

Delivery Systems: Meeting the Challenge of Change

With so many different types of consumers taking dietary supplements, delivery systems must evolve to meet their needs.

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Gone are the days of the pill, the simple pill. Gone also are the days when folks would swallow without question what was prescribed by the doctor. These are the heady days of empowerment, of the extravagance of choice, the eruption of information, the bonanza of product segmentation. In the vast field of dietary supplements, this burst of variety means that consumers can choose from a plethora of ways to get what they want.

Delivery Dynamics

Delivery systems—the methods by which nutrients are contained in dosage form—are enjoying a field day. Manufacturers are listening to the consumers instead of dictating to them, and the results are a wonder of ingenuity and science.

We now have softgels, capsules with beads, acid resistant caps, liquid shots, bi-layer tabs, pearls, powders, effervescent, sticks, bars, gels, chews, gummies, gum, jelly beans, lollipops, strips, sprays, roll-ons, sachets and patches. Did I miss anything?

The flowering of delivery systems for nutraceuticals is certainly promising, but it has a long way to go to find solid niches among consumer groups and wean consumers away from long-established habits. According to findings by A. Elizabeth Sloan, PhD, who has written a comprehensive article on the wide and growing range of contemporary delivery methods (see accompanying article, page 38), the great majority of consumers still use supplements in their traditional pill form, and yet they don't like to swallow pills. Encouraging them to grow comfortable with a new type of nutrient package could take some time.

Dr. Sloan's research reveals that capsules, tablets and softgels remain solidly at the top of the popularity chart. Liquids, soft chews and ready-to-drink beverages are in the middle, and

everything else occupies the margins. Within the industry, delivery systems are on all the drawing boards; among consumers, where older folks are growing in number, they remain somewhat of a novelty.

The Supply Side

The development of optimal delivery systems comes with its challenges, foremost among these being the delivery of the active ingredient. “An effective delivery system is the one that delivers the active ingredient to the consumer as intended,” said Reza Kamarei, vice president of science and technology at Sabinsa Corporation, East Windsor, NJ. “As far as dietary supplements are concerned, the active ingredients are dietary ingredients (vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites) intended to supplement the diet. As far as inactive ingredients (e.g., excipients) are concerned, the number and quantity of excipients should be kept at a minimum because consumers prefer smaller tablets for easier consumption. Another challenge is substantiating the claim about the delivery system. While the in vitro experiments are valuable, the in vivo clinical trial, according to Good Clinical Practice, is the ultimate proof of efficacy of a delivery system.” Among Sabinsa’s delivery systems are bi-layer tablets

According to Sam Wright, president of The Wright Group, Crowley, LA, the major challenges include high performance quality versus low costs, and the incorporation of organic, natural, non-GMO, gluten-free, trans-fat free ingredients, which must also be kosher, halal, etc. “Customers tend to want everything, but in the real world, trade-offs must also be made. Another challenge that we see as an opportunity is the reduction of R&D budgets at the manufacturer level, which has been pushed back onto ingredient suppliers,” he said. “The food industry as a group spends about .5% of revenues on R&D, as compared with 15% in the pharmaceutical industry, a 30-fold difference. Ingredient suppliers who are set up to assist customers from this standpoint are the ones who will succeed.” The Wright Group specializes in microencapsulation.

Speaking of microencapsulation, AIDP, City of Industry, CA, has invested in a proprietary process called enVantec, which provides soluble vitamins with extended stability and superior clarity. “Ensuring that the compound can withstand the delivery system is paramount,” said Kathy Lund, vice president of business development and marketing at AIDP. “Many desired compounds are not soluble or have the ability to withstand heat. AIDP offers unique soluble compounds such as a beverage grade collagen and vitamin E. Both compounds have previously been difficult to work with in liquid formats. In addition, we have conducted heat testing for Magtein, a cognitive product, and KoACT, a bone health product, with success.

“Our delivery systems allow consumers a choice in how they consume their nutrients,” Ms. Lund continued. “Consumers are asking to get their nutraceuticals in new and changing formats, including fortified foods, beverages, gels, strips and more concentrated forms. This provides on-the-go convenience and the opportunity to include enhanced nutrients at mealtime or while working out. Our compounds can be added to new formats in a pleasing manner with no adverse taste effects or visual differences.”

“The major challenges encountered in the development of an effective delivery system lie with controlling the development and manufacturing costs,” noted John Tobin, founder and president of NutraFood Science Delivery System (NSDS), Egg Harbor Township, NJ, which manufactures

Nutra3 Complex Strip Melts. “The marketplace has an established benchmark or production model cost. When there are additional materials or ingredients, carrier systems more effective and convenient, and maybe safer packaging materials, the added cost may prohibit the acceptance of the delivery system by the distributor or retailer before the consumer has a chance to review or even try the new delivery system. Production costs are always a factor for consideration.”

Fred Wehling, president of Amerilab Technologies, Minneapolis, MN, acknowledged that entrenched consumer patterns can take time to overcome. “One of the challenges of a new delivery system is the modification of old habits, i.e., ‘popping’ a tablet or capsule as an afterthought even though the delivery system is not ideal. Another challenge is giving the consumer a reason why advanced dosage forms are more expensive. The cheapest possible way to deliver a supplement is in a compressed tablet or capsule. Unfortunately, the efficacy of the supplement compared to an effervescent delivery system is simply not comparable. Stability is always a concern and adequate studies should always be undertaken to be sure the supplement is as potent at the end of its expiration date as it is the day it was manufactured.”

Mr. Wehling went on to say that Amerilab is constantly innovating and finding new and better ways to deliver ingredients to potential customers and business partners. The company specializes in fast-dissolving tablets, commonly called effervescent tablets, “which are recognized worldwide as the optimum method for delivering an active ingredient into the body,” Mr. Wehling said. “Because of the buffering effect of the resulting solution, many products are absorbed twice as fast and much more completely than they are with other dosage forms. This is proven over and over through clinical studies comparing effervescent dosage forms to conventional tablets.

“Typically, new delivery systems are introduced to give the consumer more choices in the method of taking their supplements,” he added. “While a tablet to be swallowed is still most widely used in the U.S., there are many people who cannot, or prefer not to swallow large tablets or capsules. Also, many multivitamin tablets and capsules are very hard on the stomach lining, resulting in consumers who quit taking the products because they are not well tolerated.”

“The delivery system is one of the most important features of our products,” says Kamarei of Sabinsa, which manufactures the SaNutra line of bi-layer tab dietary supplements for joint health, sleep and relaxation, skin, hair and nails, immunity and bone health. “Consumers benefit from a variety of delivery systems; from traditional compressed tablets and capsules to modern bi-layer tablets. Our international and domestic clients are also assured that the products manufactured in our facility, for any type of delivery system, maintain compliance with the applicable regulatory agencies and FDA current Good Manufacturing Practices. Also, there is a rigorous quality system in place supported by qualified personnel in the analytical chemistry, general chemistry and microbiology laboratories.”

Kamarei says that the proliferation of new delivery systems is “a reflection of the evolution of science and technology in this area. Considering the same composition of the oral dosage, bioavailability of active ingredients has become an important topic. In other words, active ingredients must become biologically available to the consumer. To achieve this goal, and beyond conventional (unmodified release), controlled release or sustained release (also called time release, extended release) have been employed by the industry. The sustained release

technology could basically be a matrix (active ingredients are dispersed within the polymer) or a reservoir (active and inactive ingredients form the core which is encapsulated by membranes). An alternative way is to enhance bioavailability via compounds such as BioPerine.”

The Wright Group manufactures an array of standard enrichment blends, custom nutrient premixes and various ingredients and ingredient systems for clients in the food, beverage and dietary supplement segments. “Our delivery systems benefit the customers in terms of ease of handling, enhanced stability, extended shelf life, controlled release properties, flavor and odor masking, solubility enhancement, protection against ingredient interactions and mouthfeel improvement,” noted Mr. Wright. “We have a variety of microencapsulation techniques useful over a wide range of shell materials and processing conditions. We work closely with our clients to create optimal nutrient systems in support of their consumer products.”

The focus on variety in delivery systems is a natural step in the evolution of the industry, Mr. Wright added. “As markets mature, they tend to fragment into smaller segments of customers seeking different benefits. Competitors seek empty spaces in these markets and new product forms are one result of this. For example, many older consumers have trouble swallowing tablets and capsules, so other product forms make sense, and this population is growing. A Baby Boomer turns 65 every eight seconds and will do so for the next 18 years.”

Moreover, Mr. Wright continued, “There has been a general convergence in the drug-OTC-food-beverage-supplement meta-industry to the point where the boundaries between these formerly distinct segments have become blurred. It is a natural function of market maturity. So now we have shots, powder sachets, gummies, shakes, nutrition bars, as well as the more typical tablets and capsules. Different product forms that are simultaneously dietary supplements, beverages and food products often have to be delivered in more creative and practical ways, so delivery systems have become more critical in formulating these complicated products.”

Earlier this year, Capsugel, based in Bornem, Belgium, introduced Plantcaps capsules, a plant-based capsule made from pullulan, which is naturally fermented from tapioca. “Because it is made of pullulan—a vegetable-derived, water-soluble polysaccharide produced through a natural fermentation process—Plantcaps is a more natural alternative. This capsule provides a premier balance of performance and purity for smart ‘green’ consumers around the globe,” said Mark Vieceli, director of sales for Capsugel Americas Region.

Plantcaps also provides an important option for customers distributing organic supplements in the U.S., which restricts organic labeling language on organic ingredients encapsulated in other non-pullulan polymers. “Certifying agencies have allowed organic labeling for some ingredients delivered in pullulan capsules in the U.S. due to the capsules’ naturally fermented source,” Mr. Vieceli explained. Plantcaps is a clean-label product that can allow for several other important product claims, including vegetable-origin, preservative-free, gluten-free, starch-free, allergen-free and non-GMO. In addition, it satisfies dietary needs with its GRAS status, kosher and halal certifications, and approval by the Vegetarian Society. The product is also suitable for the Asian regulatory environment, especially for use in Japan.

Capsugel, with facilities worldwide, also produces a line of vegetarian capsules called Vcaps.

Seniors, hospitalized people and small children, many of whom might have difficulty swallowing

pills, could turn to strips that melt in the mouth and deliver the desired ingredients. Nutra3 Complex Strip Melts are fast-melting oral strips made with advanced film technology, a self-dissolving carrier system for actives, nutraceuticals, pharmaceuticals or cosmeceuticals embedded into its base. A strip can have layers or stripes for multiple sensory effects or treatments.

NSDS' Mr. Tobin said that the strips "are able to stabilize the highest load of active ingredients ever to be assembled in an oral strip. The accurate dosage and targeted, rapid delivery through the use of this proprietary strip technology process, with science based, patented ingredients, permits the development of formulations for products that will produce positive results for the support of health and wellness for consumers globally."

Nutra3 strips have been developed for energy support, sleep support, skin and body anti-aging support, wrinkle therapy, antioxidant and anti-inflammatory support, weight management and appetite control support, and many others. NSDS can adjust the size, shape and adhesive qualities of each strip, depending on the usage required.

Tobin added that the company is in the process of developing strips for use by domesticated animals. "Dogs, cats and horses, for example, can simply lick a strip and it will not be expelled from the pet's mouth before it melts away. It doesn't get any easier than that for support products for pets."

A different type of delivery system has been developed by NuLiv Science USA, in Walnut, CA. The company's AstraGin has been shown in studies to enhance the intestinal absorption of amino acids such as arginine and tryptophan; vitamins, such as folate; glucosamine and glucose.

President Michael Wang said that patent-pending AstraGin "increases chemicals in the human body called 'transporter' and 'mRNA.' These chemicals determine how much or less specific nutrients are absorbed into the intestinal cells and thus are available to support and promote health and well-being." AstraGin is a proprietary plant-based formulation derived from highly purified, fractionated *Panax notoginseng* and *Astragalus membranaceus*.

Mr. Wang added that in vitro and in vivo studies show that AstraGin increases the absorption of amino acids such as arginine and tryptophan by 67% and 53%, respectively; increases the absorption of vitamins, such as folate, by 50%; increases glucosamine absorption by 42%; increases the absorption of glucose by 57% that is converted to glycogen in liver and muscle, and increases ATP (energy) by 18%.

"The recognition that 'absorption' is not automatic and complete (i.e., 100%), as generally misconceived for years, has finally caught the attention of many companies in the industry," Mr. Wang declared. "A lot of research has been devoted and dedicated to finding ways to increase the absorption of nutrients in the human body. NuLiv's AstraGin is one example."