IMPLEMENTING X-RAY FOR SINGLE USE SYSTEMS STERILIZATION: CURRENT STATUS

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Sterilization/decontamination by gamma irradiation is a standardized process for some medical devices, drugs and in the food field and has many advantages due to its significantly low toxicity. Many worldwide industrial sites offer gamma irradiation as a means of sterilization, and in the last decade, new irradiation technology such as X-rays or electron-beam raises, to overcome the challenges encountered e.g., due to sterilization capacity constraints. All irradiation technologies are reliable and reproducible processes and ensure sterility over time by avoiding any possible risk of contamination. It will thus reflect on post-pandemic world solutions to build capacity with high flexibility, while looking forward to anticipating future increase in sterilization demand without negative implications/repercussions in all industries where sterilization is needed. Unfortunately, these radiation processing also present disadvantages of inducing modifications for exposed materials. While X-ray industrial units are beginning to emerge, the question of a comparative study between the effects of different types of radiation and their health impact on the materials/products studied still arises. This previous lack of data represented a hurdle for medical device and biopharmaceutical manufacturers desiring to transition from gamma-ray sterilization modalities to X-ray or electron-beam. Communicating to the industry our approach and polymer effects results can support medical device and biopharmaceutical manufacturers to perform their own risk assessment when piloting the transition to alternative irradiation modalities. In an effort to help fill these data gaps previously enounced, physicochemical testing, mechanical testing, extractables testing, etc. were performed on products including their polymer components previously irradiated by the different radiation technologies (gamma and X-ray). We will then give an update on recent publications supporting X-ray equivalence, industry implementation timelines, key risks, related industry activities, and regulatory perspectives.