

Opening comments made at the Panel Discussion of the **“IPAC-RS Symposium on Extractables in Materials for OINDP”** in Chicago, IL on February 13, 2007 by **Dr. Michael Ruberto, Ciba Specialty Chemicals**

### **What does a change mean to you?**

Ciba Specialty Chemicals is one of the leading suppliers of additives, stabilizers, and colorants to the polymer industry. In most cases, Ciba does not sell directly to the pharmaceutical or medical device community; instead our customers are usually the polymer resin manufacturers, concentrate houses, and compounders. A change would be any circumstance that effects the overall quality of a product, both physically (color or appearance) or chemically (purity.) Factors that can induce a change may include sourcing raw materials from a new vendor and changing or altering reaction conditions. Ciba is an ISO 9001 registered company, and as such, has a management of change process. When a change occurs, a team of scientist and specialists from departments such as manufacturing, safety, regulatory, and analytical are assembled to evaluate the situation as well as its impact on the regulatory status of the products and our customers. Ciba also has products that are regulated by the FDA for food contact applications. There are also standardized procedures for notifying the agency of changes to these products. In general, when selecting polymers or additives that will be used in the fabrication of medical devices or packaging, it might be a good idea to select products that have food contact compliance since there is this extra level of comfort that significant product changes will be openly communicated.

### **What is an extractable?**

Compounds that can be extracted from a drug delivery system or medical packaging in the presence of certain solvents under specific conditions.