

Monte Carlo Simulations as a Product Design Tool

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Sterilization is the terminal step of medical device development, and sterilization validation is a regulatory requirement. We are developing a Monte Carlo simulation tool that can produce virtual dose maps for radiation sterilization, thereby helping medical companies to make important decisions about sterilization that will also affect the regulatory pathway early in the medical device development cycle. As these simulations only require a CAD model of the device and not a manufactured device (which is required for dose mapping at the contract sterilizer), the simulations can be used early to iterate on the design of the device and its packing whereby shorten and de-risk the design process.

Our simulation tool is geared towards engineers at medical device companies and does not require an advanced background in software engineering or radiation physics. Rather, the engineer is guided through simple steps of deciding the radiation sterilization technology, the orientation of the device in the beam, and the identification of all materials in the device. The simulation is then performed in the cloud and once complete, the engineer can review the results in a user-friendly viewer, identify minimum and maximum dose regions, and determine the dose uniformity ratio. We anticipate that our tool will offer significant benefits to the medical device development community.