Physico-chemical characterisation of nanomedicine products – Obstacle or opportunity?

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Compared to "classical" drug molecules and formulations, quality and safety assessment of nanomedicine products often requires special, sometimes non-conventional methods. Nano-related physico-chemical properties, including particle size distribution and polydispersity, particle shape, surface coating, charge, stability, drug encapsulation and drug release are all considered to be critical quality attributes with strong impact on immunological interactions, pharmacokinetics, bio-distribution and finally on overall safety of nanoformulations.

The measurement of these properties is not trivial, as in the fast growing family of nano-enabled products each new member is innovative and unique. EMA often refers to this uniqueness when justifying the lack of generalised nanomedicine regulation in Europe in the form as it exists in the US. On one hand, this allows larger flexibility regarding the application of adequate characterisation methods on both the research and regulatory body side in a field that is still fast developing. Theoretically, this flexibility is supposed to favour innovation, but innovators often complain about the uncertainty of the outcome of the final evaluation process not knowing the methods and criteria that will be actually applied at the very end of their product development path. Many times, this uncertainty is claimed to be one of the major obstacles to convince investors about the market entry of a future nanomedicine product. Thus a kind of consolidation of nanomedicine characterisation methods would not only simplify the work of regulators, but would be considered to be beneficial also for innovators.

The Joint Research Centre (JRC) of the European Commission in collaboration with expert laboratories of various European countries dedicated many efforts in the last years to develop and validate nanoparticle characterisation methods tailored for medical nanoparticles in a frame of a Horizon 2020 project. The European Nanocharacterisation Laboratory (EUNCL) provided not only a platform for testing nanomedicine product candidates but fostered the deployment and use of standard operating procedures available for the public. An example of non-conventional nanocharacterisation methods available in our laboratory, analytical ultracentrifugation will be presented with results about cross-validation by orthogonal techniques using liposomal drug formulations. Access to this instrumentation and to our research infrastructure for nanomedicine characterisation is offered for research institutes and industry as part of the Open Laboratory platform of the JRC.