Nanomedicine, from PoC to reality: the importance of an industrial perspective and GMP scale up

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Abstract: Nanotechnology and specially its application to improvement of Human health (Nanomedicine) is expected to be one of the pillars of novel products and processes in the next future, in this case to get innovative therapies. Nano-enabled therapies , together with cell and gene therapies and personalized medicine will pave the way for a revolution in the treatment of several diseases which currently have no treatment or low efficacy ones. There is a common consensus on the potential of nanomedicine to
contribute to this global improvement, but this will only be possible if all the nano medicine community is able to foster the translation of the promising results obtained at laboratory scale to real products applicable at clinical settings. This full deployment of nanomedicine must be based on the identification of the existent gaps for translation, at different levels, and on the industrialization of nanomedicines production, taking into account Good Manufacture Practices (GMP) and regulatory aspects.
From Biopraxis, the Research and Innovation Unit of the pharmaceutical Group Praxis, we have developed an intensive work to identify and propose solutions for many of those gaps. In the current moment Biopraxis holds the Chairmanship of the Nanotherapeutics Working Group in the European Technology Platform for Nanomedicine, making us a privileged stakeholder to receive inputs from the nanomedicine community and to highlight our contributions to the translation of nanomedicines. In this communication, we aim to share all these lessons learned when trying to move nanomedicine to the next steps. To do this, we have identified and proposed solutions to the different challenges at different levels, and, due to our industrial commitment, with a special focus in GMP up scale of nanomedicines production. Main challenges are the following:
Society: There is a need of higher acknowledgment and support for nanomedicine, avoiding a potential “nano-fobia”
Risks: We identify risks at two main levels: safety and environment impact, and propose preventive and corrective actions
Regulation: medicines market is a highly regulated market, and there is a need for the definition of the regulatory requirements for nanomedicines. We set the problem at three different levels: Preclinical development, clinical research and market access
Technology implementation: There is a huge amount of technology offers, which has to be discerned by industry. An open innovation scheme is proposed as a potential solution to this challenge
Industrialization: **Biopraxis** is specialized scaling up the manufacturing of diferent nanoformulations from milligram-scale laboratory synthesis up to multigram-scale production to generate sufficient material for clinical and regulatory assays. We standardise the up-scale production of nanoparticles under GMP (Fig 1) considering the main bottleneck aspects: reproducibility, stability, and non-immunogenicity (sterility and non-pyrogenicity). At the same time, we consider critical aspects of the GMPs design such as: continuous quality control, risk assessment for manufacturing process, specifications for excipients, intermediates and finished products; rooms classification, equipment, supplies (water, heat, stirring, gases…)
Business models: New paradigms need also innovative approaches to business models.
As it has been shown, current landscape for nanomedicines is full of potential, but presents a series of challenges, which need to be solved, and in many cases, only the commitment and driving action of the industry can bridge this potential valley of death. At Biopraxis we are managing several projects for the
development of nanomedicines, and we want to share our experiences and potential answers to contribute to nano-enabled therapies in the next future, in a context with the view from the Industry is sometimes difficult to find.
Nanomedicines still present some weakness on this sense, i.e. detailed cost evaluations.

Figure 1: Figure illustrating the production of nanoparticles under GMP.