

5th International Conference and Exhibition on **Pharmaceutical Regulatory Affairs**

August 03-05, 2015 Orlando, USA

Need for uniform regulatory guidelines for toxicity evaluation of nanomaterials

Krutika K Sawant and Aditi S Poddar The Maharaja Sayajirao University of Baroda, India

Nanomaterials are now becoming more common in the field of medicine such as in drug delivery systems and medical imaging devices, with lots of research being undertaken at the institutional and industrial levels. With the advent of nanomaterials, various questions have arisen: (1) Do regulatory guidelines exist for manufactured/commercially used nanomaterials which are significantly different from their macro scale chemicals or products? (2) Do we know enough about the hazards and environmental fate of these products to adequately assess risk? And (3) how much knowledge about potential risks should governments require before products are brought to market? Despite their widespread market distribution and potentially large-scale production, relatively little is known about the environmental or industrial health and safety of nanoparticles. Both industry and the public are asking if current rules, regulations, and laws are sufficient to adequately assess the risks associated with the full lifecycle, including manufacture, use, and disposal of nanomaterials. Although a few organizations across the globe are sounding warnings and expressing concern regarding the toxicity of nanomaterials, there are no binding regulatory guidelines addressing this issue. It has been a general observation that legislation lags behind technological developments; additional requirements for risk management of nanomaterials are yet to be thought upon in existing regulatory frameworks. Clear and unambiguous recognition of nanomaterials is the need of the day. Therefore, there is an urgent need for discrete regulatory guidelines focussing mainly on the safety and toxicity evaluation of nanomaterials.

Biography

Krutika K Sawant is a Professor in Pharmaceutics at the Maharaja Sayajirao University of Baroda, Vadodara Gujarat, which is one of the top universities in India. She has been awarded Gold Medal for being the University Topper at Graduate level. She has over 25 years of experience and her expertise includes formulation of controlled, targeted and novel drug delivery systems. She has guided 68 post graduate and 15 PhD students. There are more than 60 publications in peer reviewed journals and 3 book chapters to her credits. She is a reviewer for many reputed international journals.

dr_krutikasawant@yahoo.co.in

Notes: