Group 5 HYBRID NANOSTRUCTURES

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30 September, 2004

HYBRID NANOSTRUCTURES

Engineered nanostructures often involve hybrid materials—those which include biological components, or involve assemblies of disparate nanoscale materials.

At least one component should be less than 100 nm and exhibit novelty

Critical nomenclature issues

Nano-naming problems magnified with hybrids

Basis for developing nomenclature: Hierarchial: Composition, Structure,..

Size, function, primary building blocks vs bulk/aggregate, etc., intended use hierarchy?

Patent position first is called primary e.g. multiwalled nanotubes patented earlier than doublewalled

System should be open to add-ons (start from inside and work out to surface)

Need consistent/user friendly name, common community terms eg dendrimer

Drug vs device controversy, may be legal distinction, not necessarily technical. (In FDA Office of Combination Products—decision is made there—case by case basis)

Wet/dry, wet/wet, dry/dry—synergies, interfaces—
architecture standpoints, carrier (organic/inorganic/biological)

Life cycle aspects—transformations through cycle—nomenclature dependent throughout

Who is/may be doing nomenclature?

VDI group report, VAMAS?, Assoc in Japan
AAPI

IUPAC, NCCLS, ISO?, create group to go to iso,
enzyme naming group (functionality? ACS?

Who should be approached to join us?

Biologists-cell molecular biologists (Angela Belcher, Carlo Montemagno, Chad Mirkin, James Heath), biomimetic researchers

Tissue engineering community

Need to add more industry to missing entities to this group

Possible impediments to acceptance of “Nanoclature”

Lack of communication with other groups engaged in similar issues; vested stake in terms—industries, groups, crossdisciplines

Anti-global view

NGO objections to new technologies

Precautionary principle vs risk assessment—e.g., GMO issue—public perception

Other areas in nano that would benefit from standardization:

1. Reference standards, physical standards (physical artifact)

2. Standard methods of analysis, nano-sized materials standards, particle size measurements, Characterization procedures

3. Risk assessment: medical, biological, environmental
   e.g., changes in reaction to different sized materials
   standardized ways to assess risk, Hazard characterization, risk assessment, GLP

4. *Quality control in manufacturing/ product—anything specific to nano? What properties to measure to determine quality/consistency of product? May vary from sector to sector GMPs, Specifications of materials, Intermediate products—production and handling, safety

5. Problems in buying and selling nanomaterials—adequate decision information? Measures of product quantity, e.g., including matrix? Should it be on activity? Some forms on % weight; some on conductivity within polymers. Consistency of product.

6. Conformity assessment systems, Need for accrediting/certification ISO guidelines, ANSI

Other stakeholders benefiting from this exercise:

DOD
Industry groups—pharma, avomed, small businesses, SBIR
Media esp. scientific
Regulatory agencies
PTO
Consumer groups
Environmental groups
Labor
Non-regulatory government agencies
Insurance companies
IEEE nano council, ASME nano institute
WTO
CEN
Graduate students, academic researchers

General Comments

- Recommends new ISO group

- Best practices in nano from NIOSH in progress.
  In the interim, consult CDC standards for bio handling

- Group 5 recommends separate meeting in the future for hybrid nanostructures