Case Scenario for a New Nanotechnology Enabled Paint or Coating

• Identifying Risk Management Method Needs, ELSI Considerations in a Product Development Process

Developing Considerations for Day 2

Disclaimer-The case scenario is a fictitious scenario and not intended to portray any product in commercial development
Overview

- Purpose: Gain audience and subject matter expert input into the research questions that must be asked and answered as a new product is developed

- Case Scenario
  - Consider a paint or coating that will be used in both manufacturing and consumer applications
  - The product contains a novel nanoparticle that will improve product performance
  - Enhanced product capability, product safety and environmental stewardship are customer requirements
A Conceptual Model for EHS in Product Development
ISO 9001:2008

A “stage-gate” process for developing a new paint or coating

**Stage 1**

**Idea Build** - Early identification and evaluation of EHS issues/risk. Allows team to systematically plan for elimination, mitigation, minimization and management of potential hazards posed by nanoparticles in the new paint or coating.

**Stage 2**

**Viability Assessment** - Develop strategy for managing total risk (elimination, mitigation, or reduction of hazards, hazardous practices) early in product development. Identify residual risk, risk that is not yet managed or eliminated.

**Stage 3**

**Prototype Build and Test** - Identify/optimize manufacturing process, finalize hazardous material substitutions. Manage previously identified residual risk. Develop product stewardship plan with focus on paint and coating use and end of life management.

**Stage 4**

**Product Optimization** - Transfer to manufacturing, evaluate EHS issues that may arise. Finalize product stewardship plan and end of life management procedures, e.g. product take-back, disposal.

**Stage 5**

**Commercialization** - Provide EHS support to product launch. Update product stewardship plan as knowledge base in nanotechnology grows.
Thought Starters for Table Discussion

• The role of RMM and ELSI should be considered during each step of product development
  – Idea Build: What type of data is needed on the nanoparticle before a product can proceed from an idea to a research project?
  – Viability Assessment: How and when should the product developers consider consumer use, misuse and disposal?
  – Prototype: What research studies or regulatory interventions should be required prior to manufacturing?
  – Product Optimization: What type of consumer safety data is needed and how should it be communicated?
  – Commercialization: How should manufacturer keep up with new information and update product stewardship plans?