

RISK-BASED QUALIFICATION OF X-RAY STERILIZATION FOR SINGLE-USE SYSTEMS

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The urgent need for life-saving therapies as a result of the global pandemic has reinforced the criticality of flexibility in pharmaceutical manufacturing, including sterilization. The single-use bioprocess industry traditionally has employed gamma irradiation sterilization. X-ray irradiation warrants consideration as an alternate sterilization technology. X-ray irradiation offers better penetration characteristics, improved dose uniformity ratio (DUR), and less environmental impact when compared to other sterilization modalities. We will share a risk based qualification testing strategy including Extractables and data generated to support comparability of gamma irradiation and X-ray irradiation as equivalent ionizing irradiation sterilization modalities.