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# Nanotechnology: Formulation, scale-up and cGMP manufacture for clinical investigation

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Recently research work in the field of parenteral nanotechnologies has shown that many nano-objects of therapeutic interest, including (nano-crystalline suspension, emulsion, liposomes, polymeric nano-particles) can be manufactured using high pressure homogenization. Most of these studies however are focused on exploratory research activities. Amongst the hurdles to test these nano-objects in a clinical research setting and eventually reach the market are the design of stable commercial formulation, process scale-up and cGMP manufacturing in aseptic environment. Sanofi has developed a unique technology platform to support the formulation, manufacture and supply of nanotechnology based projects from preclinical, through clinical to industrialization and launch.

In the present communication the author will focus on the presentation of 3 key areas of this platform:

- A physico-chemical based approach to formulation and process engineering
- Process development and scale-up
- Parenteral cGMP pilot facilities designed to accommodate highly active product, and operate at high pressure and high temperature. This pilot line is able to supply batches from hundreds of grams to a few kilogrammes of nano-crystalline suspension, nano-emulsion or liposomes.

## Biography

Mostafa Nakach is a Pharmaceutical Engineer from Ecole des Mines d'Albi and a Master 2 graduate from Paris-sud 11 University in Pharmacotechnie and Biopharmacy. He is working within Sanofi group since 26 years. His current position is Head of Pharmaceutical Engineering section within pharmaceutical science operations. His mission is to build and to manage the required skills and capabilities in order to support R&D projects development. He also worked as API physical quality research engineer within chemical development department. His mission was focused on the process development of solid chain: from crystallization to particles engineering.

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