

## PRELIMINARY EVALUATION OF PENDOTECH® SINGLE USE SENSORS POST X-RAY IRRADIATION

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With the ongoing growth of the biopharmaceutical, vaccine, and cell and gene therapy markets, and the increasing demand on existing sterilization facilities for materials required in manufacturing processes, X-ray irradiation for sterilization has caught the eye of the industry. As an innovative industry leader, PendoTECH has evaluated the compatibility of its various Single Use Sensors with X-ray irradiation for sterilization. This poster details a preliminary study performed on PendoTECH Single Use Pressure, UV/Turbidity, and Temperature sensors. A small sample size of sensors was X-ray irradiated at 41.5 to 44.6 kGy, and then checked for physical integrity (via leak testing) and accuracy to validate the performance of the sensors. All pressure, UV/turbidity, and temperature sensors were demonstrated to be reliable, and were within specification post X-ray irradiation. Although this is a preliminary study, these results suggests that PendoTECH sensors are compatible with X-ray irradiation and they are expected to pass the full qualification currently in progress.

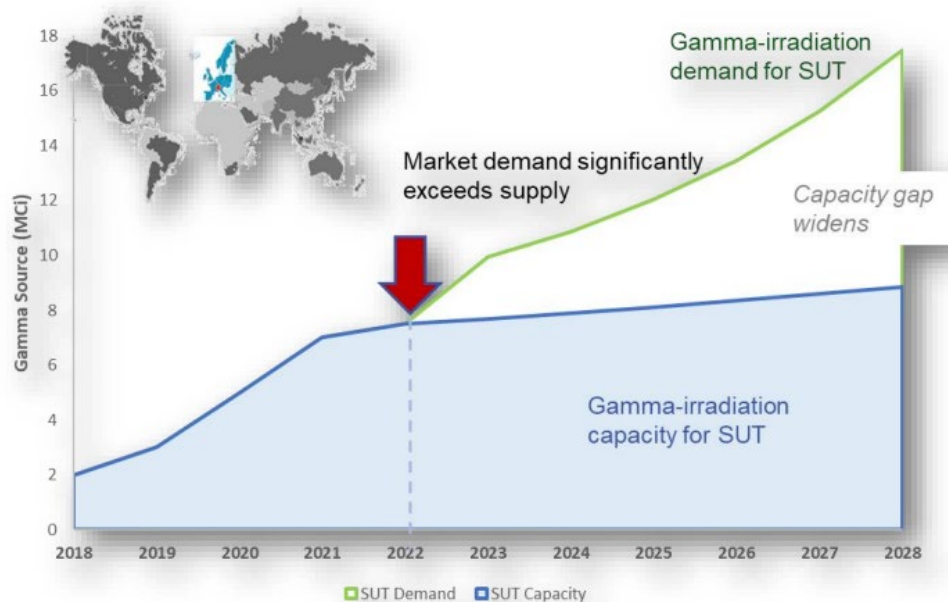


Figure 1 – Figure from BioProcess System's Alliance (BPSA) white paper on X-ray Sterilization [1] on the anticipated supply, demand, and capacity, of gamma irradiation for Single Use Technologies over the next several years.

### References

[1] Bio-Process Systems Systems Alliance (BPSA). (2021, May). X-Ray Sterilization of Single Use Bioprocess Equipment. Part I- Industry Need, Requirements, and Risk Evaluation. [https://bpsalliance.org/wp-content/uploads/2021/X-Ray-White-Paper/FINAL-BPSA-X-Ray-Sterilization-of-SU\\_051321.pdf](https://bpsalliance.org/wp-content/uploads/2021/X-Ray-White-Paper/FINAL-BPSA-X-Ray-Sterilization-of-SU_051321.pdf)