

SABINSA MANUFACTURING

SELECTING A QUALITY CONTRACT MANUFACTURER

Virgo Publications Interviews Jim Cudahy & Other Industry Leaders



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Selecting a Quality Contract Manufacturer

With the implementation of federal GMPs (good manufacturing practices) and further interest among consumers and the media in the quality of dietary supplements and related products, marketing firms are turning to respected contract manufacturers to turn out efficacious products that truly deliver the goods. INSIDER took time out to check in with some of the top companies in this field to get their take on the state of the industry and suggestions about selecting a quality partner.

What type of quality control certifications do you hold, and are you seeing increased interest in that type of accreditation?

Andrew M. Goldman, Web marketing manager, Nutricap Labs: Nutricap Labs holds GMP certifications from the Natural Products Association (NPA) and NSF, including GMP for Sport). Our customers expect us to hold GMP certification and require a copy of the certificate as proof.

Eugene Ung, director of marketing, Best Formulations: We have a California and Federal Drug License and we are NPA cGMP certified. We've had these certifications for a number of years. It takes commitment throughout the company—from the top down—to obtain and maintain these certifications. Quality is a philosophy of how you run your company, not simply a set of standard operating procedures (SOPs). We work with many good customers who understand the importance of quality, so many of them already have quality systems and audits in place. We have seen an increase in quality audits and questionnaires.

Kenn Israel, vice president of marketing, Robinson Pharma Inc.: Robinson Pharma has a Drug Manufacturing License from the State of California Department of Public Health, Food and Drug Branch. Robinson Pharma has been audited by Shuster Labs and found to be compliant with the standards established in their Retail Quality Program and is a Certified Manufacturer under these standards. Robinson Pharma has been inspected by USP as part of their DSVP program and our facilities were found to comply with the rigorous standards of this valued certification program.

Jay Kaufman, president, Paragon Laboratories: We are GMP certified by NSF and NPA, and hold organic certification from QAI. The steps involved in our attaining these certifications involved a complete review of our operational procedures and the modification of existing and/or creation of new SOPs in order to be in compliance with the rules promulgated by these third party certification organizations. Compliance with these rules allows us to continue on with our certifications by these organizations who periodically audit us for such compliance.

Lucy MacLoughlin, COO, Rhema Health Products Inc.: We are certified GMP by Health Canada and Establishment Licensed for the manufacture and packaging of OTC drug (DIN) products, and TGA approved for the manufacture of complementary medicines in Australia.

Cheryl Cahill, president, Precision Formulations: We have four quality control certifications: Silliker, cGMP, HAACP (hazard analysis critical control points) and USDA Certified Organic. Our quality control is regularly audited to make sure we are in compliance with all regulations.

Maria Czech, president, Indigo Labs: Indigo is in the middle of the transition to full Dietary Supplement GMP compliance. In the meantime, our standards have met or exceeded those for manufacturing foods. In January, we'll go live with our new standards and upgraded procedures so that all procedures will be running smoothly for our compliance deadline in June 2009.

Mark Sysler, business manager, Natural Products Packaging: We have a full set of SOPs in place that are GMP compliant. We are currently reviewing them with an outside consultant and updating them where needed so that we can be audited by a third party for GMP certification.

Darren Schneider, director of sales and marketing, CapsuleWorks: While waiting for the final version of the FDA GMPs for Dietary Supplements, our company decided to operate under USP general chapter 2750 for Dietary Supplements. We have been audited numerous times by Shuster Laboratories as part of its Retail Qualification program which includes facility and process audits as well as independent testing of our products. We have been certified by this body consistently. In addition, we have been certified under NPA's GMP Compliance program.

Kirk Neal, president, Arizona Nutritional Supplements: Arizona Nutritional Supplements is GMP certified by both the NSF and NPA, organically certified by QAI, and has its site license from Health Canada. ANS has invested millions of dollars in a state of the art plant, equipment and lab to make sure it is among the industry leaders in quality. Customers realize the exposure they will have if they continue having their products made at contract manufacturers that do not make quality and GMP compliance the cornerstone of their business. Some customers are still coming to grips with the actual cost of quality, which is still a hurdle that our industry as a whole needs to overcome.

Jim Cudahy, president, Sabinsa Corp.: Sabinsa is cGMP compliant. From an evaluation standpoint we have had a voluntary compliance audit from the FDA. From an executional standpoint we have been working for the last year or more on meeting the new federal requirements from both an operations and testing prospective.

Tony Blanch, quality assurance manager, Nutraceutix Inc.: Nutraceutix has held cGMP certification maintaining compliance to the ANSI 173 section 8 GMPs for Dietary Supplement Manufacturing through NSF since April 2005. We continue polishing our quality system to be prepared for compliance inspection for the FDA final rules.

Greg Williford, vice president, sales and customer services, Vita-Tech International Inc.: We hold state and federal drug manufacturing licenses as well as a Food Processing Certificate from California. We also have GMP certification from NPA. The State and Federal Drug Licenses and the GMP certification require extensive and intensive multiple day audits by the granting organizations. However, we have found clients are becoming more aware of the importance of a GMP-qualified lab. They realize the impact on both the quality of the product manufactured and ultimately on the retention their client base. Additionally they understand more and more that compliance to GMP is a protective mechanism that insulates their company from potential threats in the marketplace.

Chen Wu, nutritional supplements, Jiangsu Jiangshan Pharmaceutical Co. Ltd.: We've been GMP, HACCP as well as BRC certified. The manufacturing process is conducted in strict compliance with Chinese GMPs for pharmaceutical products.

Do you hold any type of special certifications such as halal or kosher, and are you seeing increased interest from the nutraceutical industry in developing products for those markets or with those standards?

Goldman: We hold organic certification from QAI and GMP for Sport from NSF. We are indeed seeing an increased interest in developing products under both standards, but the development of products under the organic standard is currently the popular trend.

Ung: We do offer Organic, Halal, and several Kosher certifications depending on customer requirements. There is increased interest in the industry for those types of products, primarily for export to foreign countries. The “Made in the USA” continues to carry a premium with dietary supplements in the international market.

Israel: Robinson Pharma is Kosher certified on certain formulations containing approved and authorized ingredients. Clearly there is a growing demand in this segment and we are finding increased interest for both Kosher and Halal products and capabilities.

Kaufman: Paragon works with all Kosher agencies. The demand for Kosher products is definitely on the rise

MacLoughlin: Although our facility is not certified kosher or halal, we have extensive experience producing kosher products on a lot specific basis. We have not observed increased interest to date from the nutraceutical industry in developing halal and kosher products.

Sysler: We are a Kosher certified manufacturer. For some companies this is important. Again, the level of interest for this has remained constant.

Neal: At ANS we produce both halal and kosher products. We are seeing a growing trend from brands to broaden their customer base so producing products that meet these standards is a plus.

Cudahy: Yes we can produce Kosher and Halal products. Remember that these products require not only manufacturing compliance but also ingredient compliance. Sabinsa is very good at ingredients.

Blanch: We receive Halal and Kosher requests and address them on a case by case basis. We are not seeing interest in special certifications increasing beyond normal levels.

John Allison, president, Valentine Enterprises: We hold both kosher and halal certifications, although we have not seen an increase in the demand for such certifications. We do have organic certification and have had moderate interest from new and existing customers. I believe it is a trend but one that has not exploded like initially thought. The cost is more for these type products and with the economy being soft, it has slowed down the momentum on these type products.

Williford: We can and do special product groups such as Kosher and Halal as well as gluten free, vegetarian, organic and others. Interest in these continues to grow although they still represent only a small percentage of the business.

What about vegetarian products—trend or fad?

Goldman: Neither, it is a marketing tool. Vegetarian products broaden the consumer market.

Ung: We feel vegetarian products are an increasing trend. Consumers have responded favorably. However, vegetarian products tend to command a premium since it can be more challenging to formulate and produce vegetarian products (due to technology, raw materials, etc.). Therefore, in the big box retailer/food drug and mass chains, we don't see much activity or demand for vegetarian products. But companies that sell in health food retail channels or direct to consumer do show increased interest in having vegetarian products to differentiate themselves in the marketplace.

As a softgel manufacturer, we have the only truly viable non-animal (vegetarian) softgel technology called V-Gel™. We can manufacture any size softgel. The industry has waited a long time for this technology as there has been an increase in popularity of essential fatty oils. Now companies can have a 100% vegetarian EFA softgel, for example, and we are working with a number of companies to develop their own line of vegetarian softgels.

Another advantage of vegetarian technologies (whether it be hard shell capsule or softgel) is to simplify product registration issues for countries that export their products. Because the shell is non-animal, companies can use a single SKU to register in multiple countries rather than having a beef shell for one country, pork shell for another, etc.

Israel: Vegetarian product demand has been increasing steadily for the past 10 years with over 5% of the general population and greater levels in LOHAS customers self identifying as vegetarian, this is a real and meaningful trend in the dietary supplement market. This trend is counterbalanced by the need in some specific categories for high potency, affordable bio-active ingredients and affordable, scaleable, and stable, dose delivery systems. While there is a growing market for these products the data indicates that animal derived ingredients and delivery technologies (gelatin based soft gels) are secure in the marketplace

Kaufman: Vegetarian products are trending upward. They are definitely not a fad

MacLoughlin: Vegetarian products appear to be a trend, and one that's likely here to stay for the long-term.

Czech: From our perspective, vegetarian products are a trend. Particularly for dietary supplements, consumers are looking to augment the nutrition they need from fruits and vegetables, so the trend for using plant-source materials is not just reflective of the move away from animal products. Vegetarian products can literally "supplement" your plant nutrient intake whether you are an omnivore, a vegetarian or a Vegan. A vegetarian product also has broader appeal.

Neal: Vegetarian products have been a large part of our business for several years. We see a growing market for these products and definitely see them as a trend and not a fad.

Cudahy: Actually Sabinsa has offered vegetarian products for quite some time. We believe it is an integral part of our product portfolio.

Blanch: Define vegetarian...There is a spectrum of requirements depending on the level of dietary restriction the individual wishes to maintain. Much of our probiotic production is suitable for ovo-lacto vegetarians but would not suit a vegan diet. The distinction is sometimes lost in labeling.

Williford: Vegetarian is definitely not a fad. This type of product is asked for on a regular basis and seems to be pretty steady state.

How do you ensure the quality of the ingredients you use in production—from purchasing standards, testing protocol, quarantine requirements, in-process batch testing, finished product testing, etc.?

Goldman: Nutricap utilizes a vendor certification program. In addition, raw materials are held under quarantine until identified and released by the quality control department to ensure material quality.

Ung: Ingredient quality definitely starts with the source. There are some raw material suppliers who are involved in the entire supply chain and production process, and there are others who are simply brokers or distributors. On our purchasing side, we always require a sample of the ingredient and Certificate of Analysis before purchasing any raw material. The sample is sent to both our R&D team, who review it from a formulation perspective (will it work in the product it's to be used in, etc.) and our laboratory to ensure the material meets specifications. Our quality team controls vendor selection for every raw material. When raw materials enter our facility, they are quarantined and a sample is pulled. The sample is sent to the lab for identity, micro testing (and any other applicable tests), and retention before being released for production. During the production process, we have a Quality Assurance team that performs in-process checks on the product. After the product is completed, our laboratory performs finished product tests (including micro) before releasing the product for shipping.

Israel: Compliance with the new cGMP standards for dietary supplements mandates proper identification, purity (absence of known adulterants, toxic metals, pesticides and environmental contaminants) and potency of ingredients and finished dosage forms. Robinson Pharma assures that label claims are met, that the product is not misbranded (containing other ingredients not claimed on the label), and that the product is safe in terms of absence of known contaminants. We accomplish these standards thru a company-wide focus on quality systems that include extensive written performance standards, ingredient specifications, production SOPs, facility compliance, and staff qualification and training to assure that all product complies with the standard established under law.

Kaufman: All Raw materials are sourced from qualified vendors. For each raw material, Paragon Laboratories has created specifications. In the specifications, there is a physical description for the raw material, a chemical description if applicable, and a listing of the test requirements for the raw material as well. Once a raw material is received, it is immediately placed into quarantine for QC review and testing. If the raw material does not meet any of the many parameters listed in the Master Raw Material Specification, then it is rejected and returned back to the supplier.

MacLoughlin: We have comprehensive controls in place including a qualified supplier program, established specifications for raw materials that all suppliers must meet and supplier assessment criterion to evaluate competitive pricing, timely supply, stability of supply, and other factors. Our Quality and Compliance department has defined testing protocols for raw materials and finished products. All

raw materials and finished products are quarantined for inspection and release or rejection by Quality Control. We conduct appropriate in-process batch testing, and finished product testing per approved finished product specifications. As a GMP-compliant facility, we have comprehensive standard operating procedures which cover all aspects of our operation. Quality is paramount.

Cahill: Our team is well trained to research and review every aspect of a product from ingredients to finished good.

Czech: We firmly believe that good quality begins before the material ever reaches our door, therefore we choose our vendors with great care. In addition to the normal sampling and identification testing dictated by GMP, we have launched an extended information requirement program that precedes vendor or material approval. We require certain documentation from our vendors and extended information on the raw materials or components we buy. We gather information on everything we buy that becomes a part of our products or has contact with our products and we're banking it into a raw material data base. Indigo's VP of Quality Assurance & Regulatory Affairs, Nicki Jacobs, was part of the group of industry professionals who developed and promoted the Standardized Information on Dietary Ingredients (SIDI™) program; and those guidelines are providing the bones for how we bank that raw material information.

We have fine-tuned our quality criteria, clearly identified our QC gateways and processing control points. We're trying to use the best of several QC systems and moving towards a TQM approach. Adhering to Dietary supplement GMP's is a way to insure that we preserve the integrity of our ingredients throughout the manufacturing processing.

Sysler: We have implemented a set of SOPs that address testing, and product review. Raw materials are tested before use, each bulk batch is tested before put into finished product and the final product is tested as well. WE have a QA manager to ensure that procedures are followed and proper documentation is developed at each stage of the process before going on to the next process. Specifications are developed for each product and compliance is mandatory before release.

Schneider: We have a supplier qualification program using surveys and audits of selected vendors. All materials from new vendors are evaluated by QC and R&D prior to approving the vendors. There is a testing program whereby all specifications are tested periodically to verify the vendors C of A including potential contaminants such as pesticides and heavy metals. A minimum of an identity test and microbiological testing are performed on every batch. Raw materials remain in quarantine until all tests are completed and the material is found to be in compliance with specifications. Finished goods are tested to assure compliance to label claims.

Neal: ANS starts by qualifying our vendors and only doing business with those that have the same attitude about quality. We make sure that each incoming raw material meets our specifications before it is released from quarantine. This is accomplished by testing for microbial contamination, irradiation detection, identification testing and, when required, potency testing. Every finished product is also tested for microbial contamination and when required, potency testing. Other finished product testing such as heavy metals, content uniformity, and pesticide testing can be completed. Stability services can also be performed for our customers in-house.

Cudahy: On purchasing standards we require vendor self audits and, when warranted, inspect vendor facilities. And as a supplier of high quality ingredients ourselves, we know what to look for. On testing protocol we go beyond the minimums of product identification (NFIR) and use HPLC for some products as appropriate. Also Micro testing and critical attribute testing are done to ensure compliance with our specifications. Of course, all products are quarantined until validation is conducted and only then are released by our QA department. In-process testing is aligned with our finished goods testing. All relevant tests are conducted “in process” based on SPC in order to best control our manufacturing process. Finished goods tests include any and all requirements (product purity and potency) with additions for Micro and any other customer requirements. Our testing capabilities are quite comprehensive.

Blanch: The new rule requires that a manufacturer ensure that raw materials meet specifications for identity, purity, strength, and composition. Nutraceutix maintains a vendor and materials qualification program that includes material analytical testing to meet specifications. Once qualified a vendor's material is then tested periodically with sampling frequency based on our historical success with the material and its potential for problems. For example herbal ingredients receive additional microbiological screening.

Williford: Drug Licenses require complete documentation of each and every step in the entire process. SOP's cover each of the steps referenced in your question and would probably total a few hundred different SOP's. From vendor audits to full microbiological testing of each raw material and finished product the checklist is long and formal from start to finish.

Wu: We have strict ingredients receiving SOPs for each ingredient we use. For all ingredients a pre-audit of the potential suppliers is a must. According to the audit we are able to choose the qualified supplier.

What type of lab testing do you do—in house, contracted out?

Goldman: Nutricap Labs has a full functioning laboratory and microbiological laboratory. Analytical instruments used include FTIR, UV/VIS, GC, HPLC, and ICP.

Ung: In addition to our R&D labs, we have a full general lab in house, which includes the ability to do raw material testing and assays, micro testing & stability testing.

Israel: Robinson Pharma has made extensive investments in our laboratories facilities, testing equipment, and lab staff. Recent upgrades and new equipment include ICP-MS, Atomic Absorption, FT-NIR, & GC with head space analyzer. This is in addition to our existing capabilities that included HPLC, Microbiological Analysis, disintegration and dissolution, physical analysis and microscopy. Robinson Pharma has increased its floor space dedicated to laboratory operations by 40% to facilitate the increase work volume and extensive capabilities. The specific goal of this investment is to increase our testing infrastructure to manage the vast majority of our testing requirements in-house, this goal has been met.

Kaufman: Paragon Laboratories maintains a fully staffed, fully equipped microbiological and analytical laboratory. In our laboratory, we have the latest in analytical instrumentation. We have the capability to perform and develop most assays in house.

MacLoughlin: Rhema utilizes third party testing labs. We've chosen this approach to date because it allows us to focus on our core business; the development, manufacturing, and packaging of dietary supplements.

Czech: Physical testing is done here because it is integral throughout our manufacturing process and there are "gateways" that cannot be cleared without rapid results. Although we are developing our in-house capabilities, we still rely on an independent testing lab for our potency testing, heavy metals analysis, and our microbiological testing. We have approved the services of two independent labs, both of whom are recognized for their Good Laboratory Practices (GLP), high standards and technology. We work closely with them so that we are involved and not just looking for go/no-go results. Testing provides us with important information about our materials and processing. Our goal is to catch things before they become problems and that involves trend analysis. Trend analysis takes some setting up, but it's worth the time and effort in terms of long term lot-to-lot uniformity.

Sysler: We do both in-house testing and contract with third party labs when required by customers or warranted by product design. Our in house lab is fully equipped with HPLC, LC/MS, AA, GC/MS, IR etc. and performs microbiology testing, challenge tests, quantitative microbiology and assay testing.

Cudahy: Physical, chemical and microbiological testing are all done in house, as our labs are capable of very comprehensive testing. Audits and special requests are done at a certified third party lab.

Blanch: Our laboratories run standard USP methodologies for physical characteristics such as weights, disintegration, and friability of the solid dose forms. The microbiology lab performs all USP purity testing and special methods for probiotic viability counts on raw materials, in process testing, and finished dose forms. The micro lab also processes a large number of stability samples for probiotic potency to support clients label claims expiration dating. We use approved outside contract laboratories for certain chemistry analyses and when third party testing is required by our clients.

Williford: Most testing is done in our fully equipped in-house analytical laboratory using HPLC's and Atomic Absorption for the various label claim items. Physical product testing such as weight variation, hardness variation, disintegration time, friability, thickness variation, etc. is also performed for each product prior to release. Full microbiological testing on all raw materials as well on all finished product is standard procedure and performed in our in-house facility.

What type of personnel training do you have in place to ensure the greatest capability of your team?

Goldman: Employees are trained in GMP's and SOP's for their job duties. Yearly refresher training is provided.

Ung: Training is an essential part to efficient running and maintaining a GMP facility. We provide regular GMP, SOP, and safety training on a regular basis to all employees, regardless of tenure. We also cross train employees in various departments so they gain additional skills and understand the entire manufacturing and quality process better.

Israel: Robinson Pharma has a well documented, continuous, and ongoing company wide training and testing program that assures general GMP knowledge and specific knowledge relevant to various job responsibilities. We utilize extensive internal and vendor based education programs to assure that our team is not only qualified but expert in their work responsibilities. Furthermore, all aspects of the production process are video monitored and recorded to facilitate an extra level of supervision that allows us to identify and retrain staff when needed.

Kaufman: Each member of our staff is trained on all relevant aspects of performing their job. Job training includes the procedures necessary for the each function, how that job function relates to other job functions. In addition each employee is regularly trained in the latest Good Manufacturing Practices.

MacLoughlin: In addition to the extensive experience the members of our executive team brought with them to Rhema they attend industry training appropriate to their job functions including: webinars, presentations at national trade shows, and specialized intensive education through industry organizations. We follow our SOP on training for Production personnel.

Czech: Indigo firmly supports employees' pursuit of certifications and training relative to our business. Last August, we sent a key employee to Process Control School. Although Indigo's products are exempt from Process Authority control, the specialized insight is invaluable for producing liquid supplements. In early 2009, we plan to send at least one key employee for HAACP training. The philosophy is to learn the state-of-the-art means for providing quality while insuring product safety and then transmit it throughout our organization. We also feel that there is much to be learned from attending industry seminars such as those presented by CRN, NPA, ASQ, or at Nutracon or SupplySide West.

Schneider: We have a 6 module GMP training that has been designed for our industry. In addition, we provide training on HACCP (Hazard Analysis Critical Control Points) and SOPs.

Neal: Arizona Nutritional Supplements does ongoing GMP training for all of its employees as well as sending its management and quality teams to continuing education every year.

Cudahy: All cGMP, job skill and required training (i.e. OSHA) are done continually, at a minimum on a monthly basis, using Sabinsa's in house resources. When you remember that Sabinsa was founded by a scientist you understand why an emphasis on quality training and science permeates everything we do.

Blanch: All team members receive general and job specific training prior to being put on the job. That training is reinforced through annual refresher courses. Some staff members attend off site training in GMP's and specific topics to assist in their development.

Williford: Our employees undergo formal GMP training on a regular and documented basis. Of course there is a different emphasis on production and manufacturing as compared to computer validation as a part of the GMP requirement, but every person undergoes job training for their respective job duties. Both managers and supervisors alike attend professional seminars, conferences, webcasts, vendor training symposiums and industry-sponsored presentations in order to stay current.

What sets your company apart from other contract manufacturers in an increasingly crowded dietary supplement/nutraceutical marketplace?

Goldman: We are a GMP facility that manufactures high quality products at a good price.

Ung: We are known most for our quality standards, R&D, and technical skills, especially in softgel manufacturing. We are one of few manufacturers that actually manufacture softgels, tablets, capsules, powders, and teas – all in house, so we can keep a close eye on quality. This exposure to a large variety of raw materials in different dosage formats, gives us quite a bit of experience in working with many different materials, in many different dosage forms. Many manufacturers don't manufacture the variety of dosage forms that we do, and they will oftentimes subcontract products that they can't make, so they are one step removed from the quality process. In addition, we have both a drug license and NPA GMP certificate. On the technical side, we excel in our ability to formulate and manufacture some of the most difficult softgel products made. With formulations getting increasingly complex, and with new ingredients always hitting the market, it's extremely challenging to put together a good, stable, and efficacious softgel formula.

Israel: Robinson Pharma is differentiated from other contract manufacturing companies based on having the largest soft gel capacity in the United States, the fastest lead times of any soft gel manufacturer, and the most comprehensive in-house offering of production services related to solid dose manufacturing. In addition to the above Robinson Pharma is a minority owned business.

Kaufman: Years of service to the industry. High level of quality with a high level of customer service. The ability to fulfill difficult orders on a tight deadline.

MacLoughlin: Several factors set Rhema apart from other contract manufacturers. First, our unique blend of experience, stability, innovation and flexibility. We have a robust infrastructure with well established protocols and processes. However, we have not lost touch with the responsiveness to our customer's dynamic needs that allowed us to grow from a handful of staff to approximately 130 individuals, and from a modest plant to a custom built 85,000 square foot facility. We remain nimble and agile. Second, our Product Development department is staffed with flavor specialists, a key strength to have in an industry where powders represent a significant percentage of the dosage forms sold and where the ingredients with which they are made often have taste profiles that are challenging to mask. Third, we are certified GMP by Health Canada, a governing body frequently regarded as one of the most stringent in the world.

Cahill: Our attention to detail and our specialty experience with liquids set us apart from other companies. Our customer service is also one of a kind. We strive to help customers reach all of their goals.

Czech: Without a doubt, what sets us apart is our selected expertise... creating and manufacturing liquid dietary supplements! We have worked hard to master the technology for making an appealing liquid supplement and the investment has paid off. Our customers are enjoying success in the marketplace and we are growing with them.

Our staff specializes in taking a concept or idea and bringing that to fruition. From cutting edge ingredients to packaging to supply chain management, we offer a turn key experience.

Sysler: Besides competitive pricing, we have the ability and flexibility for custom manufacturing, small runs and custom formulations by our R&D department. Our specialty of liquid formulations and bottling positions us in a niche market.

Schneider: For over 35 years, CapsuleWorks has been setting standards of excellence for quality, efficiency and service. Since we're vertically integrated, we source our own raw materials, do our own research and development and have our own quality control labs, so we can supply our customers with a wide range of products (capsules, softgels and tablets) with guaranteed quality. Our rigorous in-process quality control, unrivaled manufacturing technology, state-of-the-art manufacturing facilities throughout the USA, and unparalleled production capacity enable CapsuleWorks to deliver superior quality supplements at highly competitive prices. In addition to our own uncompromising standards, CapsuleWorks' manufacturing facilities are fully compliant with Shuster Laboratories Retail Qualification program. Shuster is an independent third party firm that assures manufacturing and product quality standards.

Neal: Quality and service are what sets ANS apart. We offer the highest possible quality while making sure that our customer's needs are met. We view our customers as partners in our quest to become the premier contract manufacturer in the industry.

Cudahy: As ingredient experts, we have full knowledge, and full documentation of all aspects from "seed to shelf", of not only most key active ingredients, but also an expertise in the "manufacturability" of these products. This gives us a unique ability to not only develop products and solve manufacturing problems, but to also optimize the product in performance and productivity.

Blanch: Nutraceutix has a wealth of experience in manufacturing solid oral dose forms and, particularly in the case of probiotics, can offer shelf stability data to allow our clients products to meet the expiration dating label requirements specified in 21CFR part 111. Nutraceutix is unique in combining several process and technology patents related to solid oral dose forms, with probiotic production capabilities, to produce finished probiotic products under its one collective roof – something that is a hallmark of the finest probiotic dietary supplements on the market today.

Allison: I believe it is a combination of manufacturing products to specification using DSHEA as our guideline, coupled with our ability to manufacture in a timely, efficient, and cost sensitive manner that creates an unbeatable combination .

Williford: Vita-Tech International has a proven, 55-year track record of state of the art, innovative, manufacturing and is recognized worldwide as an industry leader. Pharmaceutically licensed since 1954, Vita-Tech is known for pioneering new processes. The experienced management team is perhaps the most stable collection of professionals in the industry. The team offers a wealth of information to its clients in virtually all areas of the manufacturing experience. Continuous Drug Licenses for almost 40 years attest to the longevity and stability of the company.

Wu: The biggest difference is our vertical integration. We are the first vertically integrated Vitamin C company in the world who manufactures Vitamin C in both raw material and finished dosage forms.

Because we responsibly manufacture our own raw materials, we can guarantee quality and low overhead while focusing on your success.

What was the strangest request you received from a potential customer—whether a specialty formula, tour requirements, pricing, etc.—and how did you address it?

Goldman: A customer called us and wanted an extremely high (toxic) level of vitamins in formulas. We explained to the customer why we were unable to manufacture the product with the requested quantity and the dangers of having a product contain the ingredient at such a high level and suggested a more appropriate level.

Ung: There are several formula requests – a coffee softgel, bullion soup softgel, pest control softgel, etc. Have had several video's shot here, but we had to explain that could not claim that our manufacturing plant was theirs!

Israel: The most unusual request we have recently received was a customer wanted us to put an off-the-shelf carbonated energy beverage into soft gels. We tried to explain that this was untenable for many reasons including legality, the high water content, the carbonation, etc. We offered a formulation based on similar active ingredients but ultimately the customer got frustrated and nothing moved forward.

Cahill: Our strangest request has been to develop a product for a customer who then wants us to produce, package, and market this product, and “oh by the way” when that is all said and done they wanted us to find potential customers and sell it to them.

Sysler: Every request has its strange aspects. request for impossible delivery times and absurd price points. We try to give realistic lead times, but too many customers do not understand (or care to) the time involved in sourcing materials and components, production time and QC time. And as far as pricing, the competitiveness of prices at the retail level makes every quote a challenge for us at the wholesale level.

Neal: ANS does not view requests as strange; since we are here to serve our customer's needs and facilitate their growth. We have a very picky clientele and we like it that way.

Cudahy: I would not describe the strangest, instead the most challenging, request which would be in addressing the Prop 65 lead issue we now may all be facing. We have been able to offer solutions to many customers including assisting in making “naturally occurring” claims and reducing overall ingredient consumption through increased standardized active concentrations and improved bioavailability ingredients.

Blanch: Interesting requests pop-up all the time. Until we have investigated them they aren't dismissed as unreasonable. Our 25 year history has seen a variety of seemingly off the wall ideas that have proven to be productive for brands, retailers and consumers alike.

Allison: I would say the request that always gets me to smile is the customer who wants to buy a product for less than it costs to produce. Where do they get their information ?

Williford: Ground-up sea horses to be tableted. We ground them up and made tablets out of them. They weren't that bad!

Wu: So far as we know, the strangest request is probably something on regulatory compliance. Sometimes we received a special formula containing toxic substances. We must deal with it according to relevant laws and regulations.

What dosage forms can you supply, and are you seeing a shift in interest from more traditional forms to more "innovative" technologies?

Goldman: We manufacture products in tablet, capsule, and powder forms. Currently we are not seeing a shift from traditional forms to more "innovative" technologies.

Ung: We supply the entire range of popular oral dosage forms including tablets, capsules, softgels, powders, and teas. We see a continuing increase in companies switching over to softgel dosage forms. This is primarily due to product type and absorption issues, as well as product differentiation for a premium product.

Israel: Our primary focus at Robinson Pharma is to be the most efficient and effective producer of soft gelatin capsules in the market. Our secondary focus is to be an effective competitor for tablet and capsule production and an efficient packager of all finished solid dosage forms. While certain innovative dosage and delivery technologies have emerged, the vast bulk of market demand is for traditional proven delivery systems that we excel at proving in a rapid and cost effective manner.

Kaufman: Paragon can supply tablets, in chewable, sustained release, quick release and enteric coated forms. For capsules, we can supply both gelatin and vegetable forms.

MacLoughlin: We supply powder blends, 2 piece hard-shell capsules (gelatin and vegetarian), and tablets. While there is always interest in novel dosage forms and innovative technologies, presently we're seeing a relatively higher interest in innovative packaging options.

Czech: We specialize in concentrated liquid dosage forms made from natural-source ingredients. Our products tend to be flavored with exotic fruit concentrates like noni or goji or special berry blends. Typically, a single dose is 1 ounce (or approx. 30 milliliters).

Sysler: We specialize in liquid formulations and bottling. A majority of the contract work we do is liquid extracts and nutritional supplements in the 1 oz -32 oz bottle range. More and more companies are looking at converting the solid dosage form into liquids.

Schneider: Softgels. More people today are looking for dosage in the form of a softgel. This is something that separates us from our competition.

Neal: Arizona Nutritional Supplements produces tablets, two piece hard-shell capsules, chewables, bulk powders, and effervescent powders. We also currently offer 11 QAI and USDA approved organic tablets and powders. The organic sector is really starting to take off in our industry and once again ANS plans on being a leader.

Cudahy: Sabinsa can supply all the traditional sizes of capsules and tablets. We also can supply modified powders (granulated, milled, blended, compacted and sifted). Today's "innovative" packaging form seems to be "Stick Pack" technology. While many others now have this packaging technology, the combination of our powder modification ability for improved solubility and better "mouth feel" characteristics, with packaging, offers a great many opportunities.

Blanch: Nutraceutix supplies bulk powder, plain capsules and tablets, and advanced deliver capsules and tablets in bulk or fully finished bottled form. Within those traditional finished forms, we can produce standard capsules and tablets, chewables, and effervescents in a wide variety of shapes and sizes with or without delivery technologies suited to the particular payloads and delivery form. Certainly, as consumers become more educated about what makes a good probiotic, along with certain other active ingredients, these consumers are seeking out products that exhibit the hallmarks of effective delivery, like the patented BIO-tract® technology that Nutraceutix utilizes to produce distinctively superior probiotic health supplements for quality conscious brands.

Wu: We supply tablets and two-piece capsules. We see lots of innovative dosage forms put into practice nowadays. In most cases the new forms originate from pharmaceutical applications. After successful experiments those applications were brought to nutrition industry.

What type of formulation assistance do you offer your customers, and do they always take your advice?

Goldman: We provide our customers with any formulation assistance they request. Most customers take our advice, but we are unable to say that they always take our advice.

Ung: One of our greatest strengths is our technical expertise, including product formulation. Nowadays with the large array of various raw materials in the marketplace, it's not so simple just to throw a bunch of ingredients into a pill. You have to account for label claim accuracy, potential chemical reactions, absorption (proper dosage form to get nutrients absorbed), shelf life, etc. to ensure you have a good product in the marketplace. Absorption is becoming a more important aspect of product differentiation. Most customers take our formulation advice simply because they know we're the experts and have a wealth of knowledge and experience. But we sometimes do learn a trick or two here and there from our customers, which we also enjoy.

Israel: Robinson Pharma provides a full range of product development and ingredient sourcing services. All products that we produce and reviewed by our team of product development scientists and must be approved prior to an order being accepted. We find that this process minimizes production failures and maximizes product stability and performance.

Kaufman: Our formulation assistance provided to our customers is a partnership of sorts. We look to our customers to provide to us active ingredient information, and we in turn give them our input, compatibility and suitability for their chosen dosage form. We also look where applicable to give them our insight into the market forces that our out there relative to their choices. Being that we have years of experience in the creation of many successful products as well as our ear to the market place and our knowledge of many different ingredients, our input can be invaluable.

MacLoughlin: It covers the spectrum in terms of formulation assistance. Some customers come to us with a basic product concept and others with a near-finished formula. To some degree this guides and informs how we assist them. If they bring a concept they may not have formalized their target market(s), product positioning, pricing thresholds, etc. We inquire into these matters to determine what types of ingredients and what dosage forms are best suited to meet their objectives. We then create a formula and typically undertake bench-top trials. When companies have a final or near-final formula we can offer suggestions for further refinements such as additional innovative ingredients or revisions to ingredients to provide the optimum balance of quality and cost-competitiveness. Customers are usually quite receptive to our suggestions.

Cahill: We assist customers from concept to production. They usually have a pretty good idea of the product they want produced but need guidance with the details. That's where we step in.

Czech: We offer a broad range of assistance in formulation development. Sometimes a customer may just want a flavor adjustment, but most often, our customers require full formulation services. Even when a customer brings their own formula, we review all ingredients and make recommendations for any adjustments to ensure proper potency and stability. We have found that most customers are open to suggestions and do rely on our expertise in liquid formulations and market trends.

Sysler: Our R&D department can create custom formulations either from scratch or by evaluating existing formulas and developing a comparable formula. Most customers do not have any formulation ability and use our knowledge and experience with confidence. Most take our advice about the type of ingredients that can be used and stability.

Neal: ANS has an in-house R & D team dedicated to help our customers and potential customers with their formulas. We can offer assistance in choosing the best dosage form, flavoring, color, and complete formulations.

Cudahy: Sabinsa offers full formulation and development assistance to our customers. And as far as always taking our advice...well, you know "the customer is almost always right."

Blanch: Nutraceutix experience in formulating and tableting puts us in a unique position to help customers provide quality products to end users. We have staff and equipment dedicated to run small scale pilots of formulas for product development. Some customers have a good idea of what they want in a product. Others are very open to suggestions for formula improvements. Since we are viewed as an industry expert in probiotics, it is usually the case that we are asked to contribute to a client's formulation and product quality improvement objectives. We take great pride in doing so, and it shows in the products we produce for customers.

Allison: We provide complete turn key manufacturing from formulation to packaging. Our customers usually take our advice because we have nearly 40 years of experience in the formulation area. There is much that needs to be known in producing high quality powder products.

Wu: In most cases we communicate with our customers about the cost-saving issues. We always consider to help our customers stay competitive while ensuring the quality of their formulations. Since we are born of a manufacturer of dietary ingredients, we know how to make the formulation more competitive than they are previously designed. Fortunately our customers always take our advice.