Quality, Safety and Consistency Equals Better Business

By U.S.-China Health Products Association

May 14, 2012,

The United States and China both hold unique titles in the global dietary supplement industry. The U.S. is the global leader in regard to manufacturing and marketing finished dietary supplements and China is the largest supplier of raw materials and ingredients. As the leaders in these two areas, it is important to lead by example and also be the safest.

However, over the years there have been a variety of incidents that have placed a gray cloud over China's ingredient and food safety record. Past and continuing issues have encouraged many international manufacturers to look else where for their ingredients. Although this is not great news for China, it is however an opportunity for those Chinese suppliers that have high quality ingredients to step forward and prove that China in fact has high quality suppliers.

A recent article from Nutraceuticals World, a U.S. trade publication, stated that due to its abundant resources and competitive pricing, China is responsible for supplying upwards of 80 percent of the raw materials found in dietary supplement formulations around the world.

As China will undoubtedly remain the largest supplier of dietary supplement ingredients for the U.S., it is critical for these suppliers to understand the importance of quality and safety along the supply chain. Chinese suppliers that demonstrate compliance to U.S. FDA's Current Good Manufacturing Practices (cGMPs) will gain much more attention from U.S. buyers and see increases in business.

GMP Compliance

According to U.S. Food and Drug Administration's (U.S. FDA) 21 Code of Federal Regulations 111, all domestic and foreign companies that manufacture, package, label or hold dietary supplements must comply with U.S. FDA's Dietary Supplement cGMPs for quality control. This regulation went into full effect in June 2010.

The U.S. FDA established GMPs for dietary supplements in 2007 as a way to ensure that dietary supplements are free of contaminates, meet quality standards and are accurately labeled. This regulation was established in conjunction with the passage of the Dietary Supplement Health and Education Act of 1994, which states that the dietary supplement/ingredient manufacturer is responsible for ensuring that its products are safe before marketing them.

Because the safety of dietary supplement products and ingredients lies in the hands of U.S. manufacturers, it is of upmost importance that their suppliers are providing quality ingredients. One way to ensure quality ingredients for U.S. companies is to choose suppliers that are NSF GMP registered, as this guarantees that the facility is audited yearly for compliance to U.S. FDA GMP regulations.

The NSF Sourcing Guide is a directory for dietary supplement suppliers and manufacturers worldwide that includes all NSF GMP registered suppliers. This registration demonstrates that the facility complies with cGMP requirements. The guide is widely used by global buyers to seek out quality suppliers. Chinese suppliers that are

interested in expanding their U.S. and overseas business should work towards getting approval to be added to the guide.

Noncompliance to the U.S. GMPs can result in multiple ramifications such as public warning letters, products labeled as adulterated, seizure by authorities, injunction from manufacturing, and damage to brand and company reputation. U.S. manufacturers are legally responsible for being GMP compliant and U.S. FDA has full authority to levy fines, sue companies and even hand out prison sentences to those breaking the law. Over the last few years, the U.S. industry has seen U.S. FDA increase the number of audits and issuances of warning letters to companies not in compliance.

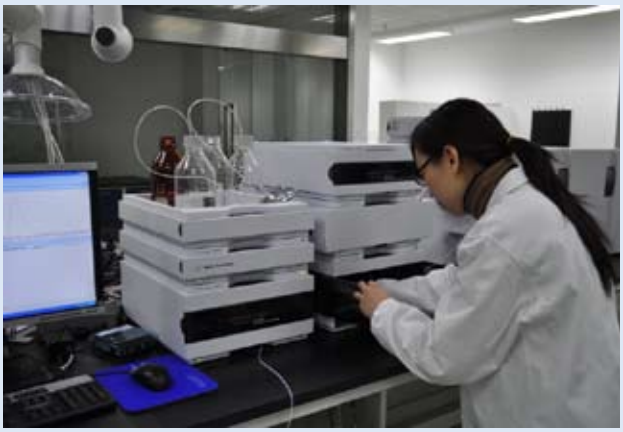
One of the U.S. – China Health Products Association's (USCHPA) board members Jarrow Formulas has been purchasing ingredients globally for decades. Their purchasing department and overall quality assurance team is very experienced in seeking out quality suppliers. This ensures their finished products meet the highest standards. Furthermore, working with quality suppliers means Jarrow receives all the necessary documentation from the supplier, which allows Jarrow to maintain clear and GMP compliant records.

USCHPA asked Jarrow to explain some of the basic requirements they look at when reviewing a new potential supplier. Here's what we learned:

First step of course is a review of the potential supplier's marketing material, which should include all their quality certificates, history and products produced etc. We look for companies that not only have their own domestic GMP registration, but also a U.S. third party GMP registration such as NSF International as well as other appropriate registrations like ISO, TGA, CERES, Kosher, etc. If the company does not have these types of registrations or the information is not readily available then my attention will move to another supplier. This is a basic first step explained Jarrow's Purchasing Manager Kay Duncan.

Jarrow's Executive Vice President, Peilin Guo added, If a company has all their certificates in order and is transparent in their communications, then the next aspect to review is the company's mission statement, technology used, R & D capabilities, and number of qualified staff with relevant degrees / training. If the company has simply purchased some equipment and is using antiquated or run of the mill technology borrowed from another company then we will most likely move on. We like to see that the company is committed to the industry and strives to increase quality through investing in qualified staff and R & D.

Also, I like to see that the President and top management of the company have health science backgrounds. If the upper management's backgrounds are in unrelated fields I tend to seek out another supplier. That's a clear signal the company was organized solely to reap profits from the growing dietary supplement industry and is not dedicated to the industry. This type of business structure is dedicated to profit and thus can lead to corner cutting



resulting in poor quality ingredients or worse economic adulteration.

We also like to see suppliers that invest in the U.S. meaning opening a sales office, joining associations like USCHPA and attending U.S. based expos like New Hope Media's Engredea. These types of investments will help the supplier understand the U.S. market better as well as show U.S. buyers they are not afraid of the spotlight.

Economical Challenges

One major challenge that Chinese suppliers face with meeting cGMP requirements is their tough economic circumstance. An increase in labor and raw material costs is making China a less economical export choice and leading to factory closures. Moreover, buyers are asking Chinese suppliers to become GMP registered while not increasing their prices, which makes GMP registration even more difficult for suppliers because they can't offset their increased costs.

Becoming GMP registered is a sizeable investment, but one that may save factories and plants from closing because it ensures that the manufacturing facility is meeting current regulations. That kind of assurance to businesses and consumers is priceless.

Raw Material Contamination

Another challenge for Chinese suppliers lies in raw material control, specifically within herb extracting plants where the process of extracting herbs is very difficult. Contamination of raw material remains an issue in these plants, and strictly monitoring the supply chain is one way to overcome this challenge and better prepare for GMP registration.

Chinese manufacturers can better prepare for being GMP registration through a number of ways, one of which pertains to staff retention. As the economy continues to struggle, employees leave factory jobs if there is more money to be earned elsewhere. This creates a challenge for maintaining quality in keeping HACCP plans and cGMPs in place, but becoming GMP registered through an accredited third party organization can provide employees with the training they need to remain valuable within their company.

There are some 300 companies worldwide that are NSF GMP registered with one-third of these coming from China.

NSF International's Health Sciences Division

NSF International's Health Sciences Division provides a wide range of certification, testing and training services for the dietary supplement industry. In February 2011, NSF opened the NSF Shanghai Testing Laboratory in Shanghai, China, to support the increasing international demand for nutritional supplement testing and certification services.

This expansion complements NSF's existing testing, registration and certification services in China and provides companies with a means to source safer products, raw materials and ingredients from Asia through independent, third-party testing, registration and certification. It also eliminates the need to ship products to the U.S. for testing, which helps to significantly streamline the import/export process.

NSF's Shanghai Laboratory Testing Services include testing dietary supplements and ingredients for pesticide residues, heavy metals (e.g. lead, cadmium) and other trace contaminants and to verify raw ingredient identification, including botanicals.

NSF Shanghai also offers onsite training programs for the health sciences industries, including Hazard Analysis and Critical Control Points (HACCP), GMP, Good Laboratory Practices (GLP), quality and regulatory compliance training programs.

Quality Assurance

At the end of the day, one of the most important things to consumers and manufacturers of dietary supplements is the safety and quality of their product.

Becoming GMP registered through a credible third party organization such as NSF International is an excellent way to establish trust with companies and consumers because it demonstrates that a product's label claims have been verified, that the product has been formulated correctly, and that it is contaminant free, as well as verifying that the facility adheres to current GMPs for dietary supplements.

Without that security, manufacturers may be less likely to trust a supplier's capabilities and consumers may not know if a certain product meets manufacturing requirements and is of the highest quality.

Investing in Quality

A perfect example of a supplier that has invested heavily early on and is now reaping the benefits is USCHPA member TSI Inc. When TSI started to build its U.S. business back in 1996, investing in quality systems, certifications and customer satisfaction was priority one. To date, TSI has five fully GMP registered facilities in China with offices in the U.S., E.U., Australia, Japan and China. Just manufacturing ingredients isn't enough anymore; buyers are looking for U.S. FDA GMP compliant companies as well as those with strong R&D and analytical resources, which TSI has invested in.

USCHPA asked TSI, what they felt was lacking in the supply chain and how to ensure their customers trust their quality. TSI CEO Joe Zhou was kind enough to lend us his insight.

We [TSI] consider ourselves a global company and as such have a responsibility to our customers around the world. This means not only having regional and international quality registrations in place, but also invest in maintaining marketing / sales offices in the countries we operate. For example, TSI has an office in the U.S., which allows our U.S. customers to communicate with us directly and conveniently. Another area that is important for our customers is liability. Let's say a U.S. company decides to buy direct from China and when the shipment arrives it isn't what was ordered or it is contaminated etc. What legal options does a U.S. company have against a Chinese entity? Liability insurance is not widely purchased in China, so from a legal standpoint this can be risky. This is why TSI has carries liability Insurance to protect itself and its customers.

Raising t he Bar on Quality

As we've seen in this article, quality ingredients, quality systems, certifications and liability are all things ingredient suppliers need to be aware of and invest in if they want to continue to sell to the global market. In today's regulatory environment, increased business and profits are tied closely to quality, safety and consistency. Both the U.S. and China have been implementing a variety of new regulations aimed at improving food safety and consumer protection. A product's quality and safety begins with its ingredients and raw materials, so make sure you are offering your customers the very best. After all, we are all consumers and should strive to produce the best for our families, friends and neighbors.

For more information on the U.S. – China Health Products Association please contact Alice Yang at alice@uschinahpa.org or visit www.uschinahpa.org

To learn more about GMP compliance and product/ingredient certification, please contact Dr. Liu Ling at lliu@nsf.org or visit NSF's website: www.nsf.org

To learn more about dietary supplement testing, Please contact Mr. Joe Zhou at zzhou@nsf.org or visit NSF China lab at www.nsfchinalab.org.

质量、安全、一致性 保障业务增长

□ 文/美中保健品协会

2012年5月14日

美国和中国在全球的膳食补充剂行业都拥有独特的头衔。美国在产品制造和成品消费上都是全球的行业领袖，而中国则是全球第一大原料和成分供应商。作为这两个领域的领导者，两国企业能够以身作则，确保产品安全尤为重要。

但是，多年来中国的原料和食品安全记录阴霾重重，事故不断。从过去到现在无间断的问题让很多国际厂商不得不考虑从别处寻找原料商。尽管这对中国并不是个好消息，但是对那些质量过硬的中国原料商来说，却是一个能脱颖而出的好机会，证明中国确实还有高质量的原料提供商。

一份美国的商业期刊《营养世界》（Nutraceuticals World）近日撰文指出，由于中国资源丰富、价格有竞争力优势，全球80%以上的膳食补充剂原材料都来自于中国。

毫无疑问，中国还将继续保持美国膳食补充剂第一大原料供应商的头衔。让这些供应商了解质量和安全在供应链中的重要性至关重要。那些通过美国药监局的现场良好制造规范（cGMPs）认证的中国供应商会得到美国买家的更多关注，同时业务也随之增长。

GMP规范

根据美国药监局代码21的联邦法规第111条，所有制造、包装、贴标和存储膳食补充剂的国内外企业都必须符合美国

药监局有关膳食补充剂cGMPs规范，以做到质量监控。本规定于2010年6月生效。

美国药监局于2007年为膳食补充剂行业建立良好生产规范（GMP）标准，确保产品免受污染、质量达标、且标签准确。GMP规范与1994年通过的《膳食补充剂健康教育法》一道，规定膳食补充剂产品及原料制造商有责任在做市场推广之前确保其产品安全。

美国市面上的膳食补充剂产品和原料的安全掌握在制造商的手中，他们的原料商能否提供高品质的原料非常重要。对美国公司来说，确保原料品质的办法之一就是从获得NSF GMP注册的企业中选择原料商。美国国家卫生基金会，简称NSF，其颁布的GMP认证意味着该企业每年都通过了美国药监局GMP规定的审核。

《NSF采购指南》是一本收录了世界各地膳食补充剂供应商和制造商的目录大全，其中所有通过NSF GMP 认证的供应商都包括在内。这个认证证明的是该企业符合cGMP的要求和规定。本指南在全球买家寻求优质供应商时广泛应用。对那些有意向在美国和海外市场扩展的中国供应商来说，若努力通过认证并添加到指南中，无疑增加了市场机遇。

违反美国GMPs规定会导致多个后果，如收到公开警告信，“掺入次品”标记，政府扣押产品，企业生产禁令等，这些后果都会严重损害产品品牌和企业声誉。美国制造商对生产符合GMP规范负法律责任，美国药监局有权对违规企业采取罚款、起诉、甚至监禁的措施。近几年，美国药监局已经增加了审计数量，对违规企业寄发的警告信数量也增加了。

美中保健品协会（USCHPA）的董事会员企业杰诺（Jarrow Formulas）几十年来都在全球采购原料。其采购部及整个质量监控团队在寻找优势供应商上经验丰富，确保其产品能达到最高的标准。优质的供应商为杰诺公司提供了所有必须的文件，所以，杰诺一直保持良好的GMP合规记录。

当美中保健品协会问杰诺，他们在挑选新的潜在供应商时会有什么基本要求。他们给出了答案。

“第一步当然是先看潜在供应商的宣传材料，包括质量证书、 企业历史和生产产品等。我们寻找的目标企业是那些不仅获得国内GMP认证，并且还获得美国第三方的GMP认证，比如美国国家卫生基金会（简称NSF）的，或者其他机构如ISO， TGA， CERES， Kosher做的GMP认证的企业。如果企业没有获得以上认证，或者此类信息不能明显提供，我们很快就会转移到下一家。”杰诺采购经理Kay Duncan说。

杰诺执行副总裁郭培林补充说，“如果企业通过了所有必需的认证，沟通也很通畅，那么下一步要看的就是企业的使命声明、 所使用的技术、研发能力和获得相关学位或培训资格人员的数量。如果该企业设备是买来的，机器也过时了，生产技术也是从别地借来的，我们很有可能也换到下一家。我们希望看到的是企业能致力于行业发展，努力提高产品质量，能对有资质的员工和研发投入资金。”

“另外，我们同样希望看到企业老总和高层都有健康科学的相关背景。如果企业高管的背景和行业毫不相干，我们也基本上不考虑了。很明显，这样的企业只是为了从不断增长的膳食补充剂行业利润里分一杯羹，而不会真正致力于行业发展。这种企业结构更像是为了赚取利润，而很可能导致产品质量低下，甚至掺假。”

“我们同样希望看到供应商能对美国有相关的投资举措，比如在美国设立销售办事处，加入美国行业协会，如美中保健品协会，参加在美国举办的展会，如New Hope主办的Engredea展等。这些

举措能让供应商更加了解美国市场，同时也向美国采购商显示他们不怕见光死。”郭培林说。

成本挑战

然而中国供应商面对cGMP规范时最大的挑战是他们艰难的经济状况。劳动力和原材料成本增加使中国企业出口成本上升，不少工厂甚至倒闭。原料买家要求中国原料商获得GMP认证，却同时还希望进口价格维持原状，这样只会导致GMP认证越来越难，因为企业无法承受再额外增加的成本。

获得GMP认证是笔不小的投资，但是这一决定可能挽回工厂和车间关门的命运，因为GMP保障了其生产设备符合当前规定。而这种信誉对企业和消费者来说都是无价的。

原材料污染

中国供应商面临的另一个挑战在于对原材料的控制，尤其是植物提取物企业，植物提取的加工过程是很不容易控制的。原材料如果受到污染则对产品影响很大。严格监控供应链是克服这一挑战的办法之一，也更容易通过GMP认证。

想要通过GMP认证，中国企业还需做好准备，其中之一就是要能留住员工。现在经济状况持续低迷，如果能找到个高薪工作，工厂员工都会离开原岗位。这给企业的维持危害分析和关键控制点（HACCP）计划和cGMPs规范都带来困难。但是通过第三方机构认证的GMP企业，能为员工提供有价值的培训，并留住人才。

全球共有300余家企业通过NSF GMP注册，而其中三分之一企业都来自中国。

美国国家卫生基金会健康科学部

美国国家卫生基金会健康科学部为膳食补充剂行业提供广泛的认证、测试和培训服务。2011年2月，NSF上海检测实验室在中国上海成立，以满足与日俱增的对营养补充剂检测和认证服务的国际需求。

上海实验室的成立有效补充了NSF在中国现有的测试、 登记和认证中国服务，通过独立的第三方测试、登记和认证，NSF为企业保障了来自亚洲的产品、原料和成分更加安全。同时，原料商也再不用把产品送到美国做检测，大大简化了进出口流程。

NSF上海实验室提供的服务包括对膳食补充剂及其原料的农药残留测试、重金属测试（如铅、镉）、其它微量污染物测试，以及对植物源原料成分的检验鉴定等。

NSF 上海实验室还提供现场健康科学培训项目，包括危害分析与关键控制点 （HACCP），GMP规范，最佳实验室管理规范 （GLP），质量和合规培训项目等。

质量保证最后，膳食补充剂的消费者和厂商最关心的事情之一就是产品的安全和质量。

通过可靠的第三方机构（如 NSF）注册GMP，则是一个建立企业与消费者之间信任的绝好方法，因为这表明产品的标签声称已经通过验证，产品配方正确，无污染，其生产设备符合当前膳食补充剂 GMP 规范。

如果没有这个安全保障，制造商则可能对供应商的能力

产生怀疑，而消费者也会有疑虑，不知道其产品是否符合生产要求，是否达到高品质。

质量投资美中保健品协会的会员企业之一TSI公司，是一个供应商在前期投入巨大后来获利颇丰的典范。TSI早在1996年就开始涉足美国业务，并在质量体系、认证和消费者满意度上优先投资。如今，TSI在中国拥有5家完全GMP注册的工厂，在美国、欧盟、澳大利亚、日本和中国均设有办事处。原料商仅作原料生产是不够的，采购商不仅要求企业通过美国药监局GMP认证，同样还希望他们有强大的研发实力和分析资源，而这块TSI已经投入很多。

美中保健品协会问到TSI，他们觉得什么在供应链中缺失了，如何确保客户对其质量的信任。TSI 首席执行官 Joe Zhou和我们分享了他的见解。

“我们认为TSI是一家全球性公司，因为对全世界的消费者我们都肩负责任。这就意味着我们不仅需要做区域和国际的质量认证，还得在我们所在国家的各大营销和销售网店保持持续投资。比如说，TSI在美国设立办事处，这就让美国消费者能和我们直接方便的沟通。另一个对消费者重要的方面则是企业责任。如果一家美国公司决定直接从中国进口，但发现到的货与订的货不一样，或者到货受污染了等等。有没有什么法律规定来处理类似事件呢？责任保险在中国尚未普及，从法律角度看来，这是有风险的。这也是为什么TSI一直投责任保险以保护自身和消费者权益。”他说。

提高质量门槛

我们可以从本文看到，如果原料供应商想在全球市场站稳脚跟，优质原料、优质系统、权威认证和客户责任，这些要素一个都不能少，需要充分认识并大力投资。在今天的规管环境下，业务和利润增加与否与产品质量、 安全和一致性密切相关。中美两国一直都在执行各种旨在改善食品安全和保护消费者权益的新法规。一个产品的质量和安全始于其原料和成分的质量和安全，因此必须确保你为消费者提供的都是最好的。毕竟，我们每个人都是消费者，我们都在努力生产出最好的产品来呈献给我们的朋友、邻居和家人。

有关美中保健品详细信息，请联系Alice Yang，邮箱alice@uschinahpa.org或查询协会官网www.uschinahpa.org

有关GMP规范和产品或原料注册，请联系刘玲博士，邮箱lliu@nsf.org或查询NSF官网www.nsf.org

有关膳食补充剂测试，请联系周子卿先生，邮箱zzhou@nsf.org或查询NSF中国实验室官网www.nsfchinalab.org