

## **Discussion - Risk Evaluations in Implementing X-ray for Single-Use Systems Sterilization, Samuel Dorey, Sartorius**

*Wednesday, 20 September 2023 16:00 (1 hour)*

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.