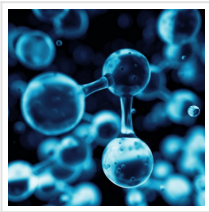
New Nanotechnology Standard Supports Product Quality during Manufacturing Processes



2020-08-31
A newly published ISO nanotechnology standard, ISO 21363, will enable the industry to properly design and perform physicochemical characterization of nanomaterials to ensure product quality during manufacturing processes, and will also support biocompatibility and safety evaluation.

Nearly eight years in the making, it is the first standard developed by ISO Technical Committee 229, Nanotechnologies, Joint Working Group 2, Measurement and characterization. The standard was a global effort involving industry and government, and experts representing the U.S., Japan, China, Australia, Germany, and South Korea.

What ISO 21363 Means for Nanotechnology

ISO 21363:2020, Nanotechnologies — Measurements of particle size and shape distributions by transmission electron microscopy, specifies how to capture, measure, and analyze transmission electron microscopy images to obtain particle size and shape distributions in the nanoscale. The document broadly is applicable to nano-objects as well as to particles with sizes larger than 100 nanometer (nm).

The standard provides detailed instruction on how to: prepare nanoparticle samples for study, calibrate the microscope, acquire images and how many to be statistically relevant, and analysis and report data. It will also permit mechanisms for regulatory agencies to make consistent regulatory decisions.

The ISO standard began as a round robin (RR) study within the United States. Led by Dr. Eric Grulke, a senior materials scientist of the University of Kentucky, who passed away in 2019, the RR was initially focused on a NIST reference material of gold nanoparticles. Participants included representatives from U.S. government, including the National Institute for Occupational Safety and Health (NIOSH), the National Institute of Standards and Technology,

FDA as well as industry, i.e., HP and DuPont.

After the U.S.-focused RR testing and validation, a proposal was taken to ISO/TC 229 in 2016 for development as an international standard. Additional RR testing was done at the international level, under the auspices of VAMAS (the Versailles Project on Advanced Materials and Standards), utilizing additional materials and additional participants: gold nanoparticles, gold nanorods, titania, carbon black, and colloidal silica.

"It is quite rare to have an accomplished academic researcher actively involved in documentary standards development for so many years," said Dr. Angela Hight Walker of NIST, former TAG WG 2 Chair and close colleague of Dr. Grulke. "Dr. Grulke's work was critical to the research going on throughout the world where nanoparticle size and shape are important. Developing this standard was a way to ensure the quality of Transmission Electron Microscopy (TEM) measurements included in publications was of the highest quality. We were blessed to have Eric on ISO TC 229 committee and his years of outstanding leadership cannot be overstated."

What's Next for ISO TC 229 JWG 2?

JWG 2 is currently looking into relevant standards for liposomes utilized in medical applications, as well as working with graphene and 2D quantum material.

The American National Standards Institute (ANSI) Nanotechnology Standards Panel (ANSI-NSP) continues to support standards development that enable the safety and efficiency of nanotechnology-driven materials, products, and processes around the globe. Read more about ANSI-NSP efforts.

Read the original article on American National Standards Institute (ANSI).