

Whole Foods Magazine - E-mail interview
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1) How have trends in the natural foods/supplements/personal care industry affected the contract manufacturing industry? What's hot?

Increased obligations for written procedures, manufacturing operations, and quality control has forced nutritional organizations to invest a great deal of time and capital. The biggest challenge for contract manufacturers of dietary supplements is the requirement for full testing of all active dietary ingredients. CPC reacted to this new regulation by more than doubling the size of our analytical laboratory and implementing full testing on products – testing to confirm the FDA's requisite of identity, purity, quality, strength, and composition of dietary supplements. We will employ in 2009 approximately 50 full time chemists. Along with comprehensive analytical testing, CPC performs accelerated stability testing as well as validation on products.

In terms of what's hot, we see a significant increase in the amount of both modified time-release and combination products. Customers are excited about the one-stop product that has multiple indications – whether it is long lasting or multi-functional. CPC has reacted to this trend by installing state-of-the-art high shear granulation and fluid bed drying equipment to enhance capabilities and technologies. Another area of great interest is packaging – more specifically, developing new ways to deliver dosages. One area where CPC has invested is stick-pack packaging. This type of system offers a wide range of advantages and there is a great deal of attraction and growth in this space.

2) How closely do you feel a contract manufacturer should work with a client on product development or new delivery technology? How closely do you counsel clients when their formulations need some improvement?

As a contract manufacturer, CPC has an intimate relationship with customers to better understand the qualities, characteristics and timelines they would like to achieve for their product. We encourage on-site audits, face-to-face conferences and meetings (or teleconferences) throughout the life cycle of the product to make sure we are on track. CPC is dedicated from conception to commercialization to ensure quality and efficiency. Early discussions regarding ingredients, compatibility concerns, tooling and other developmental issues are addressed.

3) For those looking for a contract manufacturer for the first time, what is your advice for what to look for in the selection process? What questions should they ask a potential contract manufacturer?

The contract manufacturer will turn your idea into reality and this relationship should be viewed as a business collaboration. As you select a contract manufacturer, you are

choosing a business partner and the success of the project is highly dependent on the manufacturer.

One should look for a multi-faceted company, an organization that can provide developmental formulation support, have the production capacity to manufacture the required volumes, and have the capabilities to package in the necessary configurations.

Be sure to make it a point to audit the company and manufacturing facility – see the production area, review company documentation including SOPs, trainings, etc. Request the company to supply all certifications and results of recent FDA audits. If there were any observations by the Agency, how severe were they and have they been resolved.

4) Please candidly discuss how this tough economy climate has affected the contract manufacturing industry.

Though the economic climate is not all that optimistic, CPC has seen a continual growth in its core business.

In an effort to limit capital investments and reduce overhead as well as gain access to the wealth of expertise and technological advances offered by contract manufacturing firms, our customers have been outsourcing more substantial parts of their business. Many big Pharma companies such as Pfizer and GlaxoSmithKline have sold off manufacturing facilities in the past year creating additional opportunities.

That being said, due to global economic conditions such as supply & demand, export tax credits and more stringent EPA & FDA regulations, cost of raw materials has steadily increased over the past few years. There has been a constant battle to keep costs down. To remain competitive, CPC has hired full-time employees throughout the global market place in countries such as India and China.

5) Please describe your capabilities in the contract manufacturing category. What new offerings did you bring in during 2008, and (if you can discuss), what is planned for 2009? What certifications do you hold?

CPC develops, manufactures and packages solid oral dosage Rx pharmaceuticals, over-the-counter drugs and premium dietary supplements for many of the world's largest pharmaceutical companies, retailers and wholesalers. Our relevant experience in complex manufacturing, formulation development and scale up ensures we can apply a wealth of expertise to address all obstacles in the life cycle of a project. As a result, CPC excels at identifying and meeting the unique needs of each customer worldwide. CPC has expanded its capabilities and capacities in 2008 and will continue to do so in 2009. With substantial investment in new technology and new construction underway, CPC will meet demands of the growing market and remain at the forefront of the contract manufacturing business.

Certifications and Registrations at CPC:

1. Registered with the US Food and Drug Administration (FDA) as a Drug Manufacturer
2. Registered with the Center for Food Safety and Applied Nutrition (CFSAN) as a Food Producer
3. Registered as a drug manufacturer with New York State Department of Health
4. Registered with the New York State and Drug Enforcement Agency as a manufacturer of Controlled Substances - inspected by agents of NYS, FDA and DEA in relationship to the relevant business activities
5. Registered with and complies with the requirements of the NYS and Suffolk County Departments of Environmental Conservation
6. Certified by NSF since 2003
7. Inspected annually by Shuster Labs
8. Inspected and certified by Q&C, as meeting the requirements of the Health Protection Branch, Canada
9. CPC certifies that it conforms to all local, state and federal requirements