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## BIOPHYSICAL TECHNOLOGIES IN VACCINES

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**Key Words:** intrinsic and extrinsic particles characterization, customer complaints, comparability, in-house biophysical laboratory.

Vaccine safety, in agreement with different countries pharmacopeia, requires characterization and identification of the intrinsic and extrinsic particles nature when occurring at any step of production. It also covers eventual customer complaints and health authorities concerns. To efficiently achieve these tasks, pharmaceutical companies need to have a laboratory specialized in biophysical technologies for particle characterization. As in many cases intrinsic and extrinsic particles of identical nature are recurrent issues, an efficient recording of historical troubleshooting resolution will speed their characterization and identification. This requires the set-up of an in-house biophysical laboratory. In addition, ensure the comparability of raw materials and batches, which is also crucial to maintain high quality standards of vaccines, might be covered by this biophysical laboratory which should be equipped with the most frequent technologies used for these purposes: i) biophysical methods, such as Raman, Infrared, energy dispersive X-ray Spectroscopies, X-ray diffraction, Circular dichroism, micro-calorimetry, differential scanning fluorimetry; ii) imaging tools, such as scanning and transmission electron microscopies, macroscopy and light microscopy and iii) statistical approaches as well as image processing and analysis. Here we will present examples about how these different technologies contribute to characterize and identify particles and to compare different productions lots.