

REGULATORY APPROACHES TO NOVEL NANOMATERIALS: Unique Benefits versus Unique Risks

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SUMMARY:

Nanomaterials are of special interest in the Life Sciences largely on the basis of their unique supramolecular structures that confer tunable spectroscopic, chemical and biomechanical properties at very small particle sizes. Subtle changes in supramolecular structure at the nanometer scale can result in substantial changes in basic physical, chemical and biological properties. Effective regulation of these materials, therefore, requires a complete understanding of the relationship between particle size, composition, supramolecular structure and complexity on the one hand, and spectroscopic properties, chemical reactivity and biomechanical strength/stability on the other. While some of these relationships may become generalizable, most are likely to be unique for each type of nanomaterial. As a result, companies producing nanomaterials for drug, device and diagnostics markets should be encouraged to develop and calibrate tools for analyzing the composition, supramolecular structure and complexity of their products in parallel with development of the products themselves. Regulatory agencies should develop an independent expertise in evaluating the complexity and supramolecular structures of nanomaterials to both evaluate and guide pre- and post-market evaluation of these novel products.

Three different classes of nanomaterials for the life sciences are envisioned:

- Novel small molecules with low complexity- These can be addressed by processes and procedures already in place for regulation of small molecule drugs.
- Nanomaterials of intermediate complexity (microheterogeneity) similar to that found in the current class of biologicals regulated by the agency- These can be addressed by processes and procedures already in place for biologicals.
- Nanomaterials with multifunctional activities and a high degree of complexity based on supramolecular aggregation properties- These will require new tools and new processes/procedures for effective regulation. It is likely that many of the tools used to evaluate these high-complexity materials will need to be developed and provided by the applicant companies. This in turn, may raise interesting and challenging intellectual property issues that are critical for effective regulation of this class of biomaterials.