

Regulatory and CMC Considerations of Nanotechnology Pharma applications

Menashe Levy, PhD, CTO, Clexio Biosciences.

Nanotechnology is an emerging science with increasing number of applications and indications. Regulation authorities approach to nanomaterials is similar to other drug products, but the review process requires adequate identification and management of risks and benefits associated with the use of nanomaterials in drug products.

This short presentation describes the regulatory guidance to drug products containing nanomaterials and discusses the Critical Quality Attributes (CQA's) of nanomaterials.