The Nanomedicines Alliance: An Industry Perspective on Nanomedicines

Frank J. Malinoski*
Chief Medical Officer, Liquidia Technologies, Vice Chair, Nanomedicines Alliance, USA

Abstract

The field of nanomedicines has expanded significantly in recent years in the breadth of compounds under development as well as in the types of technology that are being applied to generate and define nanomedicines. The pathway to licensure of new nanomedicines is well defined by existing regulations and guidance. The future of nanomedicines requires collaboration between industry and regulatory agencies to ensure that safe and effective nanomedicines emerge from this field.

Perspective

The history of licensed nanomedicines dates back to 1989, with the introduction of propofol liposomes for anesthesia and later additional liposomal, colloidal suspensions, and pegylated forms of active ingredients have followed in oncology, infectious disease, and ophthalmology [1]. Yet, recent advances in nanotechnology now offer significant potential to revolutionize treatment in multiple clinical areas with novel approaches that have expanded the types of nanostructures and the types of active molecules incorporated in nanomedicines [2,3].

As illustrated in Table 1, nanomedicines are quite different from other nanotechnology-based particles in intent, composition, and application. In contrast to nanomaterials used in manufacturing of construction and other materials, nanomedicines are specifically intended for human exposure and deliver significant benefits to patients. As such, nanomedicines are stringently tested and regulated by the Food and Drug Administration and other national authorities to ensure that they have a favorable benefit:risk profile in their intended human exposure. Further, while material science applications of nanotechnology typically involve single, uniform components at or with nanoscale features, nanomedicines are often complex combinations of active ingredients, matrix (carrier) materials and possibly targeting molecules in well-defined formulations.

The Nanomedicines Alliance (http://www.nanomedicines-alliance.org) is an organization of pharmaceutical and biotechnology companies formed in 2010 that occupies a unique place in industry. This group of companies focuses energy on promoting the scientific development, safe use, regulatory and legislative advancement, and public knowledge of nanomedicines and nanotechnology-based devices. The Alliance provides a forum for its members to exchange scientific knowledge and best practices in nanomedicine development. The group has established partnership with other governmental and non-governmental organizations, including FDA, National Cancer Institute Nanotechnology Characterization Lab, and the NCI Alliance for Nanotechnology in Cancer, to advance science and standards in this area. The Alliance also publishes monthly newsletters to appraise industry, government and the general public of regulatory and legislative developments, scientific breakthroughs, and upcoming nanotechnology-related events and conferences.

In 2013, the Nanomedicines Alliance hosted its inaugural symposium Nanomedicines: Charting a Roadmap to Commercialization. The symposium’s five presentations and corresponding breakout sessions, addressed topics in nanomedicinal design, preclinical pharmacology, chemistry, manufacturing and controls, toxicology/ADME, and clinical studies are described in detail elsewhere, Nanomedicine Drug Development: A Scientific Symposium “Charting A Roadmap to Commercialization” [4].

After careful review of the FDA’s track record in review and approval of nanomedicines, The Nanomedicines Alliance maintains that the current US regulatory framework for evaluating nanomedicines is sufficient for current industry needs. This regulatory framework allows specific considerations of each medicine on a case-by-case basis. Such an evaluation strategy is necessary for the field of nanomedicines due to the diversity in characterization and physicochemical properties of difference types of nanoparticles involved. The Nanomedicines Alliance continues to advocate for nanotechnology-based medicine to industry and regulatory stakeholders through conference presentations and sponsorships, publications, and the organization of panels and roundtables as we help ensure and promote awareness of the best science and technology has to offer through nanomedicines in order to enable the delivery of safe and effective treatments that meet the needs of patients.

*Corresponding author: Frank J. Malinoski, Chief Medical Officer, Liquidia Technologies, Vice Chair, Nanomedicines Alliance, USA, Tel: 1.919.328.4430/1.919.641.5882; E-mail: Frank.Malinoski@Liquidia.com

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