

Characterization CoR

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- Focus on reproducible science through characterization, and characterize properties relevant to biological impact
Avoid duplication of efforts – OECD and others
- Nanomaterial characterization of nanomaterial in systems (results are dependent on nature of dispersion media, serum, and other 'exposure' conditions), fix all conditions
- Reproducibility and manufacturability and batch to batch variations are important issues now becoming possible to study (and resolve?) meaningfully
- Balance between absolute characterization vs appropriate characterization enough for regulatory consideration

- With reference to characterization, we should connect scientists – who look for toxicity/nanosafety and those that develop drugs that use nanomaterial as safer vehicles.
- Inter-laboratory studies of nanomaterial characterization methods AND biological studies to help assign Precision and Bias in measurements
- Assign priority for standards; Reference material standards: NIST: 10, 30, 60 nm colloidal gold, recently Silver, Biomodal silica, silica particles

Next steps:

- Exchange of faculty and students to promote skills
- Conduct Inter-lab studies – helps in guidance and standards
- Write a review between EU and US scientists with scientists from regions

Questions

1. Which properties/aspects of nanomaterials characterization are key in defining their biological impacts from a data reproducibility stand point?
2. How can those properties be identified, measured qualitatively and quantitatively by current techniques, thereby providing the characterization of those materials in the biological/nanosafety context
3. Which aspects of the total systems (nanoparticle properties, exposure conditions, environment etc.) must be fixed or controlled to render the system reproducible, and fully characterized from the point of view of biology/nanomedicine?
4. If new methods are required to accomplish these tasks, what are the technical challenges and how should they be developed into robust reproducible assays?
5. What standards are needed to facilitate regulatory review and commercialization?