**Risk Evaluations in implementing X-ray for Single-Use Systems sterilization**

**Samuel Dorey**, Sartorius Stedim FMT S.A.S, Z.I. Les Paluds, Avenue de Jouques CS91051, 13781 Aubagne Cedex, France, [samuel.dorey@sartorius.com](mailto:samuel.dorey@sartorius.com)

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The single-use disposable technologies for biopharmaceutical manufacturing combine single-use holistic processes and facility strategy to overcome scale limitations and enable cost-efficient manufacturing to support the growing demand for many biologics. This industry is facing challenges with irradiation sterilization capacity resulting in assessing X-rays as a suitable and equivalent alternative to gamma. Comparative studies between the effects of different types of radiation and their health impact on the materials/products studied arise. The Bioprocess Systems Alliance (BPSA) published a consensus risk-based qualification approach including materials, physical, functional, chemical, and biological investigation to assess the impact of X-ray vs gamma. The Team Nablo project also proposed a holistic research approach covering several disciplines. To achieve its goals, the team has integrated technological, academic, and industrial research. The BioPhorum X-ray workstream will also publish Guidance for risk evaluation of X-ray irradiation of single-use systems. This will be providing a robust, consistent, and repeatable methodology to assess the inclusion of X-ray irradiation of previously gamma irradiated-treated single-use products. We then propose an insight in the different risk evaluations available currently to simplify the adoption of X-ray for the sterilization purpose.