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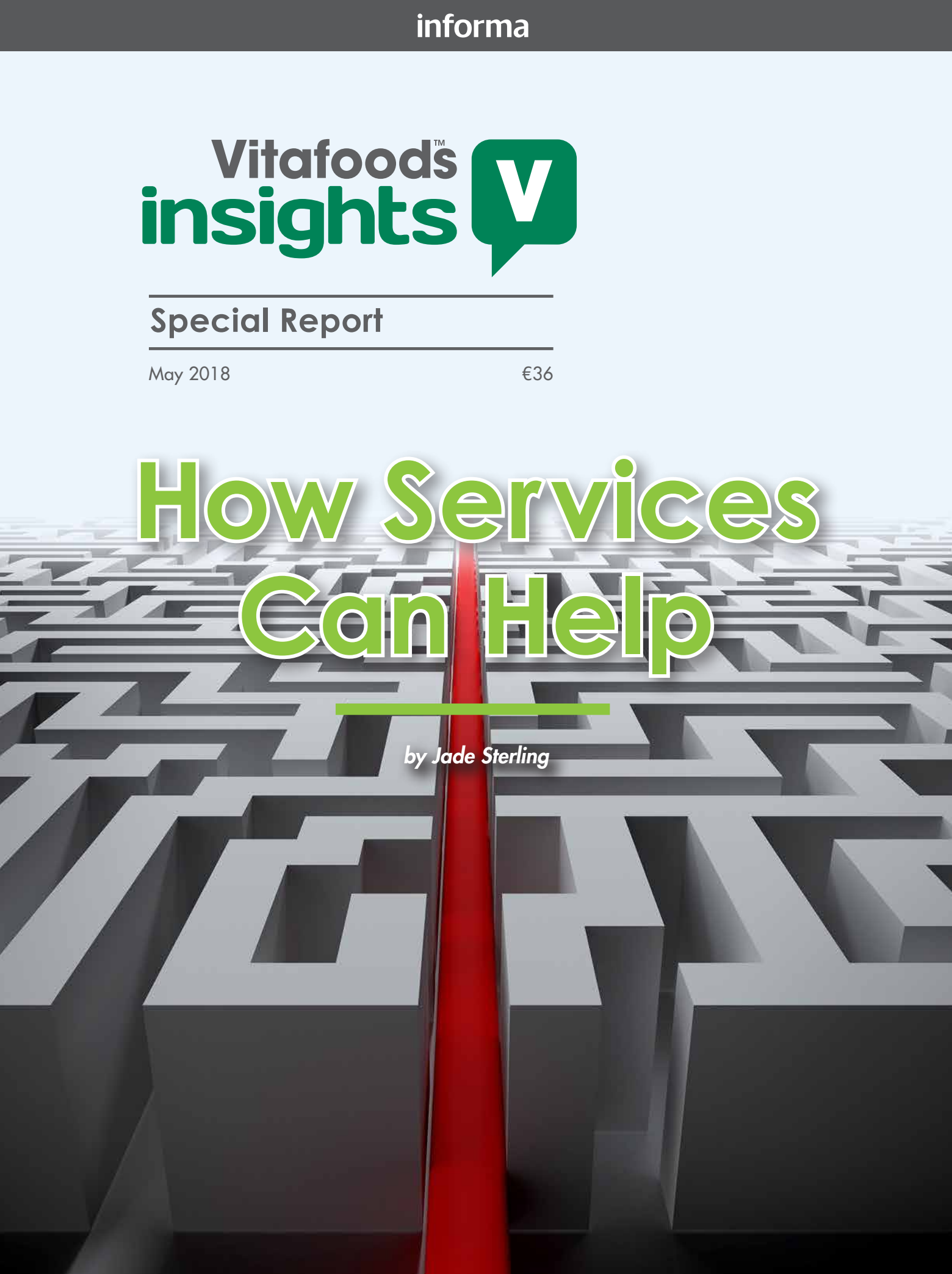

How Services Can Help

by Jade Sterling

The global market for dietary supplements and functional foods continues to grow strongly and there's no shortage of start-up companies or well-established conglomerates dipping their toes into the space. Regardless of company size, there are significant barriers to market entry, ranging from high investment costs and tough regulation to the need for expert marketing and technical knowhow. The solution for many is to team up with specialist contract manufacturers, private label suppliers and other service providers to help transform a bright idea into a successful product.

Any organisation looking to succeed must find ways to overcome the obstacles that can trip up companies trying to enter the market for the first time. The industry demands extensive expertise and resources in marketing and regulation, in addition to technical capabilities and costly production facilities; this creates obvious barriers to entry for smaller players and start-ups.

The convergence of medicine, food and technology creates a battleground in which food and pharma companies compete for dominance of the sector. Food companies have strong expertise in large-scale manufacturing and global logistics that reach into the mass market, but their research expertise does not go as deep as that of the pharmaceuticals industry. Successful companies must hit the bullseye in six main areas: technology, product strategy, compliance, marketing, supply chain management and corporate deal-making.[1]

While it's not accurate to say it's harder to break into the nutraceutical domain than it is the pharmaceutical arena, the process can be more complicated. Often, there isn't one direct route to market for a nutraceutical player (traditional ingredient, Novel Food, dietary supplement…) and brand-owners need to be savvy in choosing which path to take: which offers the shortest distance to the finish line but will also lead to success. This is why companies that provide guidance on legal, nutritional and scientific matters, market analysis, and clinical trials play such a critical role in getting new products to market.

> **The global health and wellness market is bursting with opportunity and attracting interest from hopeful new entrants around the world. However, not all of these companies will succeed; the product failure rate is high, but that doesn't seem to be much of a deterrent.**

Market Research

The nutraceuticals and functional food markets are increasingly fluid. Trends come and go and the customer base is constantly demanding more; even generational differences influence how consumers perceive and purchase products. There's plenty of evidence the marketing skills of many companies are not up to speed with the evolution in this area, and that marketers may even miss the simple difference between food and nutrition marketing. The many failures in marketing stem from a lack of understanding of the consumer's needs, acceptance, knowledge and trust. Brand-owners must consider lifestyle needs and the product's relevance to daily life. They must also consider consumer awareness and interest in a specific ingredient and how they want it; do they want a traditional pill format or do they want added functionality?

> **There's a reason market research firms can charge a premium for their research and reports; brand-owners must understand their target market and the fluctuations occurring. After all, a sound marketing strategy begins and ends with the consumer. Secondary and primary research are vital, and marketing services can help to clearly define the potential customer.**

With research from Euromonitor International, a global market intelligence provider, showing the natural ingredients industry will continue to grow over the next five years, brand-owners need effective plans to identify and reach their changing target markets. Typically, manufacturers invest and spend the majority of their budgets on scientific research, clinical studies, materials and production; consequently, they face the issue of not allocating sufficient funds towards market research and then marketing efforts. If businesses want to keep up with current market trends and maintain their competitive edge, market research is essential.

Research not only identifies potential new consumers, but also helps businesses understand their existing customers. When looking at your product, it's important to consider the following questions:

- Who uses your product?
- Why do your consumers choose your products over competitors?
- How do your products solve a challenge?
- Who or what influences your consumers' purchasing decisions?
- How do your consumers use your product?

Market research results arm businesses with information, which they can use to set achievable and realistic goals for continued product development and business growth. Businesses can make more informed decisions regarding pricing or distribution

channels and reflect on existing operations and practices. Market research helps identify areas for possible business expansion, while also determining market competition and brand awareness.

By conducting market research on a regular basis, a business can keep up with the dynamics of the economy and demography, while keeping abreast of new regulations and technology. But regular market research can be time-consuming, hence the availability of external market research organisations. Companies like Mintel, Innova Market Insights or Happen can provide the information needed—for a price.

In choosing a market research service, determine the need for secondary or primary research: secondary research is based on information from studies previously performed by other organisations—Nielsen ratings, for example—and is easy to obtain. Secondary market research is readily-available and often low-cost, but it is not customised to your business needs, so it may not be as useful as primary market research.

Primary market research is tailored to a company's particular needs and involves focus groups, surveys, field tests, interviews and observations to let you investigate a specific interest. By personalising the service, primary research delivers more specific results and can give an accurate representation of a particular market; but this is a significantly more expensive undertaking than secondary research.

To get the most from an investment in market research, use both kinds: secondary research to identify the target demographic and lay the groundwork, then primary research to determine key insights from this audience.

Manufacturing

Clinical Trials

'Companies have been turning away from the goal of achieving a health claim under the Nutrition and Health Claims Regulation,' says Iris Hardewig, Senior Consultant for Product Development at analyze & realize. The bar for obtaining a positive opinion from the European Food Safety Authority (EFSA) and an approved claim has been set extremely high, with very few products and ingredients succeeding. 'Many fall back on generic claims, which are still very attractive,' continues Hardewig. 'The drawback is the lack of USP for that product.'

However, the drift away from formal health claims has not meant any abandonment of clinical research; rather, clinical trials offer a huge competitive advantage and an element of exclusivity. 'A lot of our research is still driven by the EU health claims regulation,' says Barry Skillington, Sales and Marketing Director at Atlantia. 'But the majority originates with companies looking to establish B2B marketing claims. For example, if a bulk seller of protein wants its product to command a premium, a clinical data set can be the differentiator.'

There's also the issue of consumer distrust and industry transparency to consider; in a time when fewer than half of consumers[2] believe supplement claims are honest and backed by science, an authorised EFSA health claim is a real asset.

Josh Baisley, Director of Clinical Trials at Nutrasource, agrees claims drive the need for clinical research and says ingredient suppliers have lots of questions to ask themselves before they can start a clinical trial: 'What is your global strategy? What markets are you looking to break into? What are the regulatory requirements in making a health claim? The answers to these will define how much clinical trial background you need.'

Clinical trials tend to last between 12 and 18 months; 'If you hear it's faster than that, then something isn't being done!' adds Baisley. The first three to four months is the start-up period, from time of contract execution between CRO and sponsors, and where the bulk of the planning is done: this includes project management plans, communications plans, establishing protocol, reviewing regulatory obligations, writing consent forms, applying to regulatory commissions, and obtaining ethics approval. The next step is determining the sites for the study; if the CRO has a site, recruitment can begin immediately. Otherwise, there will need be a time investment to identify sites to participate.

Recruitment time varies depending on the required population size and demographic and the number of sites needed; this can be anywhere from one month to several months. Treatment period or supplementation period is as long as the protocol defines: this is the 'testing' phase. 'Remember: this phase includes the time from the last subject entering the study to when they leave,' says Baisley. After this, six to eight weeks are dedicated to data analysis and report writing, with editing and reviewing taking another four to six weeks.

'Running a clinical trial is a bit like building a house: there are thousands of processes all going on at once, but everything has to be in order for the final product to be completed,' adds Baisley. Naturally, there is a range of prices when it comes to designing a clinical trial, depending on a variety of factors, including population size and number of sites involved. The prices can put some companies off, but Baisley is keen to point out trials show both safety in humans and efficacy, which support health claim applications: 'These claims will differentiate you in the marketplace, so it's an investment, but it pays off. It's all relative.'

When organising a clinical trial, it's often not enough to simply show up with an ingredient and test it. Regulatory requirements present challenges and this is particularly clear for probiotics. A probiotic strain must be fully sequenced and published in a peer-reviewed journal for safety assessment and there must be a complete antibiotic resistance and susceptibility profile included. Baisley says this is because you need to know what antibiotics will affect the strain during the trial: if used in an immunocompromised population, there's a chance of overgrowth, which is rare 'but something to consider'. Concurrently, knowing which antibiotics could affect the strain is crucial to ensuring the trial population doesn't take those; while it's unethical to prevent the use of antibiotics at any time, knowing the strain's profile helps to ensure those subjects are taken out of the analysis or to choose antibiotics that won't affect the ingredient.

If clinical trials are out of reach for a start-up, ingredient suppliers can attempt to differentiate their products by qualifying for an alternative category outside mainstream supplements. A company offering advisory services can help manufacturers determine which route to take.

Contract Manufacturers and Private Label

Once a brand-owner has decided which direction to take in going to market, and has confirmed the safety and efficacy of its ingredients, the manufacturing process is the next step. Technical knowhow and costly manufacturing set ups deter many start-up companies from producing in-house; this is where outsourcing to a contract manufacturer or private label provider can pay dividends.

Contract manufacturers and private label firms can be considered the catalyst for much of the innovation in the industry. Good ideas cost nothing, but bringing them to life can be complex and expensive—contract manufacturers offer a practical and affordable service which enables entrepreneurs to turn their dreams into a reality.

Contract manufacturing is an outsourced solution to manufacturing a product: finished product companies choose contract manufacturers when they lack the equipment necessary or the capacity to produce high volumes. Contract manufacturers produce a product to strict parameters: usually, the concepts, recipes and designs are well-defined and the contract manufacturer simply produces according to these requirements. Private label supplier obligations to the consumer go much further: a private label supplier develops an idea into a product, feeding into recipes and concepts to help customers create their final product. 'Private label requires a deep understanding of what the customer wants and how to turn that into a finished product,' explains Rob Wanrooij, Account Manager at VSI. Choosing outsourced production may be the only realistic way for newcomers to enter the market, to avoid the high set up costs associated with manufacturing.

While the contract manufacturer or private label supplier can handle everything from production to quality control, brand-owners need to be aware the onus for marketing, selling and distributing remains with them.

> **Without contract manufacturers, many of the exciting nutrition products on the market today would still be at the planning stage.**

When establishing a partnership with a contract manufacturer or private label supplier, customers should keep in mind there is a huge difference between a company with GMP certification, and a company without it. 'Nutraceuticals should be manufactured to the same high standards as pharmaceuticals, as quality is the key to efficacy,' says Daniela Ferraz, Marketing Communication Manager for Labialfarma Group. 'We are

heading towards a new stage in the history of nutraceuticals and the creation of the GMP certification specifically for producers of this kind of product is an undeniable necessity.' There are other industry standards to consider; the basic quality standard ISO 9001 should always be adhered to, but others may also be important, depending on the client, the product and the target market, kosher, Halal or organic certification.

Brand-owners also need to make sure expectations are agreed up front as to the expected services; this will save headaches and disagreements down the line. As selecting the right partner can be a daunting prospect, there are matchmaking companies helping to connect brand owners and manufacturers.

'People who take supplements expect them to be safe and contain quality ingredients; they expect what's on the label to be in the product,' says Dr Bob Pietrowski, Vice President Global Health Sciences, NSF International. 'Dietary supplement manufacturers must ensure these legitimate expectations are consistently met—batch after batch.' Enter good manufacturing practices (GMPs), strict, risk-based practices and procedures for manufacturing facilities. Should an issue arise, a GMP will be in place to enable the manufacturer recognise, investigate and take appropriate planned action to protect the consumer and marketplace from exposure to any potentially harmful ingredients or practices. An effective GMP can reduce risk, help companies save money, uphold a company's reputation and help to create a competitive edge in an increasingly crowded market. 'Pharmaceutical companies have been required by law to have GMPs in place for decades,' continues Dr Pietrowski. 'The benefits of GMP are just as relevant to the dietary supplement industry as they are to the pharmaceutical industry.'

Ensuring product quality

One of the most critical components of GMPs is quality control: the process of sampling, testing and comparing results with pre-agreed specifications as part of the overall quality assurance process. For supplement manufacturers, a well-designed quality control system does not focus simply on finished product testing, but uses the most appropriate analytical techniques to assure the quality of materials throughout the process. Testing and quality assurance providers bring their expertise in this area; certification of dietary supplements has more than doubled in recent years as retailers and consumers seek assurance of the safety and quality of products, according to Cheryl Luther, General Manager for Dietary Supplements and Beverage Quality at NSF International. Third-party certification and independent testing are services offered by a variety of different companies.

Regulation

Regulation is another area that can be tricky to navigate for companies on unfamiliar territory, particularly in Europe. The EU Nutrition and Health Claims Regulation (EC) No 1924/2006 is commonly considered one of the more difficult aspects of bringing a product to market, as it is littered with potential pitfalls for labelling functional foods, for example. Meanwhile, supplements fall under Food Supplements Directive 2002/46/EC, which brings its own set of requirements, and then individual Member States have different notification and maximum levels requirements too. Of course, this is all on top of the more general food safety, labelling, and consumer protection rules. Negotiating the EU's complex legislative framework is one of the biggest challenges nutraceutical companies face today.

> **From the Nutrition and Health Claims Regulation to the lack of harmonisation between Member States, marketing ingredients and finished products in the European nutrition sector can be a daunting task.**

The market for nutraceuticals is not the same globally, and the main reason for this is differing regulation in each country. In the EU, any product claiming a health benefit must first be certified by EFSA, and only a small proportion of claims are approved; Canada operates a similarly demanding process. In Japan, however, nutraceuticals do not need to pass stringent government tests if they do not claim to treat or prevent a specific disease. In the United States, a structure or function claim is permitted for supplements, but disease claims are prohibited for that class of goods. This lack of harmonisation globally means companies must adapt their marketing strategies to the regulations of each country, with varying nutritional claims and even ingredients, depending on the rules and consumer preferences.

European consulting firms can help to navigate the regulatory maze at Union level, and local law firms can aid at national level. Services dealing with regulatory compliance cover all areas of the supply chain, from ingredient suppliers to finished products and can help with health claims, entering new markets, and reviewing marketing communications for compliance to health claim advertising.

Importantly, brand-owners must remember they are accountable for every stage in the production process. Regulatory compliance is mandatory at all points during production and distribution, and brand-owners must work closely with their ingredient suppliers and contract manufacturers to ensure everything is above board. Regulatory services can

help brand-owners in checking for compliance before signing contracts and advise customers on what to look for when choosing a service provider.

Taking advantage of the market opportunity for supplements and functional foods often means partnering with companies that have expertise in bringing products to market. Whether a company is looking for simple production support or a turn-key operation with formulations, marketing insights and regulatory expertise, the industry has a breadth of services to deliver.

Ultimately, specialist services provide experience and resources to both well-established brands and start-up companies. In the fast-moving, highly-regulated and often very technical industry sectors of functional foods, supplements and nutraceuticals, this can often be the difference between failure and success.

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