NanoPilot project: A Pilot plant for the production of Polymer based Nanopharmaceuticals in Compliance with GMP.

Marco Marradi, A. Benito, I. Loinaz, L.F. Ruiz, D. Dupin and H. J. Grande
Fundación CIDETEC, Paseo de Miramón, 196, 20009 Donostia –San Sebastián (Spain)
mmarradi@cidetec.es

Nanomedicine is expected to gain in importance in the near future, especially in the field of drug-delivery, where the use of nanovehicles could: a) increase the availability of an active pharmaceutical ingredeints (API); b) target specific sites of action with a direct benefit in the reduction of side effects and increase of efficacy; c) deliver drugs across biological barriers; d) combine several drugs with synergic effects in the same vehicle, and; e) combine imaging and therapy in the same carrier[1]. There are some marketed nanotherapeutic products for parenteral and oral administration [2] and more under development. In addition, other administration routes will be probably accessible in the near future according to preclinical and clinical investigations, as for example, ocular, pulmonary, nasal, dermal or vaginal [3]. It is time to push those promising developments to the clinical stage, i) generating robust and translatable manufacturing processes, ii) completing full toxicological preclinical studies and iii) validating those new nanopharmaceuticals in clinical trials. This statement will be only possible if technology developers can easily validate their manufacturing processes and scale them up according to regulation requirements.

NanoPilot, is a H2020 funded EU project that will cover this need by setting-up a pilot plant operating under Good Manufacturing Practice (GMP) for the production of small batches of polymer-based nanopharmaceuticals under GMP. The pilot plant has been designed to be flexible and work in campaign to produce a wide range of nanopharmaceuticals. Quality System has been already implemented and Nanopilot Pilot Plant will apply for the first GMP manufacturing authorization in 2017 for non-sterile lyophilisates. At the end of the project sterile lyophilisates and liquids would be also produced. Three different nanopharmaceuticals production processes are being implemented in the frame of the project to apply for those authorizations:
a) A short interfering RNA (siRNA) for the treatment of ocular pain associated with dry eye syndrome.
b) HIV nanovaccine that combines different peptides in its formulation.
c) Hyaluronan based particles, for the treatment of interstitial cystitis/painful bladder syndrome (IC/PBS).

References

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Figures

Figure 1: Nanopilot: A project to move forward Nanomedicine from Lab to Clinical trials