

# CMP &

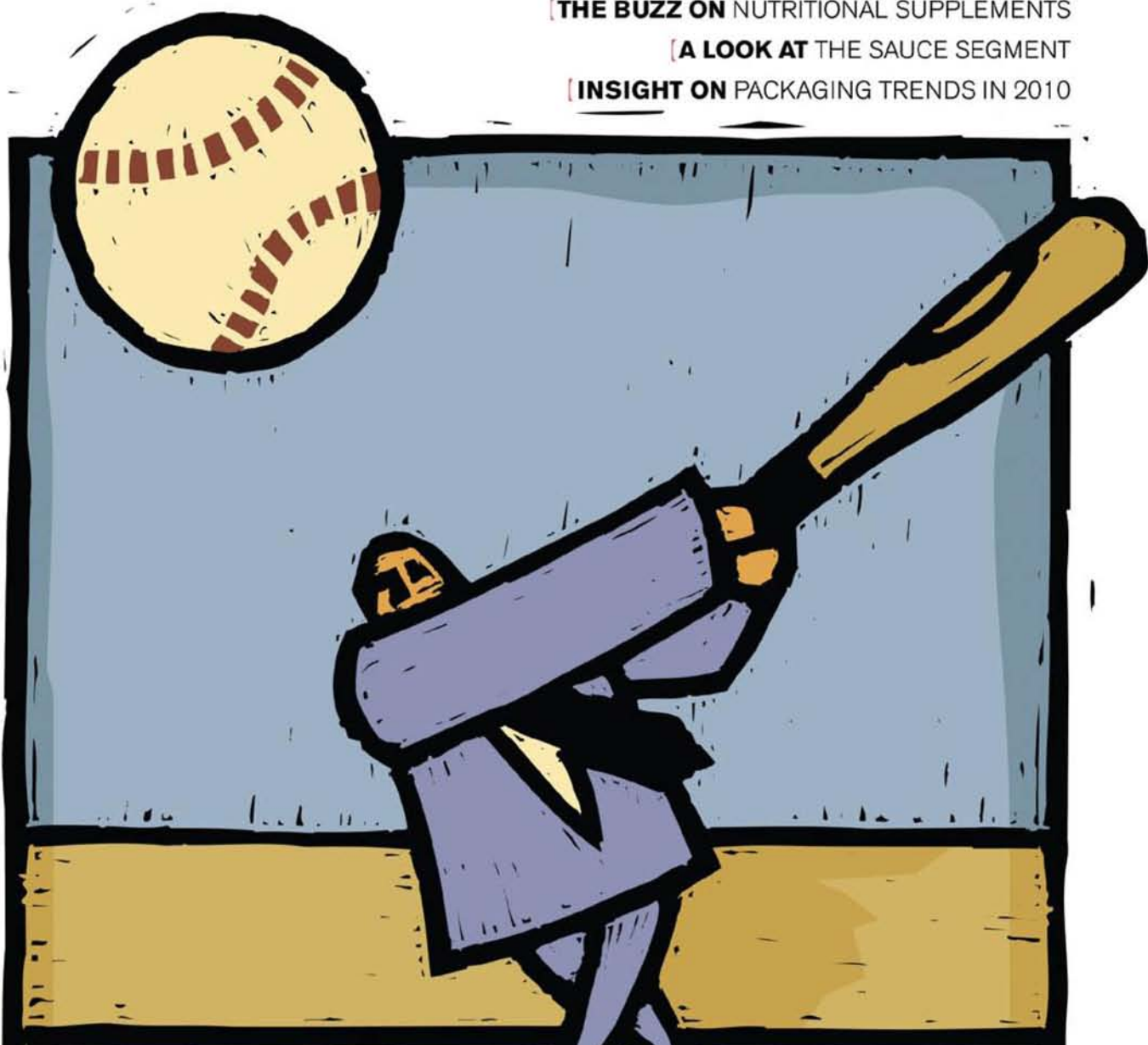
COVERING FOOD, BEVERAGE, PERSONAL CARE, PHARMA

## ALSO IN THIS ISSUE...

[THE BUZZ ON NUTRITIONAL SUPPLEMENTS

[A LOOK AT THE SAUCE SEGMENT

[INSIGHT ON PACKAGING TRENDS IN 2010



## SWING FOR THE FENCES

Don't let the market's economic curve balls derail your branding game plan.

# A Master Plan

A combination of meticulous planning, rigorous testing and continuous commitment to procedures ensures high quality in every step of the commercialization process.

**S**anta Claus isn't the only one that should be making a list and checking it twice. Companies committed to high-quality production from idea conception through commercialization would benefit from specific quality-control plans derived and agreed upon by both suppliers and brand owners. Plans that are available in writing make every party accountable and make continuous improvement a more realistic endeavor, especially given ever-evolving government regulations.

To help shed some light on creating efficiency and effectiveness in quality assurance, Laura Serkanic, vice president of quality at Contract Pharmacal Corp. (CPC), Hauppauge, N.Y., recently shared some insight with *CM&P*:

**Q** What is the most important QC issue when it comes to the contract manufacturing industry?

**A** The most important QC issues in the contract manufacturing industry are, first, meeting all the domestic and international requirements for QC testing of raw materials, bulk and finished product; and, second, completing all the required analytical testing within a timeframe that meets the client's go-to-market deadlines.

**Q** How do you ensure quality control throughout the product life cycle?

**A** We ensure quality control throughout the product life cycle by adequately planning for proper testing from the R&D phase through the raw material evaluation, in-process, finished-product and stability-testing phases — and continuing to maintain high standards for testing for all subsequent production runs.

We also operate according to meticulous Standard Operating Procedures (SOPs) in strict compliance with current Good Manufacturing Practices (cGMPs) and perform rigorous product sampling to consistently ensure the highest level of product quality for our customers.

**Q** What kinds of QC issues are you looking for?

**A** We are always looking to maintain the highest product quality standards, and the best way to do that is through proper validation of production equipment and procedures, packaging equipment and procedures, testing equipment and procedures and cleaning equipment and procedures. This is achieved by following a solid Master Validation Plan, which includes:

1. Equipment qualifications (IQ/OQ/PQ) in manufacturing, packaging and quality control
2. Analytical test method validations
3. Manufacturing and packaging process validations
4. Cleaning validations
5. Impurity testing of residual solvents and degradants

**Q** How have the fluctuating costs of raw materials, as well as transportation, affected your quality-control program?

**A** Fluctuating costs of raw materials and transportation have translated into an expansion of raw material sourcing projects, which means an explosion of new vendor and raw material qualifications. As a result, CPC invests a significant amount of time exploring and qualifying new raw material suppliers to ensure that we always receive the highest-quality raw materials at the lowest cost. ▶

▶ Continued from page 25

**Q** Are brand owners demanding more from your company in QC given heightened product safety concerns? How so?

**A** Given our clients' heightened awareness of product safety issues, such as the chemical melamine, genetically modified organisms (GMOs), irradiation and viral safety, clients are demanding much more stringent requirements for the screening of raw materials. Some brand owners are becoming more involved in the selection of raw material vendors as well, and they often want proof of a government audit or inspections and special certifications from the vendor.

**Q** How would you characterize a typical brand owner's attitude about quality control?

**A** The typical brand owner is always interested in getting quality product, so brand owners are now becoming more involved with contract manufacturers in establishing a partnership throughout the life cycle of the product, from development of the product to product production, testing and release.

**Q** What do you think is the best balance of control between supplier and brand owner in handling quality assurance?

**A** The best balance of control between supplier and brand owner in handling quality assurance is a partnership whereby the supplier provides an outline of a quality assurance plan with the required steps and timelines for each project, and then the supplier and brand owner review the plan together until a mutual quality agreement is established.

**Q** How can you ensure that the brand owner is handling your products appropriately up until the final delivery to its customer?

**A** The importance of establishing a solid partnership between supplier and brand owner with clear communication on all potential QA/QC issues, including proper product storage and handling, helps to ensure that the product is handled appropriately up to the final days of delivery to the customer.

We ensure that the product labeling is clear, so that both our customer and their customers understand the proper storage and handling procedures. An approved Quality Agreement between supplier and brand owner is essential in helping to outline areas of responsibility and liability throughout the product life cycle.

**Q** How do you see quality assurance standards changing into the future?

**A** Quality assurance standards are on the rise as both brand owners and government regulatory agencies are raising their levels of expectations for product quality and safety. The FDA has introduced a new mechanism for designing, analyzing and controlling manufacturing processes, called Process Analytical Technology (PAT), which involves establishing and measuring critical process parameters that affect critical quality attributes.

This is a risk-assessment approach to analyzing production procedures, which aims at greater efficiency, consistency and higher quality standards. The widening of international quality assurance requirements is resulting in higher quality standards worldwide. And this trend will continue well into the future.

**Q** As a quality assurance professional, what do you need from brand owners to make your job easier/even more fully ensure perfect quality consistency?

**A** As quality assurance professionals in the contract manufacturing industry, we need as much information as possible about the project at the onset — especially for international projects — and any country-specific, unique regulatory requirements or lists of non-allowable excipients in each product for different countries.

We need to interface with the customer regularly to discuss the time required to meet domestic and international regulatory requirements, which must be made transparent at the start of the development phase. This will help ensure that we meet the brand owner's go-to-market deadlines. Brand owner input, expectations and feedback are all essential along the path to commercialization. ■