Lessons learned in creating biomedical nanoparticles for human use

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Over the past six years, the National Cancer Institute's (NCI) Nanotechnology Characterization Laboratory (NCL), a key component of the NCI's Alliance for Nanotechnology in Cancer, has characterized more than 250 different nanomaterials developed by over 75 research groups. This extensive experience has given NCL staff a unique perspective on how to design safe and biocompatible nanomaterials for human use. In a paper published in the journal *Integrative Biology*, the NCL team shared some of the lessons they have learned.

The NCL performs and standardizes the pre-clinical characterization of nanomaterials intended for cancer therapeutics and diagnostics developed by researchers from academia, government, and industry. The Lab serves as a national resource and knowledge base for cancer researchers, and facilitates the development and translation of nanoscale particles and devices for clinical applications. Scott McNeil, the NCL's director, and seven colleagues compiled the common pitfalls that nonmaterial developers encounter on their path from basic research, to products that will be tested as agents for imaging or delivering drugs to tumors in humans.

One important lesson for nanomaterial developers, who tend to be academic researchers with little experience developing products intended for clinical use, is that they need to focus more on ensuring that the materials they develop for testing in animals, and eventually humans, are sterile. A recent review of 75 samples arriving at the NCL for testing found that more than one-third showed evidence of bacterial

contamination.

Another important lesson was that commercially available materials, whether they are nanomaterials or chemicals used to make nanomaterials, are not always what they appear to be. In some cases, these raw materials are contaminated with bacterial toxins, in other cases the products do not meet the specifications advertised by the manufacturers. Dr. McNeil and his colleagues note that “it is in the researchers’ best interest to always characterize materials before proceeding with synthesis and more expensive functionalization and biological testing.”

NCL staff also found that investigators need to do a better job purifying their nanomaterials of residue remaining from the processes they use to manufacture their nanoparticles and other formulations. In some cases, nanomaterials that appeared to be toxic were in fact biocompatible. Instead, it was production impurities that were causing toxicity issues. Additionally, NCL studies have shown that nanomaterial toxicity can often be eliminated by choosing slightly different starting materials that are incorporated into the final product but that do not play a role as an imaging agent or anticancer drug.

The last two lessons have to do with the importance of developing the right methods for assessing a nanomaterial’s stability in the body and the rate at which it releases its cargo at the intended target, the tumor. NCL team leaders recommend that nanomaterial developers employ multiple assays before beginning animal studies to determine these characteristics of their nanomaterials because single assays can often paint an incomplete picture that can lead to wasted time and money.

The work that produced these findings is described in more detail in a paper titled “Common pitfalls in nanotechnology: lessons from the NCI’s Nanotechnology Characterization Laboratory.” An abstract of this paper

is available at the journal's website.

More information: Abstract: DOI: 10.1039/C2IB20117H

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