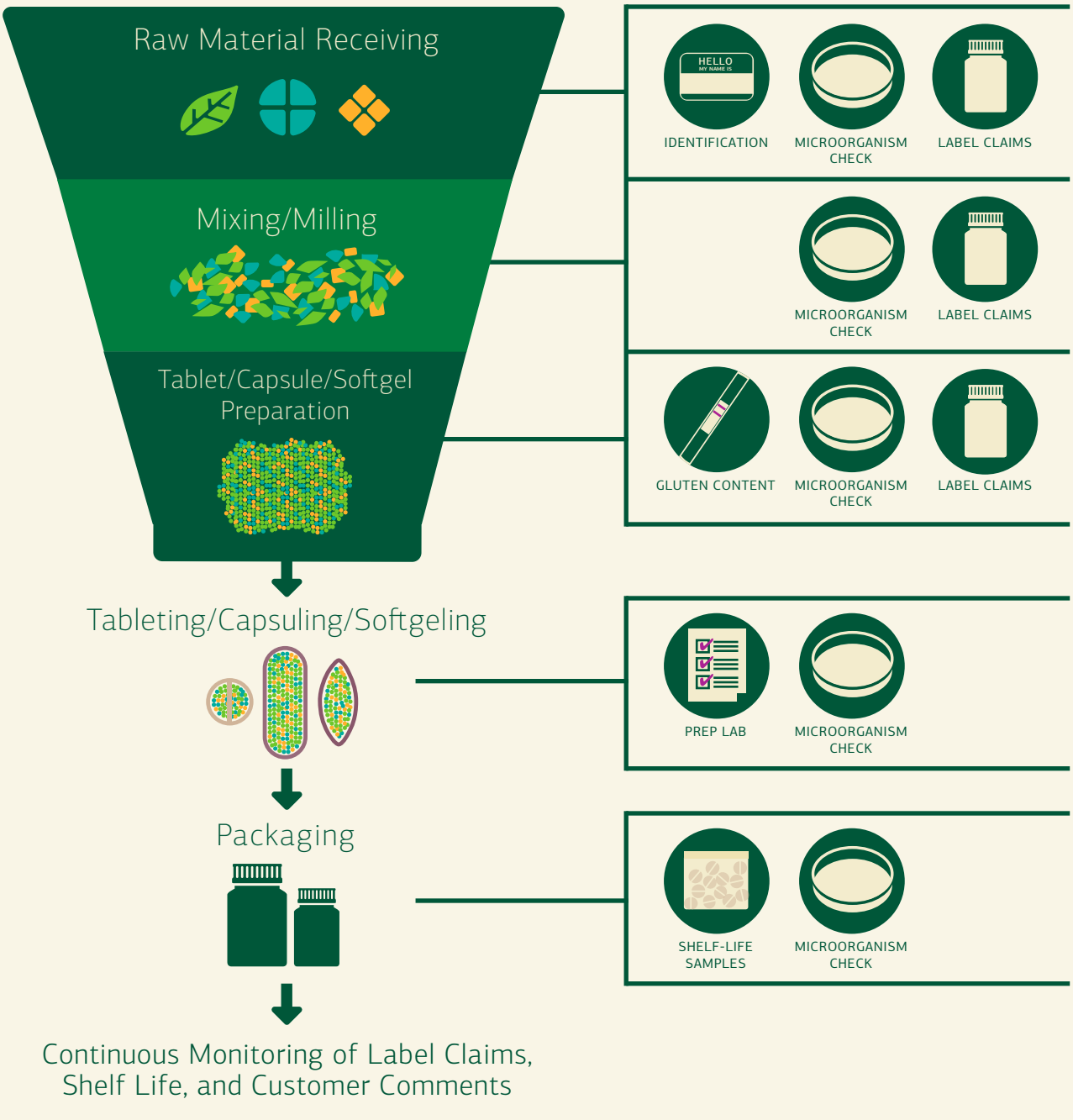
Each product batch is tested an average of six times.

QUALITY CHECKS

From Raw Ingredient to Final Product

QUALITY ASSURANCE | **QUALITY CONTROL**

SUPPLIER AUDITS
MOST RAW MATERIALS



Research and Development at Standard Process

A New Era of Innovation

Standard Process has embarked on the next era of innovation. As a company, we've always been driven to excellence in our efforts to transform lives through whole food nutrition therapy. Now we are elevating our commitment to change lives to the next level by significantly investing in clinical science, patient outcomes, and practitioner education. This is how we will drive innovation for the future.

Our commitment began with the establishment of the new Standard Process Nutrition Innovation Center, which opened in early 2018.

A Standard Process microbiologist identifies cells that will be used in detoxification studies.

Standard Process Nutrition Innovation Center

It is located at the prestigious North Carolina Research Campus (NCRC) in Kannapolis, North Carolina, which is a 350-acre research center where corporations, universities, and health care organizations forge a public-private partnership that is transforming science at the intersection of human health and nutrition. Our Nutrition Innovation Center will become a leading focal point for innovation in nutritional therapy for health care practitioners, developing new solutions for patient care, and advancing the science of whole food nutrition therapy.

The Standard Process Nutrition Innovation Center is a catalyst for this next era of innovation. Our center will be the leading and only active clinical research center of its kind, being fully dedicated to supporting the present and future needs of health care practitioners and their practices by focusing on clinical outcomes in therapeutic care as well as product-specific benefits and outcomes. No other branded company in our category of business currently has the commitment and dedicated, active facility that this site does for both mid- and long-term support of whole food clinical nutrition. This is a logical next step for Standard Process, which has supported the foundations of health in integrative and functional medicine for nearly 90 years.

The center also recognizes the intricate and essential link between individual health and the environment. To that end, the center will also focus on advancement of organic agriculture. This will include investigating techniques that optimize nutrient density of whole food crops and researching actual benefits that whole food nutrition provides in managing health outcomes.