

Dietary supplements

How far we've come...How far we'll go

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INTRODUCTION

With every opportunity comes challenge. From new regulations and fluctuating costs to the integrity of materials and the quality of products, nutraceutical companies must tackle many challenges to succeed in today's competitive marketplace.

They must market high-quality products at competitive pricing, service retail with a dependable supply of products, execute creative branding and marketing strategies – and deliver on their promise of value to consumers, whose purchasing patterns have shifted in the face of an economic downturn. A tall order for any brand.

This article pinpoints the growing market opportunities that exist around the world – and can help brand owners pave the road to success in a thriving industry that grew from humble beginnings.

In 1911, a Polish chemist working in London discovered what he termed "vitamines". While deemed a major medical advancement at the time, the vitamin was a bitter pill to swallow for many doctors who insisted that only food could supply the body with the nutrients it needed. Even the subsequent discoveries of vitamins A and C left the medical community skeptical, believing this was both the beginning and the end of the vitamin.

But by the 1920s, it became clear that vitamins helped maintain health. In 1932, an American researcher discovered that a lack of vitamin C had been the cause of scurvy for countless sailors for hundreds of years. Fast

forward to the '90s – and consumer sales of vitamins were flourishing. Today, the vitamin is just one component of a worldwide phenomenon: the widespread use of dietary supplements to achieve and maintain health and wellness.

Opportunities...and Roadblocks

It has been a long and winding road for dietary supplements.

Years after their general acceptance, the U.S. government introduced the Dietary Supplement and Health Education Act of 1994 (DSHEA) – the first formal signal of the government's recognition that dietary supplements can help promote health and prevent disease. This legislation authorized the establishment of the Office of Dietary Supplements within the National Institutes of Health (NIH) to help promote scientific research of the benefits of dietary supplements and to serve as advisor on related issues to other government agencies. This legislation also established a new regulatory framework for supplements



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children under the age of 12 – provide marketing opportunities for the industry with products such as Gummy Vites multivitamins, taste-masking ingredients, and dosage forms produced in iconic images.

And we cannot forget our senior generation. With a significant percentage of the European population over the age of 60 (1) – and 30 million Americans turning 65 over the next decade – today's aging population offers the nutraceutical industry additional room for growth. In fact, the global

sales, manage costs, and ensure product quality. They must deliver the dietary supplements that consumers want and will continue to buy – even in the face of tough economic times. And they must accomplish all this while navigating increasingly complex regulatory environments.

While DSHEA created more opportunity for the nutraceutical industry in the United States, it also introduced a series of new requirements for supplement manufacturers, including:

- Thorough raw materials testing and auditing of suppliers;
- Stability programs to confirm expiration dating;
- Strict adherence to cGMPs during manufacturing and packaging;
- Complete, detailed documentation for all processing;
- Validation of procedures, equipment, and testing methods.

One relatively new regulation poses yet another challenge. The FDA's Final Rule on cGMPs often requires dietary supplement manufacturers to conduct full testing on all active ingredients in multi-active products. In the past, supplement manufacturers only were required to test certain ingredients, or "markers," in such products.

While full testing promotes quality, it presents challenges for the nutraceutical industry because some dietary supplements contain as many as 40 active ingredients. Manufacturers like Contract Pharmaceutical Corp. (CPC) – with experience conducting full stability testing and process validation on multi-active prescription supplements – will be well positioned to meet these requirements.

Dietary supplement manufacturers in the United States must regularly monitor FDA regulations to ensure strict, ongoing compliance with cGMPs. Requirements for cGMPs went into effect in 2008 for large supplement manufacturers and are being

to help regulate product quality; and the U.S. Food and Drug Administration (FDA) began regulating dietary supplements as food. Because supplements would not be regulated as drug products, DSHEA opened the window of opportunity for nutraceutical companies to bring more nutritional products to market.

However, on the heels of DSHEA, raw material suppliers around the world had trouble keeping pace with the exploding demand from companies seeking to manufacture and market supplements. Negative media attention began to focus on dietary supplements, primarily due to false advertising claims, loose compliance with current Good Manufacturing Practices (cGMPs) on the part of some manufacturers, and certain ingredients that were deemed unsafe, such as ephedrine.

The state of the industry is much healthier today. Once a fledgling market, dietary supplements have found their true identity and a loyal following – and they continue to drive strong revenues and present new growth opportunities for brand owners.

LEAVE NO DEMOGRAPHIC UNTAPPED

Today's expanding market opportunity crisscrosses all geographies and demographics.

Baby Boomers – those born between 1946 and 1964 – increasingly seek natural products for heart and joint health as well as weight management and anti-aging solutions.

Gen-Yers – consumers from their teens to their 30s – continue to join the ranks of dietary supplement users, most often buying fitness, energy, and prenatal products. And there are 72 million of them in the United States alone.

Even our youngest consumers –

market for nutritional supplements will reach nearly \$ 50 billion by 2013 – up from \$ 39 billion in 2007 (2).

A Snapshot of the Surge

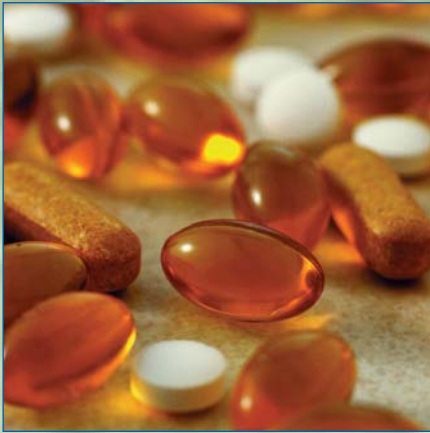
- While 52% of U.S. adults reported taking dietary supplements from 1999-2000 (3), that number jumped to 73% in 2002 (4).
- Studies have shown that 85% of the European population understands that preventive care is required to pursue optimum quality of life. Many see vitamins, minerals, and herbal supplements as the solution, driving sales (5).
- Consumption of dietary supplements is widespread among adolescents, a habit often detected by pediatricians and adolescent physicians (6).
- Among older age groups, the prevalence of dietary supplement use increased from 30% in the early 1970s to more than 60% by 2000 (7).

With virtually every demographic in play in every corner of the world, the opportunities for nutraceutical companies are seemingly endless. Those with the ability to identify specific trends – and develop and market products that help prevent and treat specific health conditions – will reap the rewards of this burgeoning market.

WITH OPPORTUNITY COMES CHALLENGE

Challenge is no stranger to the nutraceutical industry. Brand owners must drive





phased in for smaller manufacturers through 2010.

Meanwhile, government healthcare reforms across Eastern Europe are leading to an increasingly complicated regulatory environment throughout this region as well. The fact is, regulatory hurdles cross all borders, presenting a unique set of challenges to the nutraceutical industry worldwide.

ACHIEVING SUCCESS

Through each and every challenge, nutraceutical companies must keep a close eye on the end goal – building a strong, quality brand to compete in today's increasingly competitive marketplace.

Many factors contribute to the success of your brands and your business – and selecting the right contract manufacturer is clearly one of them. You need a partner to help you clear the hurdles and leverage the opportunities in the market. You need a partner who will develop and manufacture the highest-quality dietary supplements that meet consumer demand – ultimately helping you achieve success.

Here are three steps to ensuring that your contract manufacturer brings the most value to your business.

Perform Due Diligence

Exceptional people and processes will ensure the quality of your products – so make sure your contract manufacturer employs both. Confirm that your partner has strong R&D and quality assurance teams and operates according to Standard Operating Procedures (SOPs) in strict compliance with cGMPs. Another consideration is whether your contract manufacturer maintains a broad and complete knowledge of regulatory



requirements in global markets – and a reliable overseas shipping network.

You want nothing but the best equipment manufacturing your products. Check your contract manufacturer's equipment roster and confirm that routine maintenance is performed. The FDA mandates regular maintenance – but all equipment should be maintained as often as needed to ensure efficient production and product quality. Also verify that your contract manufacturer employs highly experienced managers to operate the equipment and oversee the production of your products.

Of course, a supplement is only as good as its raw materials. Make sure your contract manufacturer maintains a large worldwide network of trusted raw material providers, closely manages the supply chain, and audits all raw material vendors to ensure cGMP compliance.

Communicate Openly

At the outset of every project, work with your contract manufacturer to establish a mutual understanding of the process and timelines around the development and manufacture of your dietary supplements. Discuss budget constraints and set goals for raw material costs. This close collaboration will help ensure that your finished products always meet your original specifications.

Maintain consistent communications throughout the life of your project to effectively manage expectations, deadlines, and results. From concept to commercialization, your contract manufacturer should speed your time to market – ultimately helping you gain competitive advantage.

Build Your Brand

The right packaging showcases your brand while offering consumer convenience – so choose a contract manufacturer with strong packaging capabilities. Your provider should help you develop packaging in high consumer demand – such as stick packs, child-resistant pouches, or easy-open bottles for arthritis supplements. Leverage your contract manufacturer's graphic-design team to design packaging that attracts consumers and adheres to regulatory guidelines. Last, but not least, find a flexible partner. The right contract manufacturer will be flexible enough to meet your every packaging and manufacturing requirement – from new line extensions to specialty marketing programs – to help promote your brand.

CONCLUSION

Nearly a century ago, the discovery of one chemist led to the establishment of a new product category – and a worldwide health phenomenon.

The dietary supplement industry has grown leaps and bounds since its earliest days. The number of dietary and herbal supplements has soared from about 4,000 just 15 years ago to more than 40,000 today (8). With a widening demographic base, growing consumer demand, and increasing medical-community support, the future growth potential is tremendous for what is already a multi-billion-dollar industry.



For more information about CPC and its products and services, visit www.cpc.com call +1 631.231.4610 or email info@cpc.com.

REFERENCES

- 1) "Strategic Analysis of the European Dietary Supplements Markets"; Frost & Sullivan, 2005, May 21; www.frost.com/prod/servlet/report-brochure.pag?id=B402-01-00-00-00
- 2) "Nutraceuticals: Global Markets and Processing Technologies"; BCC Research; Wellesley, MA, October 2008; www.bccresearch.com/pressroom/fod013c.html
- 3) RADIMER K. *et al.* "Dietary supplement use by U.S. adults: Data from the National Health and Nutrition Examination Survey, 1999-2000" *American Journal of Epidemiology* **2004**, *160* (4), 339-49
- 4) U.S. Food and Drug Administration Health and Diet Survey, 2002
- 5) "European Dietary Supplements: Health is Wealth"; Frost & Sullivan, 2005, May 13; www.frost.com/prod/servlet/market-insight-top.pag?docid=38076249
- 6) ALVES C., LIMA R.V. "Dietary supplement use by adolescents" *J. Pediatr. (Rio J)* **2009**, *85* (4), 287-94; www.ncbi.nlm.nih.gov/pubmed/19585056?ordinalpos=25&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum
- 7) Series of National Health and Nutrition Examination Surveys in the United States
- 8) *The Associated Press* 2009, July 6