



Judi 19 Mars 2015, salle des thèses de 14 h à 15 h

**Nano-technology: formulation, scale-up and cGMP
manufacture for clinical investigation**

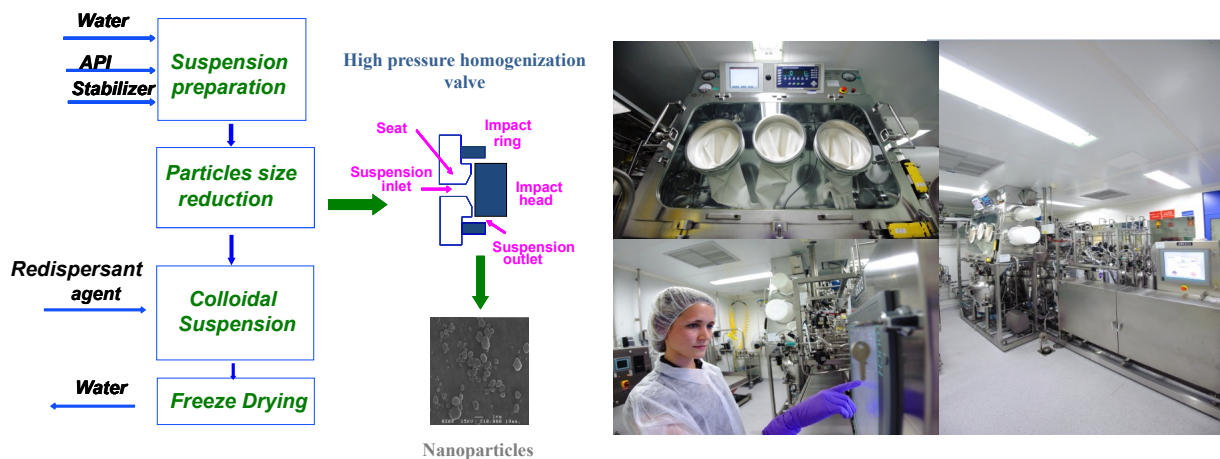
Stéphanie GRECO

Laboratory of Pharmaceutical Engineering, Sanofi, Vitry-sur-Seine, France

Recently research work in the field of parenteral nanotechnologies has shown that many nano-objets of therapeutic interest, including (nano-crystalline suspension, emulsion, liposomes, polymeric nanoparticles) 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 we will focus on the presentation of 3 key areas of this platform:

- (i) A physico-chemical based approach to formulation and process engineering
- (ii) Process development and scale-up
- (iii) 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.



Flow chart of HPH process and cGMP pilot installation.

Contact :

François-Xavier LEGRAND (☎ : 4 56 82, ✉ : francois-xavier.legrand@u-psud.fr)