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Scaling-up of nanotechnologies development for clinical investigations and commercial launch

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Recently research works on parenteral nanotechnologies have shown that many nano objects of therapeutic interest including (Nano crystalline suspension, Emulsion, liposomes and polymeric nanoparticles) can be used as enabling technologies to overcome the associated issues with API solubility. However, most of these studies are focused on exploratory research activities. One of the major hurdles to reach the market is pharmaceutical development; it is design of stable commercial formulation, process scaling up and cGMP manufacturing in aseptic environment. In this presentation, an overview of the different processes of manufacturing of nano drug delivery systems will be provided. Then the scale-up and scale-down strategies will be reviewed. A case study will exemplify how to avoid falling into the trap of developing an academic manufacturing process that cannot be scaleable and leading to an unaffordable development.

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