



ALAMY

Excipient sourcing savvy

Maintaining a secure supply of the inactive ingredient in drugs is an increasingly critical and complex task

CLAY BOSWELL/NEW YORK

FORMULATION HAS never been more important to the efficacy and value of drug products. However, the supply chain remains the drug manufacturer's main concern, and in today's marketplace, ensuring the safety and reliability of supply is more challenging than ever, as two presenters will show at the upcoming ExcipientFest Americas 2008.

"The main risks are the global nature of the excipient business and the traditional pricing structure of most excipients," says Chris Moreton of Waltham, Massachusetts-based FinnBrit Consulting. A 30-year veteran of the pharmaceutical industry, he will speak on the topic of "Excipient Sourcing in the Global Market: How to Avoid Another Panama."

"Excipients are considered 'inert carriers' and sometimes not held in the regard they should be, in my opinion. But without excipients, most drugs are not particularly convenient," observes Moreton.

One consequence is that active pharmaceutical ingredients (APIs) generally come under much greater scrutiny than excipients, but the market has changed.

"The risks are increasing because the global nature of the business has meant that

increasingly, sourcing is offshore and the opportunities for fraud may increase," says Moreton.

People have died in Panama, Haiti, Nigeria, Bangladesh and India because of adulterated excipients, he points out. "Here in the US, toothpaste contaminated with diethylene glycol [DEG] was found in Georgia."

To minimize the risk of such incidents, Moreton has straightforward advice: "Stop thinking about lowest price, and start thinking about strong supplier relationships with properly audited manufacturers and supply chains – on-site audits, not questionnaires."

STRATEGIC PARTNERS

Large pharma companies are partnering with excipient suppliers, says Bill Webb, director of quality for Eurand, a specialty pharmaceutical firm based in Pennsylvania, US, that develops novel drug-delivery technologies and products.

"For example, if you have an excipient that is only available from one manufacturer, the survival of that supplier will directly impact

your bottom line," he says. "As a result, pharma companies become willing to make a strategic investment in equipment, training or infrastructure, with the supplier to ensure the continued success and profitability of their product or product line."

Pharma companies have also been adapting their qualification and oversight of suppliers, says Webb, who will speak on the topic of "Excipient Qualification Processes Used by Pharma Companies – A Comparison versus FDA Requirements," at the DCAT event.

"In today's marketplace, we continue to evaluate supplier systems, but we do so based on what has been determined as appropriate and acceptable systems for the US, Europe, or Japan, ensuring the supplier is aware of these standards and is compliant," he says. Inspections and communication are also more frequent.

The attitude of the US Food & Drug Administration (FDA) has likewise evolved.

"The FDA has determined through inspections, regulatory filings and more-complex submissions that excipient suppliers are no longer an 'afterthought' to the agency or pharma companies, but are a critical and vital part of any formulation," says Webb.

Webb expects the FDA to gradually impose tighter restrictions on excipient suppliers using guidance modeled after Q7A, an internationally harmonized current Good Manufacturing Practice (cGMP) guideline for active ingredients, existing GMP guidelines devised by the International Pharmaceutical Excipient Council (IPEC), or perhaps another example.

"Following their initiatives for compliance in the 21st century, the entire scope of product formulation ingredients are now the focus, not just APIs," he says.

These higher expectations reflect the esteem that excipient suppliers receive today, says Webb. However, he does not advocate mandatory cGMPs such as those the EU is considering, "as it would be extremely costly and would not provide a commensurate value."

Moreton concurs. "In my opinion, there are already sufficient guidelines, for example, IPEC-PQG Excipient GMP Guide," he says. "The enforcement has to come from the excipient purchasers. If they insist, and audit to check, it will happen." ■



» ExcipientFest is now operated by DCAT, the Drug, Chemical and Associated Technologies Association. ExcipientFest Americas 2008 will be held from April 16–17 in San Juan, Puerto Rico. Go to www.dcat.org for more information.