

## IMPLEMENTING X-RAY FOR SINGLE USE SYSTEMS STERILIZATION

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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 modality such as X-rays or electron-beam raises. These methods make also possible the sterilization of products without significant heating and to handle them directly in their final packaging, to overcome the challenges encountered e.g., due to sterilization capacity constraints. All irradiation modalities 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. Some factors could affect the observed changes, such as their chemical composition, additives, or the presence of oxygen in the environment. X-ray industrial units are beginning to emerge, and the question of a comparative study between the effects of different types of radiation and their health impact on the materials/products studied arises. This current lack of data represents 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. will be performed on products including their polymer components previously irradiated by the different irradiation modalities (gamma and X-ray).

### Highlights:

- Support biomanufacturers to perform their own risk assessment when piloting the supplementing of alternative irradiation modalities to ensure business continuity during sterilization processes
- Comparative study between the effects at materials/components & sub-assemblies/products of different types of ionizing radiations
- Understanding the parameters inducing modifications for exposed SUS to irradiation
- Physicochemical testing, mechanical testing, extractables testing, functional testing, activation, etc. will be performed on products and their polymer components previously irradiated (gamma and X-ray).