

Nanotoxicology Workshop Summary

Session D: Nanotherapeutics

Moderator: Anthony P. Green, Ph.D.

Participants: University Faculty (5); Pharmaceutical (3); Economic Development (2)

This session, devoted to the challenges of bringing nano-based therapeutic products to market. This is especially challenging given the diverse nature of the applications. Participants in this session represented sectors in imaging, targeted drug delivery, theranostics (the combination of diagnostics and therapy in a single entity) gene therapy, cell therapy, toxicology, formulation and manufacturing.

The discussion among the participants focused on the emerging stage of the technologies and the lack of critical information required to advance them. Five major barriers were identified:

1. Better Biology. There is a need for better understanding of the biology between normal and pathological environments. This will facilitate the design of more efficient nanoparticles for multi-functional products, better modes of targeted delivery, transport across membranes and more specific mechanisms of action.
2. Better Animal Models for the design of experiments. The group focused on the lack of disease-specific animal models and the difficulty of extrapolating data derived from current animal models to inform clinical development. In general, this pathway has been inefficient at best.
3. Better Controls. Significant discussion focused on the poor choice or total lack of controls for experiments. This led to the focus on the need to improve product characterization, definitions of product “purity” and detection/analytical methods. The need for better controls and more advanced analytical techniques from public entities such as the NanoCharacterization Lab/NCI and NIST was also emphasized.
4. Better Metrics for risk/benefit. Given the early stage of these new technologies, it is difficult to assess risk/benefit. However, this important attribute of any new technology needs to be incorporated early in the development process.
5. Better Communication. The importance of provided more and better information about these new technologies will help allay both justified and unjustified fears. Education is the key and all agreed it is up to the nano community to be more aggressive in this area.