

Ending the low standards in growing nutraceutical production

By STEQ America. September 1, 2016

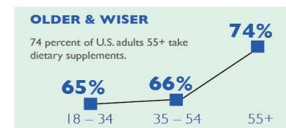
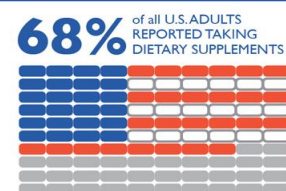
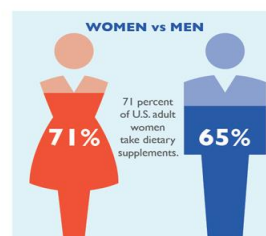


The process of producing solid nutraceuticals is currently under severe scrutiny after various sample inspections conducted by the FDA have revealed a paramount cause for concern. In their newly released September 2016 issue, Consumer Reports features an article claiming, after considerable research and analysis, that 15 dietary supplements currently on the market may cause health concerns for consumers. They're also asserting that some of these may even cause cancer.

In the latest survey conducted by Ipsos Public Affairs on behalf of the Council for Responsible Nutrition (CRN), results showed that 68% of U.S. adults reported taking dietary supplements. That's more than two-thirds of the U.S. adult population. Considering these statistics coexist with the above alarming findings by Consumer Reports, it's important to investigate this further because of the potential consequences. But first, let's clarify the difference, if any, between dietary supplements and nutraceuticals.

The Dietary Supplement Consumer

More than two-thirds of U.S. adults take dietary supplements, according to the most recent (2014) annual survey conducted by Ipsos Public Affairs on behalf of the Council for Responsible Nutrition (CRN).



CRN Consumer Survey on dietary supplements

What is a dietary supplement?

It's a product that's intended to do just that – supplement the diet. Minerals, vitamins, oil-based products, fibrous materials, herbs and other substances are all classified as dietary supplements.

What is a nutraceutical?

In addition to supplementing the diet, nutraceuticals can also help with preventing disease. What's important to note though, is that the term "nutraceutical" is not actually recognized by the FDA. The term that *is* used by the FDA, is "dietary supplement". So, essentially, the two terms – dietary supplement and nutraceutical – can be used interchangeably.

Those purchasing nutraceuticals are doing so in order to promote their overall health and wellness, fill nutrient gaps in their diet, support bone health and immune health, and reduce the risk of America's dominant killer: heart disease. What's mind-altering in a chilling way, is that the vast majority of nutraceuticals have not even been clinically evaluated. It's because of this that we don't know whether these products are indeed beneficial or in fact the polar opposite - harmful to health. The number one goal of those in the business of nutraceutical manufacturing should be to manufacture safe products. Especially since these products are not only used as dietary supplements, but are also prescribed by doctors as pharmaceutical drugs.

Tablets and capsules have been at the forefront of dosage forms for nutraceuticals and pharmaceuticals for about 200 years. Currently, the nutraceutical industry is experiencing a growth in innovative and customized solid dosage forms. This includes orally disintegrating tablets, chewable tablets and controlled-release tablet forms. There is also a push towards more natural, raw material ingredients as consumers become more and more health conscious. The shift towards these new alternatives mean that children and the elderly especially are being offered an alternative way to more easily consume their nutraceuticals in a tablet or capsule, and in a more organic form. They are small and versatile and benefit manufacturers in that they can be produced in high volumes and quickly. This means high-output, low-cost. This is why it's concerning that up until more recently, the quality of these tablets and capsules have been below par. But a change is on the horizon. Because of the simple fact that nutraceuticals are products that are ingested, they are starting to be the subject of quality control checks that are as stringent as those applied to foods, cosmetics and pharmaceutical products. Apart from the U.S. Food and Drug Administration, the NPA (Natural Products Association) is also increasingly dedicated to continually strengthening the standards of nutraceuticals in the United States.

When creating a nutraceutical product, researchers and developers are faced with the arduous task of ensuring the correct quantity of each of the ingredients (active pharmaceutical ingredients and excipients) are incorporated into every tablet or capsule. It is because of this blend of substances that these products are more susceptible to separation and flow issues during production. If the formulation is affected by incorrect uniformity and powder flow, the dosage form will not execute exactly what it's intended to do.

What's the solution?

To avoid any end-product quality control problems or worse, consumer health issues, it becomes essential for nutraceutical developers and manufacturers to invest in excellent facility equipment with validation controls to minimize the risk of contaminants, verify and document the production formulation, and to allow the user to monitor real-time reproducible test results.



ERWEKA is a leading international manufacturer of German designed, engineered and manufactured test equipment for the nutraceutical and pharmaceutical industry. Their new EasyCheck tablet combination tester features fully automatic testing for up to five parameters. This compact unit is 100% compliant with all common pharmacopeias and like all ERWEKA equipment, excels above all in its class through innovative

design, premium components, and essential features that are synonymous with the brand and recognized all over the world.

The EasyCheck offers:

- An integrated weighing cell that weighs samples automatically
- An advanced magazine that provides 20 test positions for samples
- An intuitive touch display that allows for the storage of up to 100 products/methods.

Additionally, the EasyCheck Pro is offered with a test memory for up to 1 million test results, 21 CFR Part 11 compliant Audit Trail feature and a data report export function. Equipment with these types of attributes are what provide any nutraceutical manufacturer the reliability, process integrity and the comfort of equipment longevity that is naturally associated with the ERWEKA brand.

See a video of the EasyCheck tablet combination tester in action here:

<https://www.youtube.com/watch?v=L90KRH-xG8I>

The reliability of the EasyCheck and other production and testing equipment involved in making nutraceutical tablets and capsules, and their ability to produce and document quality results, allow manufacturers to be diligent about meeting regulatory guidelines with regards to hardness, disintegration, friability, weight, color and dissolution time. Employees should also know what's expected throughout the entire testing process and should not settle for anything less than the standards put forth by those organizations such as the United States Pharmacopeia.

Times are changing. The nutraceutical industry is rapidly on the rise towards the higher standards of the pharmaceutical industry. Just as the FDA is increasingly scrutinizing the quality of nutraceutical finished-products, so is the ubiquitous, knowledgeable consumer. They are looking for products that are free from allergens, artificial ingredients, and most importantly, do what they say they do. It is because of factors like these that manufacturers of nutraceuticals must make the effort to invest in equipment and processes that adhere to quality control guidelines and are GMP (Good Manufacturing Practice) compliant. Now, more than ever, is the time for these companies to ensure that they execute nothing less than a reliable operation that would surpass FDA, NPA and consumer expectations.

*Contact **STEQ America**, your exclusive ERWEKA representative in North America, for your customized quote or additional technical information today*

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References:

1. CRN Consumer Survey on Dietary Supplements, 2014: <http://www.crnusa.org/CRNconsumersurvey/2014/>
2. Consumer Reports, "15 supplement ingredients to always avoid". September 2016: <http://www.consumerreports.org/vitamins-supplements/15-supplement-ingredients-to-always-avoid/>

About STEQ America

STEQ America is dedicated to helping biotechnology and pharmaceutical companies find the right information and solutions to be leaders in their industry. We do this by providing premium products that feature the latest, most innovative technologies, with the highest standards that come with reliable longevity.

What we can offer

European engineered and manufactured solutions for dissolution, disintegration, hardness, friability, blister density, granulate and powder flow testing for the pharmaceutical, veterinary, chemical, food and biotechnology industries, with a focus on laboratory needs and research and development. We also offer solutions for the storage of hazardous and flammable materials, cleaning and drying in pharmaceutical manufacturing environments, and bio-medical freezers and refrigerators. Ask us about our mobile, autonomous cleanroom containment options.